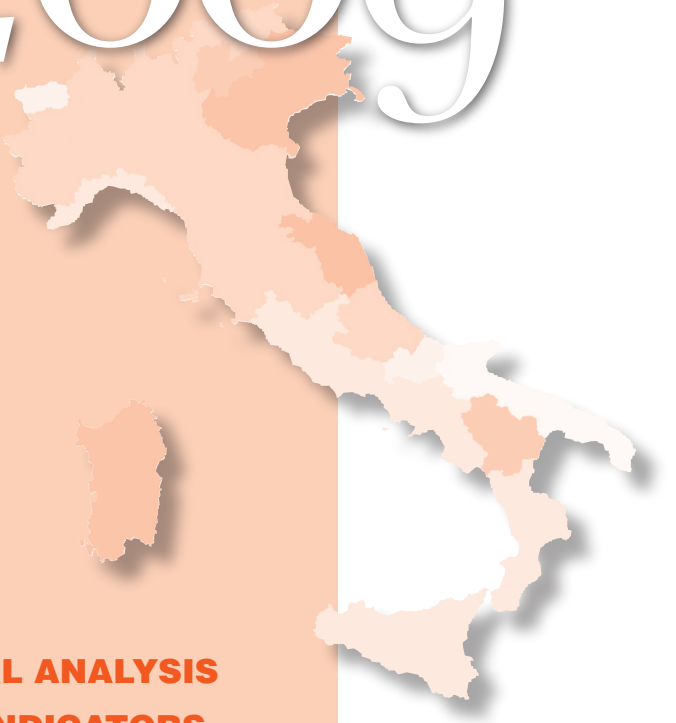
AMD Annals 2009



LONGITUDINAL ANALYSIS OF QUALITY INDICATORS OF DIABETES CARE IN ITALY (2004-2007)

The AMD Annals 2009 Working Group* and
Antonino Cimino, Gualtiero de Bigontina,
Danila Fava, Carlo B. Giorda,
Illidio Meloncelli, Antonio Nicolucci,
Fabio Pellegrini, Maria Chiara Rossi,
Giacomo Vespasiani

AMD
Affiliata IDF
ASSOCIAZIONE MEDICI DIABETOLOGI

Viale Carlo Felice, 77 – 00185 Roma, Italy
Tel. 06.700.05.99 – Fax 06.700.04.99
E-mail: segreteria@aemmedi.it
http://www.aemmedi.it

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(data referred to May 2009)

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Introduction

Dear Colleagues,

The four-year results reported in the Annals are a concrete demonstration of our activity in diabetes care. Through outcomes assessment we have strengthened our professional identity and given value to our organization within the health care pathway of persons with diabetes.

The 2009 Annals provide a longitudinal perspective on the last four years. Patterns of change in our clinical practice have emerged from an analysis by preselected indicators of the AMD Data Files: what was once a still portrait is now a dynamic portrayal.

The data for the 2009 Annals were collected in 2008 and compared with those of the four-year period 2004 through 2007. Thus, for the first time, the data analysis refers not to a single year but rather to a longer period. This has enabled us to make various different analyses on the same data set, and, as always, without incurring extra work for the diabetes centers collaborating in the initiative.

Last year we drafted a list of ten basic rules for participation and use of the data stored in the national database. Also last year, the AMD distributed the Quality Indicators Software program (version 2) so that each center could analyze their data as done in the analysis of the national Annals, with the maximum guarantee of data protection. The software program also allows for longitudinal analysis of individual patients, which facilitates the correlation between actions and results in a way that is much more secure than possible with the national Annals.

Despite the difficulty of obtaining specific answers from aggregated data, the longitudinal design of the 2009 Annals and future editions will be increasingly directed at finding solutions and presenting the data clearly. We believe this editorial policy, neither easy to design nor to create, will ensure the Annals growing attention which it would otherwise risk losing.

Data collection is conducted yearly and presented either during the AMD national conference or in the interim year to the collaborating centers. To achieve this result within the expected timeframe, while allowing a margin for completing the work, with respect to past practice, the editorial committee has decided to collect the data not following the calendar year but rather from June to June. In this way, data collection starts just after the AMD national conference in May, leaving a time window open until the following May for data collection and analysis and printing the Annals. This organizational change will have no impact on data quality and comparability.

Another important objective is to extend participation in the initiative to as many centers as possible. To do this, we plan to invite the participants to report on national and perhaps also on personal data, in the attempt to find starting points for designing Annals that can be of interest and use to everyone. The Annals are not and are not intended as an epidemiologic study, a diabetes registry or an exercise in health care statistics, but rather as a tool that can enable us to do our work better. Currently, over 50% of the data and the centers originate from northern Italy; therefore, the central and southern areas of the country need to be more involved in an initiative which represents an opportunity for professional growth for all of us.

The 2009 Annals are increasingly seen as an instrument and opportunity for improving diabetes care: viewing the changes in the clinical results and comparing them with those obtained by others will allow us to identify areas for improvement at each center and thereby seek pathways of professional growth.

This enormous database will be a valuable resource for public health care agencies: the database could, upon request, provide clinical data with which administrative data can be integrated to define the quality of care at the regional level and thus form a true disease management tool in the hands of the diabetologist, the health

care professional that tracks and measures the health care pathway.

We are indebted to those who assisted in data collection, the national executive board for their staunch support, the Study and Research Center and the Quality Group for organizational assistance, and the Consorzio Mario Negri Sud for statistical data analysis with the unconditional support of LifeScan.

We have overcome various hurdles in creating this project; others lie ahead. Some may try to copy us and may even do better than we have. The national and international recognition the Annals have gained will encourage us to do more and better. This will not be possible without the continued help of the AMD.

Giacomo Vespasiani
AMD Annals, Coordinator

Umberto Valentini
Study and Research Center, Director

*AMD Annals 2009 Working Group: List of investigators and centers

AUTHORS	INSTITUTION	UNIT	TOWN
Antonino Pipitone, Ezio Bodner, Andrea Bonanome	Ospedale Civile di Adria	Ambulatorio di Diabetologia	Adria (RO)
Ivano Testa, Massimo Boemi, Roberto Giansanti, Fabio Romagnoli, Roberto Testa, Rossana Rabini, Gabriele Brandoni	I.N.R.C.A.	U.O. di Diabetologia e Malattie del Ricambio	Ancona
Vincenzo Paciotti, Pasquale Alfidi, Bruno Verdecchia	Ospedale di Avezzano "SS. Filippo e Nicola"	Diabetologia	Avezzano (AQ)
Alberto Marangoni, Alessandro Pianta, Maria Ferrari	Ospedale Bassiano	Medicina Interna	Bassano del Grappa
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Franco Marini, Lucia Bondesan	Ospedale S. Biagio	Diabetologia	Bovolone (VR)
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Gianfranco De Blasi, Michael Bergmann	Ospedale Generale Provinciale di Bressanone Collinetta	Medicina II - Servizio Diabetologico	Bressanone (BZ)
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Brigitte Viehweider	Ospedale di Brunico	Servizio Diabetologico e Associato, Medicina Interna	Brunico (BZ)
Luciano Carboni, Maria Pia Turco, Alessandro Delogu, Mirella Floris, Maria Grazia Murtas, Laura Farris	Ospedale S.S. Trinità	Reparto di Geriatria Servizio di Diabetologia	Cagliari
Mario Manai, Francesca Spanu	Ospedale Civile S. Giovanni di Dio	Servizio di Diabetologia e Malattie Metaboliche	Cagliari
Marco Songini, Giampiero Piras, Roberto Seguro, Renata Floris, Graziella Corona, Marcella Lai, Stanislao Lostia, Elisabetta Piras	Azienda Ospedaliera G. Brotzu	Struttura Complessa di Diabetologia - Dipartimento di Medicina Interna	Cagliari
Maria Dolci, Mary Mori, Fabio Baccetti, Giovanna Gregori	ASL 1 - Ospedale di Carrara	U.O. di Diabetologia	Carrara (MS)
Luigi Capretti, Guglielmina Speroni, Anna Carbone, Luciano Fugazza	Ospedale Casalpusterlengo S. Angelo Lodigiano	Unità operativa di medicina - Centro ambulatoriale di diabetologia	Casalpusterlengo (MO)
Giuseppe Pozzuoli, Mario Laudato, Maria Barone, Giovanbattista Stasio	Centro Diabetologico Sovradistrettuale ASL Caserta 1	Ambulatorio Caserta	Caserta
Juliette Grosso, Brunella Di Nardo, Loredana Rossi, Antonietta Sciulli	Presidio Ospedaliero Castel di Sangro	U.O. di Diabetologia	Castel di Sangro (AQ)
Loris Confortin, Narciso Marin, Mario Lamonica	Ospedale San Giacomo Apostolo	S.S. Dipartimento di Diabetologia	Castelfranco (TV)
Ignazio Lorenti	Azienda Ospedaliera di Cannizzaro	Servizio di Diabetologia e Malattie Metaboliche	Catania
Vincenzo Starnone, Andrea Del Buono, Anna Maria Terracciano	Distretto 43 Cellole 2	Centro di diabetologia prevenzione diagnosi e cura del diabete mellito e sue complicanze	Cellole (CE)
Angelo Boscolo Bariga, Gianni Ballarin, Andrea Nogara, Stefano De Boni	Ospedale di Chioggia	Servizio di Diabetologia di Chioggia	Chioggia (VE)

AUTHORS	INSTITUTION	UNIT	TOWN
Anna Chiambretti, Riccardo Fornengo, Elena Maria Mularoni	Ospedale Civico di Chivasso ASL 7	S.S.V.D. di Diabetologia e Malattie Metaboliche	Chivasso (TO)
Alberto Rocca, Paolo Rumi, Barbara Balzarini	Ospedale Bassini	Medicina Interna	Cinisello Balsamo (MI)
Maria Antonietta Pellegrini, Claudio Noacco, Laura Tonutti, Giorgio Venturini	Azienda Ospedaliera Universitaria S. Maria della Misericordia	Diabetologia e Malattie Metaboliche	Cividale del Friuli (UD)
Graziano Santantonio, Giampiero Baldi, Luciano Massa	Ospedale San Paolo	Ambulatorio di Diabetologia	Civitavecchia (RM)
Giosuè Ghilardi, Patrizia Fiorina	Ospedale S. Biagio	Servizio Diabetologico	Clusone (BG)
Luigi Capretti, Guglielmina Speroni, Luciano Fugazza	Ospedale di Codogno	Unità operativa di medicina - Centro ambulatoriale di diabetologia	Codogno (LO)
Cinzia Massafra, Augusto Lovagnini Scher	A.O. San Gerardo	Ambulatorio di Diabetologia	Cologno Monzese (MI)
Giuseppe Panebianco, Federica Tadiotto	USL 17 - Ospedale di Conselve	Centro U.O.S.D. Diabetologia	Conselve (PD)
Dario Gaiti, Ezio Alberto Bosi, Giuseppina Chierici, Silvia Pilla, Melita Copelli, Pietro Zanichelli, Lorella Bertelli, Paola Caretta, Valeria Vezzani, Simona Bodecchi	Ospedale Civile San Sebastiano	Servizio di Diabetologia	Correggio (RE)
Alfonso Longobucco	Azienda Sanitaria n. 4 - Poliambulatorio di Cosenza	Servizio di Diabetologia e Endocrinologia	Cosenza
Patrizia Ruggeri, Annarita Mondani, Romano Persico,Cristiana Rossi	Azienda Istituti Ospedalieri	U.O. centro diabetologico	Cremona
Giampaolo Magro	Div. Endocrinologia e Diabete	Ospedale S. Croce di Cuneo	Cuneo
Nicoletta Musacchio, Annalisa Giancaterini, Augusto Lovagnini Scher	A.O.S. Gerardo di Monza Presidio Territoriale di Cusano Milanino	Centro Integrazione Territoriale	Cusano Milanino (MI)
Giuseppe Marelli	Ospedale Civile di Desio	U.O. Diabetologia e Malattie Metaboliche	Desio (MI)
Giuseppe Placentino	Ospedale S. Biagio	U.O. di Diabetologia	Domodossola (VB)
Donata Richini, Stefano Molinari, Roberto Strazzeri	Ospedale di Esine	U.O. Struttura Semplice di Diabetologia e Malattie del Metabolismo	Esine (BS)
Giuseppe Panebianco, Michele D'Ambrosio, Virgilio Da Tos	USL 17 - Ospedale civile di Este	Centro U.O.S.D. Diabetologia	Este (PD)
Luisella Cotti, Gabriella Garrapa	Ospedale S. Croce	U.O. Diabetologia	Fano (PU)
Paolo Foglini, Claudio Bedetta, Elena Tortato, Paola Pantanetti, Rossana Manicotti	Ospedale di Fermo	U.O.S. di Diabetologia e Malattie del Metabolismo	Fermo
Elisa Forte, Concetta Marrocco	Ospedale S. Giovanni di Dio	Ambulatorio di diabetologia struttura complessa di medicina	Fondi (LT)
Adriana Torri, Domenico Sommariva	Ospedale G. Salvini	Medicina Interna 1 - Ambulatorio di Diabetologia	Garbagnate Milanese (MI)
Claudio Taboga, Barbara Catone	Ospedale Civile San Michele - Gemona del Friuli	Ambulatorio Diabetologico	Gemona del Friuli (UD)
Guglielmo Ghisoni, Francesca Fabbri, Marina Torresan, Roberto Crovetto	Ospedale di Nervi	Servizio di Diabetologia	Genova
Giuseppe Campobasso	ASL BARI 5 - Distretto Sociosanitario 2	Ambulatorio di Endocrinologia	Gioia del Colle (BA)
Ercole D'Ugo	Presidio Ospedaliero di Gissi	Diabetologia	Gissi (CH)
Marina Merni, Barbara Brunato	Presidio Ospedaliero di Gorizia	Ambulatorio di Diabetologia	Gorizia
Mauro Rossi, Gigliola Sabbatini, Fabrizio Quadri, Laura Sambuco	P.O. di Grosseto - Stabilimento Misericordia	U.O. Diabetologia	Grosseto

AUTHORS	INSTITUTION	UNIT	TOWN
Ezio Alberto Bosi, Giuseppina Chierici, Silvia Pilla, Dario Gaiti, Melita Copelli, Pietro Zanichelli, Lorella Bertelli, Paola Caretta, Valeria Vezzani, Simona Bodecchi	Area Nord AUSL RE Guastalla - Correggio	Servizio di Diabetologia	Guastalla (RE)
Rossella Iannarelli	Ospedale San Salvatore	U.O. Diabetologia	L'Aquila
Mario Pupillo, Angelo De Luca, Daniela Antenucci, Anita Minnucci, Cluadia Di Florio, Assunta Carnevale, Giovanna Angelicola, Angela Bosco, Rosanna Fresco, Giuseppina Di Marco	Ospedale Renzetti ASL Lanciano Vasto	Diabetologia e Malattie Metaboliche	Lanciano (CH)
Franco Marini, Leonardo Cogo	Maters Salutis	U.O. Diabetologia ed Endocrinologia - Servizio di Diabetologia	Legnago (VR)
Rosamaria Meniconi, Stefania Bertoli, Sabrina Cosimi	USL 12 Viareggio - Ospedale Versilia	U.O. Diabetologia e Malattie Metaboliche	Lido di Camaiore (LU)
Francesco Giannini, Alberto di Carlo, Ilaria Casadidio	Ospedale Campo di Marte	Servizio Autonomo di Diabetologia e Malattie Metaboliche	Lucca
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Giovanni Saitta	ASL 5 Messina	Servizio di Diabetologia	Messina
Domenico Cucinotta, Antonino Di Benedetto	Policlinico G. Mastino	Dip. Med. Int. U.O. Malattie Metaboliche	Messina
Pietro Pata, Teresa Mancuso	Ospedale Piemonte	S.C. Diabetologia	Messina
Alfredo Zocca, Barbara Aiello, Maurizio Picca	P.O. Macedonio Melloni	Ambulatorio di Diabetologia	Milano
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Marco Comoglio, Roberta Manti	Distretto Sanitario ASL 8 Moncalieri	Unità Operativa Dipartimentale Diabetologia e Malattie Metaboliche	Moncalieri (TO)
Anna Maria Cernigoi, Carla Tortul, Barbara Brunato, Marina Merni	Ospedale San Polo	Servizio di Diabetologia e Malattie Metaboliche	Monfalcone (GO)
Giuseppe Panebianco, Federica Tadiotto	USL 17	Centro U.O.S.D. Diabetologia	Monselice (PD)
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Antonio Volpi, Anna Coracina, Anna Maria Cospite	Ospedale Civile di Montebelluna ASL 8 Veneto	Dipartimento di Medicina, Diabetologia	Montebelluna (TV)

AUTHORS	INSTITUTION	UNIT	TOWN
Valeria Manicardi, Massimo Michelini, Lorenzo Finardi, Simona Galliani, Rita Cilloni, Marika Iemmi	Ospedale di Montecchio	U.O. di Diabetologia	Montecchio (RE)
Simonetta Lombardi, Mee Jung Mattarello	Ospedale di Montecchio Maggiore ALS 5	U.O.S. Dipartimentale Diabetologia ed Endocrinologia	Montecchio Maggiore (VI)
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Salvatore Turco, Anna Amelia Turco, Ciro Iovine, Claudia De Natale	Dipartimento di medicina clinica e sperimentale Università "Federico II"	Servizio di Diabetologia	Napoli
Luciano Zenari, Lorenzo Bertulini, Claudia Sorgato	Ospedale Sacrocuore	U.O. di Diabetologia	Negrar (VR)
Alfonso Gigante, Anna Maria Cicalò, Concetta Clausi, Rossella Cau	Ospedale C. Zonchello	Servizio di Diabetologia	Nuoro
Silvia Calebich, Cinzia Burlotti	Clinica S. Rocco	Unità Operativa di Medicina Interna	Ome (BS)
Giuseppe Saglietti, Giuseppe Placentino, Antonella Schellino	Ospedale di Omegna	S.C. di Diabetologia e Malattie del Metabolismo	Omegna (VB)
Francesco Mastinu, Marina Cossu, Gianfranco Madau, Maria Franca Mulas, Simonetta Zuccheddu	Ospedale San Martino ASL 5 Oristano	U. O. di Diabetologia	Oristano
Giuseppe Torchio, Patrizia Palumbo, Adolfo Bianchi	Clinica San Carlo	Sevizio di Diabetologia	Paderno Dugnano (MI)
Giuseppe Mattina	Poliambulatorio Biondo USL 6 Palermo	Servizio di Diabetologia	Palermo
Ivana Zavaroni, Alessandra Dei Cas, Laura Franzini, Elisa Usberti, Monica Antonimi, Nadia Anelli, Rita Poli	Università degli studi di Parma	Dipartimento di Medicina Interna e Scienze Biomediche - Sezione di Medicina Interna	Parma
Enio Picchio, Paola Del Sindaco	USL 2 di Perugia	U.O. Diabetologia	Perugia
Adriano Spalluto, Luigi Maggiulli, Lara Ricciardelli	Azienda Ospedaliera San Salvatore	Servizio di Diabetologia e Malattie Metaboliche	Pesaro (PU)
Giuliana La Penna	Osp. Civile dello Spirito Santo	Servizio di Diabetologia	Pescara (PE)
Renzo Gelisio, Carmela Vinci	Ospedale di Portogruaro	Servizio di Diabetologia	Portogruaro (RO)
Adolfo Arcangeli, Lucia Ianni, Monica Lorenzetti, Angela Marsocci	Presidio Ospedaliero ASL 4 Prato	Dipartimento di Diabetologia e Malattie Metaboliche	Prato
Paolo Di Bartolo, Antonio Scaramuzza, Piero Melandri	Presidio Ospedaliero di Ravenna	U.O. Diabetologia	Ravenna
Celestino Giovannini	Servizio Diabetologia Polo Sanitario Reggio Calabria Nord ASL 11	Servizio di Diabetologia e Malattie del Ricambio	Reggio Calabria
Emilio Rastelli	Ospedale G. Ceccarini	Ambulatorio di Diabetologia Div. Medicina	Riccione (RN)
Sergio Leotta, Concetta Suraci, Natale Visalli, Alberto Gagliardi, Lucia Fontana, Maria Altomare, Silvia Carletti, Santina Abbruzzese	Ospedale Sandro Pertini	Struttura Complessa Dietologia-Diabetologia Malattie Metaboliche	Roma
Francesco Chiaramonte, Renato Giordano, Mauro Rossini, Giuseppina Migneco	Ospedale Santo Spirito	U.O.C. Diabetologia	Roma
Fabio Piergiovanni, Danila Fava, Angela Simonetta, Fiorella Massimiani	Azienda Ospedaliera San Giovanni Addolorata	U.O.S.D. di Malattie Metaboliche e Diabetologia	Roma
Rocco Bulzomì	Quarto distretto sanitario ASL Roma B	Struttura Cartagine	Roma
Giuseppe Armentano, Maria Grazia Restuccia	Centro Diabetologico DEA - S.S.N. ASL 3 Rossano		Rossano (CS)

AUTHORS	INSTITUTION	UNIT	TOWN
Stefano Genovese, Fabiana Locatelli	Istituto Clinico Humanitas IRCCS	U.O. di Diabetologia ed Endocrinologia	Rozzano (MI)
Tiziano Croato, Manola Nicoletti, Nazareno Trojan	Ospedale S. Vito al Tagliamento	Medicina, Ambulatorio di Diabetologia	San Vito al Tagliamento (PN)
Patrizia Li Volsi, Giorgio Zanette	AO Santa Maria degli Angeli	U.O.S. di Diabetologia	Salice (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)
Paolo Bordin, Laura Perale	Ospedale Sant'Antonio	Unità operativa di medicina	San Daniele del Friuli (UD)
Renzo Gelisio, Milena Zanon	Ospedale San Donà di Piave	Servizio di Diabetologia	San Donà di Piave (VE)
Vincenzo Sica	Ospedale San Gavino Monreale ASL 6 Sanluri	Servizio di Diabetologia	Sanluri (CA)
Roberto Sturaro, Maurizio Raffa	Ospedale Civile di Sanremo	Diabetologia	Sanremo (IM)
Luca Lione	ASL 2 Savonese	Ambulatorio di Diabetologia	Savona
Francesco Calcaterra, Fedele Cataldi, Marina Miola	Ospedale di Schio	Unità Operativa di Diabetologia ed Endocrinologia	Schio (VI)
Silvana Manfrini, Silvia Rilli	Ospedale di Senigallia	U.O. Diabetologia	Senigallia (AN)
Italo Tanganelli	Azienda Ospedaliera Universitaria Senese	Biotecnologie Applicate alle Malattie del Ricambio	Siena
Giuseppe Felace, Ida Fumagalli	Ospedale San Giovanni dei Battuti di Spilimbergo	Medicina - Ambulatorio di Diabetologia	Spilimbergo (PN)
Giovanni Divizia, Mafalda Agliani	Ospedale Generale San Matteo degli Infermi	U.O. Diabetologia	Spoleto (PG)
Augusto Travaglini, Patrizia Draghi	Azienda Ospedaliera "Santa Maria"	U.O. Clinica Medica - Ambulatorio Malattie Dismetaboliche	Terni
Paolo Acler, Tiziana Romanelli, Sandro Inchiostro	Ospedale Santa Chiara di Trento	Servizio di Diabetologia	Trento
Riccardo Candido, Elisabetta Caroli, Elena Manca, Alessandra Petrucco, Roberto Da Ros, Paolo Da Col, Elisabetta Tommasi, Nevia daris, Maria Grazia Cogliatti, Angelina Pianca, Emanuela Fragiacomo	Azienda per i Servizi Sanitari n. 1 Triestina	S.C. Centro Diabetologico	Trieste
Mario Vasta, Maurizio Sudano, Maria Grazia Pronti, Gigliola Martinelli, Mauro Andreani, Giordana Ciandrini, Stefania Lani	ASUR Zona 2 - Ospedale Civile di Urbino	S.I.T. Diabetologia e Malattie Metaboliche	Urbino
Anna Rosa Bogazzi, Giovanna Bendinelli	Ospedale di Venaria	Struttura semplice di Diabetologia	Venaria Reale (TO)
Margherita Pais, Ermanno Moro	Ospedale civile di Venezia	Servizio di Diabetologia	Venezia
Francesco Cervellino, Armando Zampino, Rosa Sinisi	Ospedale San Francesco ASL 1	Unità Speciale di Diabetologia	Venosa (PZ)
Antonella Schellino	Ospedale Castelli	Struttura Complessa di Diabetologia e Malattie Metaboliche	Verbania Pallanza (VB)
Roberto Mingardi, Luciano Lora, Cristina Stocchiero	Servizio di Diabetologia Casa di Cura Villa Berica	Dipartimento Medicina Unità Operativa del Piede diabetico e della Medicina Vascolare	Vicenza
Alfonso Basso, Elisabetta Brun, Marco Strazzabosco, Maria Simoncini, Consuelo Grigoletto, Francesco Zen, Chiara Alberta Mesturino	Ospedale San Bortolo	Endocrinologia e Malattie Metaboliche - Servizio di Diabetologia	Vicenza

Methods

The content of the 2009 AMD Annals differs from previous editions. With the growing number of collaborating centers and the creation of a huge national database containing data collected over the last four years (2004 through 2007), this year it was possible to analyze the progress of diabetes care in Italy, thanks also to the AMD Annals.

A total of 124 centers collaborated in the initiative. All have an electronic-records system (electronic medical record) in place with advanced configuration of functionalities for routine patient management and standard extraction of data that constitute the AMD Data File. The AMD Data File is the core knowledge tool in that it provides the necessary information for describing process indicators, intermediate outcome indicators and prescribed medications.

As underlined in previous editions, a reliable analysis of care quality cannot be conducted without a correct and complete electronic-medical record. Partial entry of data on patient management makes it impossible to distinguish between omission of a given procedure (e.g., fundoscopy) and omission of reporting that it was actually performed. As will be discussed below, this problem precluded the use of several indicators and influenced the selection of centers that had collaborated in the past. However, also the analysis of changes recorded on quality/completeness of data (data goodness) over the last four years is in itself an important part of quality health care.

CENTER SELECTION CRITERIA

The same selection criteria were adopted as in previous editions; these filters were applied every year. This means that the number of analyzable centers may vary by year. The criteria exclude centers that report less than 10 patients with type 1 diabetes (T1DM) and less than 100 with type 2 diabetes (T2DM). This is done to ensure that clinical practice is sufficiently representative. Similarly, in the intermediate outcome assessment, centers were excluded from the analysis if they provided data for a specific outcome in less than 10 patients with T1DM and in less than 100 patients with T2DM.

POPULATION SELECTION CRITERIA

For each year only "active" patients were analyzed, i.e., patients with T1DM or T2DM who attended a diabetes center at least once each reference year to have a clinical assessment, their glycated hemoglobin (HbA1c) tested or receive a diabetes therapy prescription. Patients meeting at least one of these criteria were defined as "active".

DEFINITION OF THE GOLD STANDARD AND DATA GOODNESS

To evaluate the evolution of data goodness over the four-year period, the same criteria of "minimum acceptable completeness" adopted in the previous editions were applied to identify those centers upon which the gold standard values could be calculated. In detail, from the ordinate distribution of values recorded by the centers with minimum acceptable completeness of data, the 75th percentile was calculated for process indicators and favorable outcome measures and the 25th percentile for unfavorable outcome measures. These values became the yardstick for comparison.

The approach taken in the 2009 Annals differs in that the classic gold standard was not estimated since it changes from year to year. Instead, the focus of the analysis was the comparison versus the results the centers obtained each year with respect to 2004.

In this connection, the variation in the number of centers that surpassed each year the following threshold values of minimum acceptable completeness was taken as a measure of the increase in data goodness:

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

METHODS OF ANALYSIS

The calculation of the indicators and the characteristics of the study population are reported separately for persons with T1DM or T2DM. Since the range of normal HbA1c values varied among centers, the values underwent mathematical transformation to permit comparative evaluation. In other words, the value for each patient was divided by the upper limit of the normal range. This value was then multiplied by 6.0 in order to interpret all the data on HbA1c, having as a normal reference value 6.0.

When not reported on the electronic-medical record, the LDL cholesterol values were calculated using the Friedwald formula, whenever the triglyceride values were <400 mg/dl. Obviously, LDL cholesterol values were calculated only if the electronic-medical record also contained the values for total cholesterol, HDL and triglycerides tested at the same visit.

GENERAL DESCRIPTIVE DATA

The study population characteristics are reported separately for persons with T1DM or T2DM. The data comprise sociodemographic characteristics (age, sex) and clinical parameters (BMI, HbA1c, blood pressure, triglycerides, total cholesterol, HDL and LDL cholesterol, use of specific drug classes).

SELECTION OF INDICATORS

As mentioned above, this report is based in part on the indicators included in the AMD Data-Indicator File. Centers were excluded from the analysis if they provided data for a given indicator on less than 10 active patients with T1DM or less than 100 active patients with T2DM.

Process indicators

The process indicators were monitoring at least once a year the following parameters:

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

A further process indicator (mean number of visits by type of treatment) was evaluated in the centers that recorded having performed at least one visit in at least 80% of active patients. This selection was necessary because some centers did not use an electronic-medical record for quantifying the services delivered, so that not all the examinations performed were recorded in the data field for creating the AMD Data File.

Of note is that among the process indicators in the AMD Data-Indicator File fundoscopy and neuropathy examinations were not included in the analysis. The results of these examinations are often reported on the electronic-medical records as text and therefore cannot be utilized for statistical analysis.

Intermediate outcome indicators

The intermediate outcome indicators were:

- Percentage of patients with HbA1c ≤7% or ≥9%
- Percentage of patients with LDL cholesterol <100 mg/dl or ≥130 mg/dl
- Percentage of patients with blood pressure ≤130/85 mmHg or ≥140/90 mmHg
- Mean BMI value
- Percentage of smokers

For all these indicators the denominator was the number of patients with at least one measurement of these parameters during the index year.

The last two indicators were calculated only for those centers that provided sufficient data on current treatment (at least 5% of patients being treated with statins and at least 10% of patients receiving antihypertensive therapy).

The percentage of smokers was calculated only for those centers that reported a minimum 10% prevalence of smokers.

Prescribed medications

The percentage was calculated of patients with T1DM and T2DM receiving drugs from the following classes:

- *Antidiabetic agents* (only T2DM): insulin, metformin, sulfonylureas and glitazones
- *Lipid-lowering agents*: statins
- *Antihypertensive agents*: ACE inhibitors, angiotensine receptor blockers (ARBs), beta-blockers, ≥2 antihypertensives

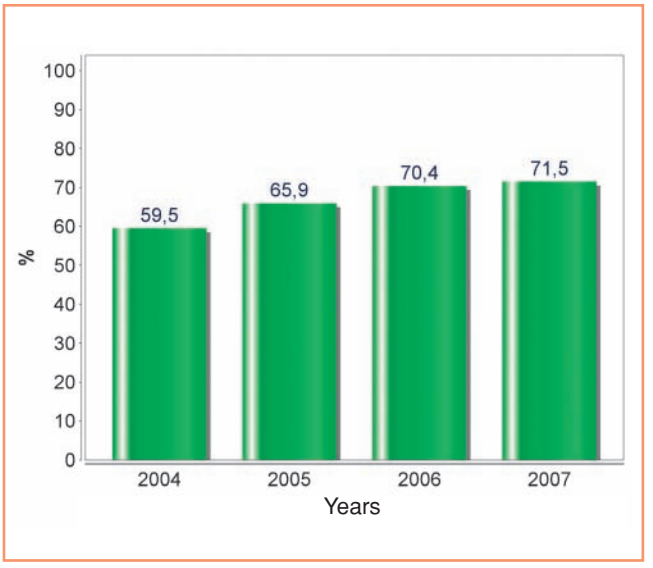
Final outcome indicators

These indicators, though of great relevance and appropriately contemplated in the AMD Indicator-Data File System, could not be evaluated in this report. As with other process indicators, information on long-term complications is often reported as text on the electronic-medical record rather than in a standard codified format (although such formats are present on the electronic-medical record).

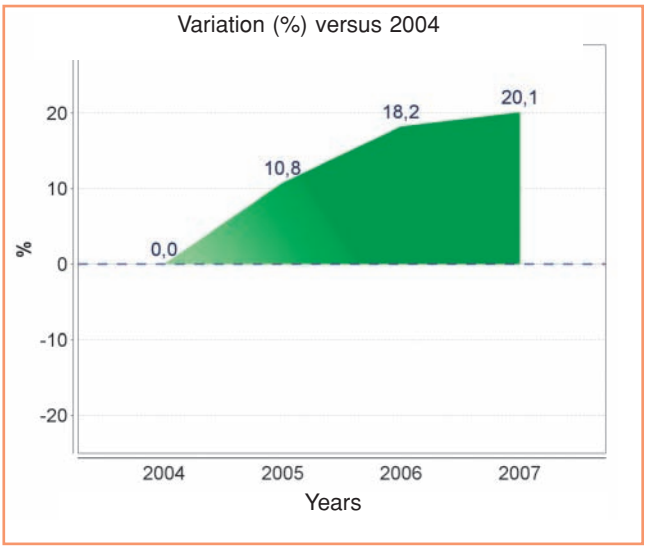
GRAPHIC REPRESENTATION OF THE DATA

Also in the 2009 Annals, great importance was placed on the graphic representation of the results as an aid to data comprehension. Besides tables and histograms, the data on preselected indicators are given as:

Histograms indicate the change over the course of the four years in the percentage of patients monitored for a specific parameter or patients who reached a certain outcome or were treated with drugs from a specific class. While the histograms visualize the changes in absolute terms, the mountain graphs present information on relative percent variation. For example, from the above graph one can estimate that for a given parameter there was an absolute increase of 12% (from 59.5% to 71.5%) between 2004 and 2007.

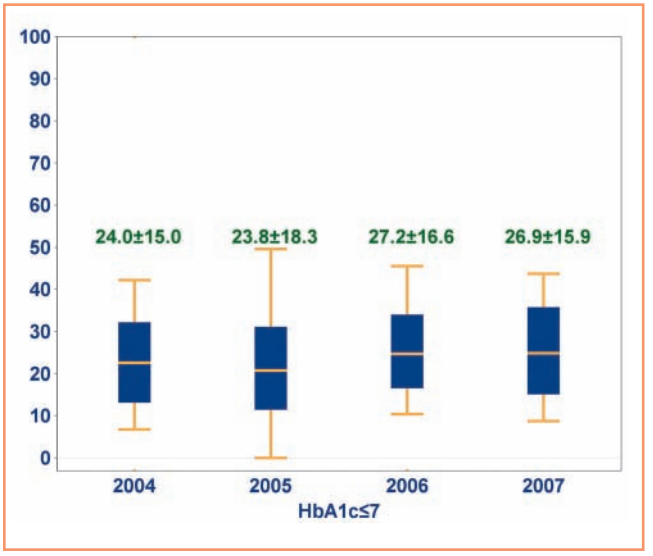


Mountain graphs illustrate for each year versus 2004 the increase/decrease related to the percentage of patients who had undergone a monitoring procedure, reached a certain outcome or had been treated with a drug from a specific class. For example, in the comparison of 2004 and 2007 data, the relative variation was calculated using the following formula: (% in 2007 - % in 2004) / % in 2004.



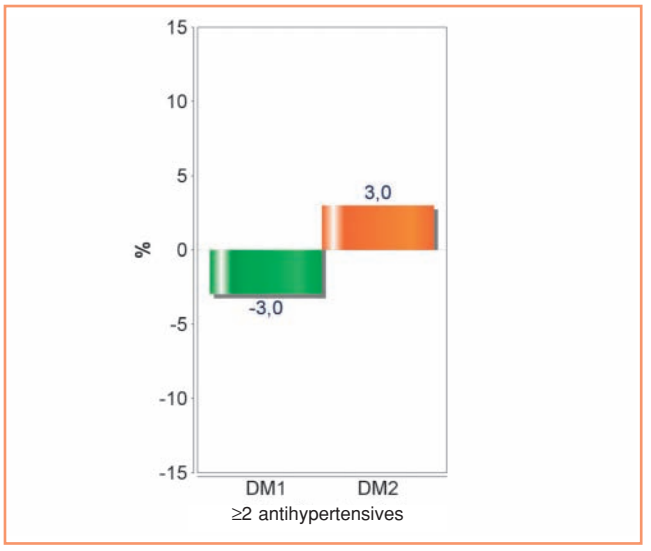
For instance, in reference to the previous histogram, one can estimate that for the parameter in question there was a relative increase of 20.1% [(71.5-59.5) / 59.5].

Box plots summarize in simple and comprehensive fashion the characteristics of a variable's distribution. As shown in the next figure, a box plot is a rectangle crossed by a horizontal line that defines the median, while the top and bottom sides correspond to the 75th and the 25th percentiles, respectively. The T bars at the top and the bottom correspond to the 90th and the 10th percentiles, respectively. The box widths and the T bars show how variable the index in question is: if the box has a flattened shape, the measurement is relatively homogenous



within the population under study, whereas if the box is stretched, the measure tends to assume very different values within the population. Box plots were used to illustrate the distribution of the mean values of HbA1c, systolic blood pressure, diastolic blood pressure, lipid profile, BMI, and intercenter variability with respect to the proportion of patients who underwent a monitoring procedure, achieved a favorable or unfavorable outcome or were treated with specific medications.

Bar graphs express the absolute difference of percentages between 2007 and 2004. Values above zero indicate an increase over time of the indicator; values below zero indicate a decrease.



VOLUME LAYOUT

All analyses were repeated on the entire patient sample according to type of diabetes. In the redesigned 2009 Annals, the chapter subdivisions are not structured around the type of indicator or graphic representation, but rather according to the clinical parameter in question. For example, process indicator, intermediate outcome measure, intercenter variability, and prescribed medications are illustrated together for HbA1c.

Additional analyses in the 2009 Annals include:

- Analysis of quality indicators according to geographic macro-area (North, Center, South)
- Characteristics of persons with T2DM who attended a diabetes center for the first time (at both the national and regional levels)
- Evaluation of the impact the Annals had on the quality of care delivered at the centers collaborating in the initiative in past years versus those that sent data for the first time in 2007.

Premise to data presentation

In all, 124 centers provided data on over 500,000 patients examined between 2004 and 2007. The following figures were obtained after applying the center selection filters and identifying the active patients:

Number of centers and patients included in the year-by-year analysis

	2004	2005	2006	2007
No. of analyzable centers	85	97	102	116
Persons with T1DM	5647	6612	8455	11,941
Persons with T2DM	106,319	123,953	151,113	191,967

Utilizing the threshold values reported in the section on Methods-Data Goodness, the number of centers that met the criteria for minimum acceptable completeness increased considerably between 2004 and 2007. This indicates that the centers have been placing more attention on the quality of the data entered on the electronic-medical record and signals an improvement in the quality of care.

Data goodness

	2004	2005	2006	2007
Analyzable centers	85	97	102	116
Centers with acceptable completeness of data	33	41	49	64
Proportion (%)	38.8%	42.3%	48.0%	55.2%

TYPE 1
DIABETES MELLITUS

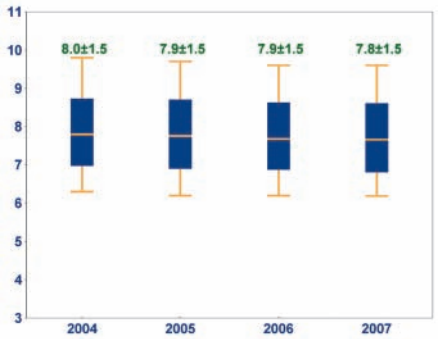
CHARACTERISTICS OF PATIENTS WITH TYPE 1 DIABETES MELLITUS (T1DM)

The table below illustrates the characteristics of the population according to type of diabetes and year.

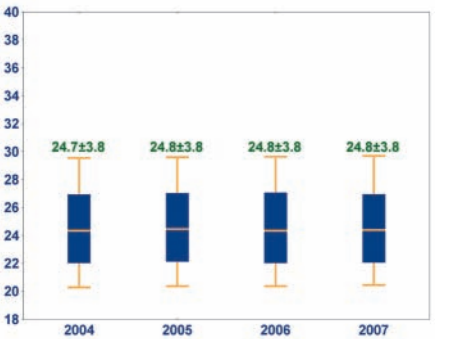
	2004	2005	2006	2007
No.	5647	6612	8455	11,941
Male (%)	54.5	54.5	55.2	55.0
Age (%)				
0-15	1.0	0.6	0.7	0.5
15-25	9.2	8.9	8.5	7.7
25-35	20.2	19.9	18.7	18.7
35-45	23.1	24.1	25.0	25.3
45-55	17.0	16.7	18.0	19.1
55-65	13.0	13.5	13.9	14.2
65-75	10.4	10.9	10.1	9.6
>75	6.1	5.4	5.1	4.9
First visit (%)	11.0	13.9	14.6	11.3
Mean no. of visits	3.1	3.0	2.9	2.9

Between 2004 and 2007 there was a slight decrease in the proportion of older patients, while the proportion of younger patients did not apparently increase, despite a consistent increase of over 10% in the rate of first-time visits. This was accompanied by a slight decrease in the mean number of visits performed per patient.

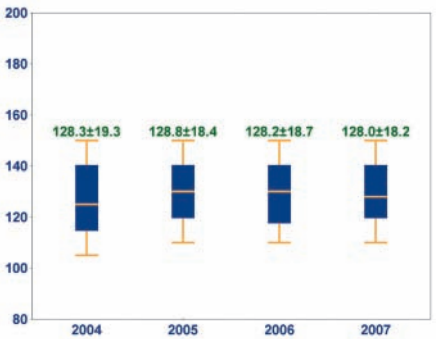
DISTRIBUTION OF MEAN VALUES OF MAIN CLINICAL PARAMETERS



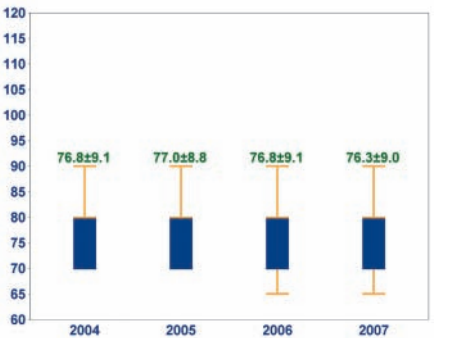
HbA1c



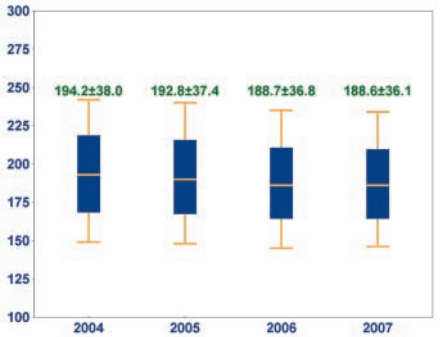
BMI



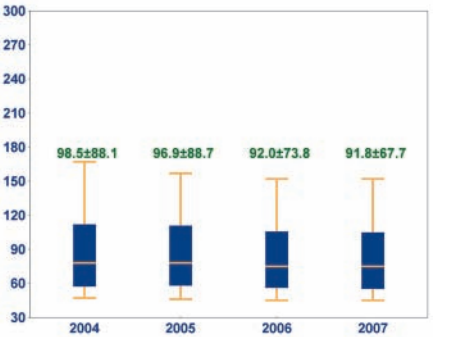
Systolic blood pressure



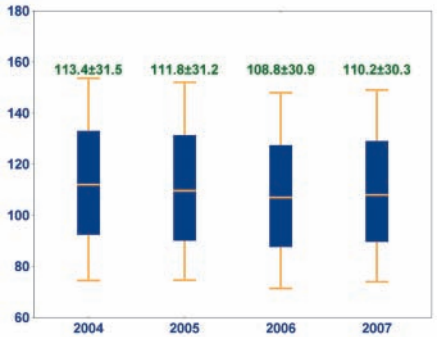
Diastolic blood pressure



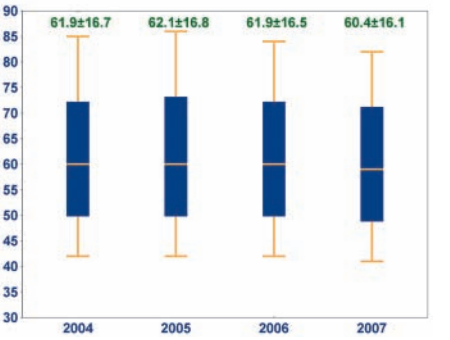
Total cholesterol



Triglycerides



LDL cholesterol



HDL cholesterol

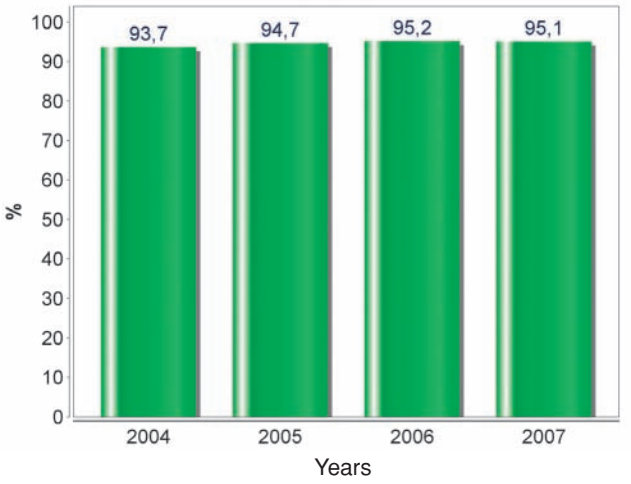
The data on the entire population of persons with T1DM show a slight reduction over time for HbA1c levels and lipid profile parameters. The mean blood pressure and BMI values remained unchanged.

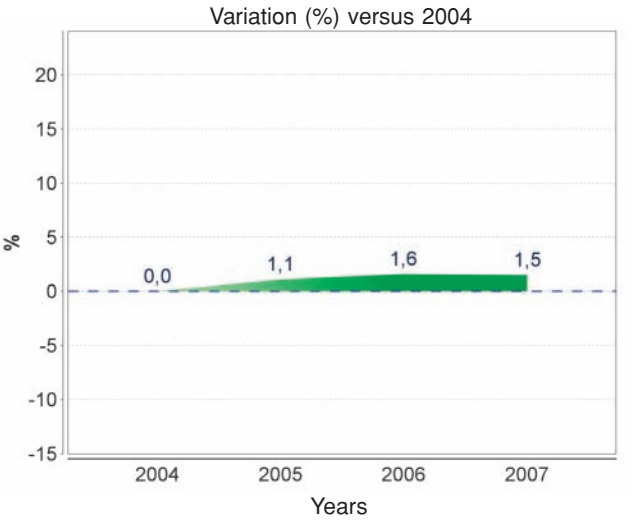
Glycated hemoglobin

This section explores the changes in the indicators of metabolic control and takes into consideration process indicators and intermediate outcome indicators (favorable and unfavorable). Also analyzed was whether there was a reduction in intercenter variability, which represents another important aspect of quality of care.

PROCESS INDICATORS

Patients who had their HbA1c measured at least once

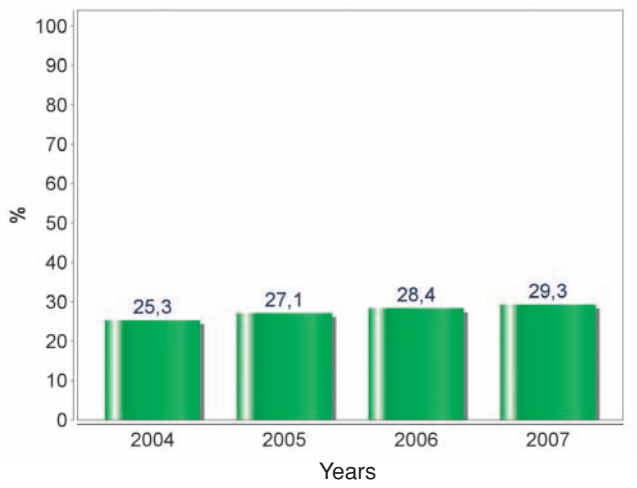


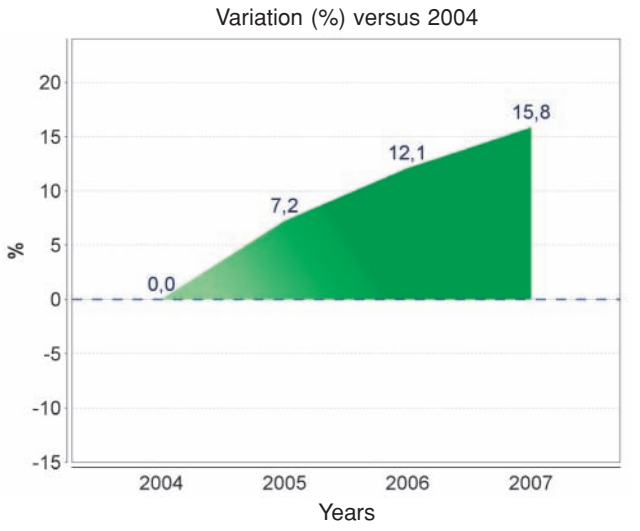


Since 2004, HbA1c monitoring has constituted the most satisfactory process indicator, performed in over 90% of patients across all four years, as shown in the bar graph. The percentage increase in the proportion of patients who had their HbA1c monitored at least once yearly rose slightly, as shown in the mountain graph.

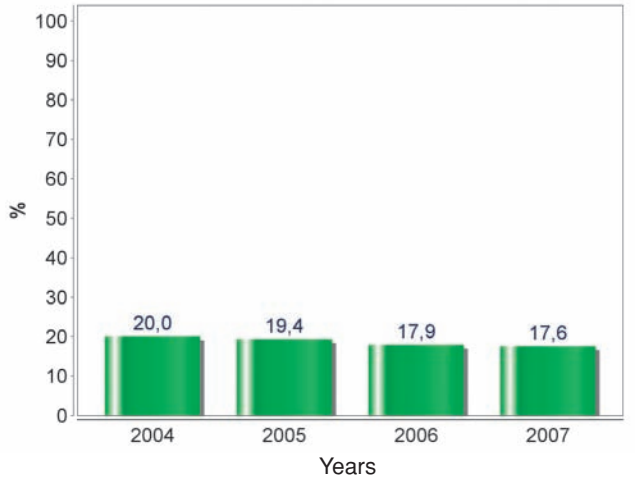
INTERMEDIATE OUTCOME INDICATORS

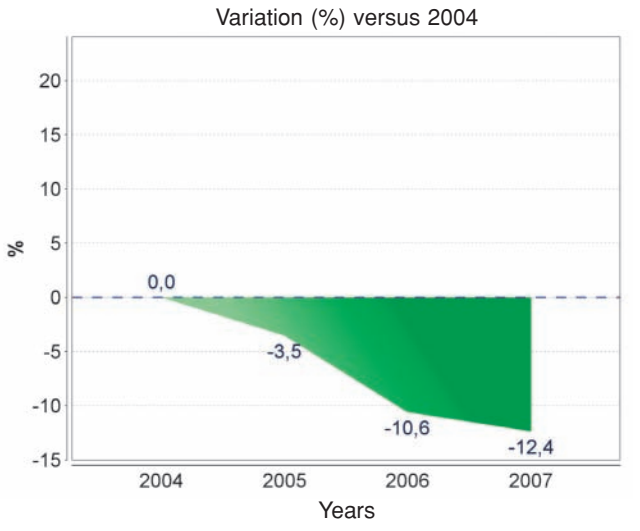
Patients with HbA1c ≤7%





Patients with HbA1c ≥9%



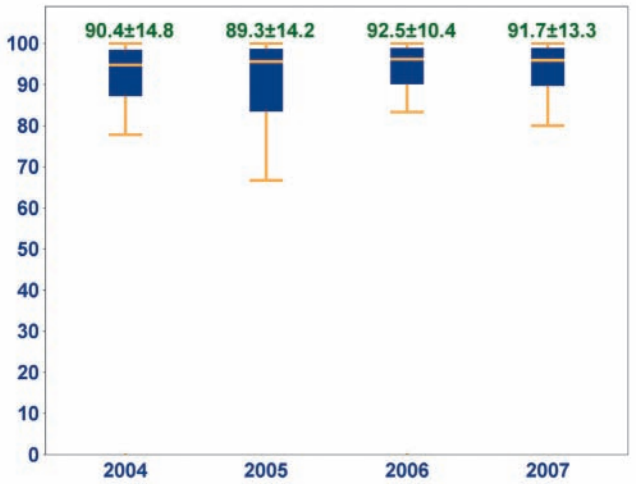


There was constant rise (from 25% to 29%) in the proportion of patients with target HbA1c values, with a relative percent increase of approximately 16%. Parallel to the increase in the percentage of persons with good metabolic control, the proportion of those with HbA1c >9% decreased from 20% to 17.6%, with a relative reduction of 12.4%.

Intercenter variability according to year

PROCESS INDICATORS

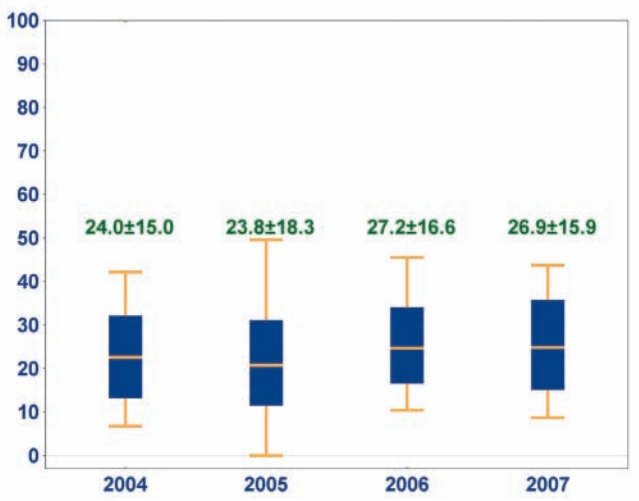
Patients who had their HbA1c measured at least once



Since 2004, HbA1c monitoring has constituted the process indicator with the lowest intercenter variability. Except for a drop in 2005, perhaps because of the entry of new centers less experienced in data recording, over the following years the variability remained acceptable and decreased further versus 2004.

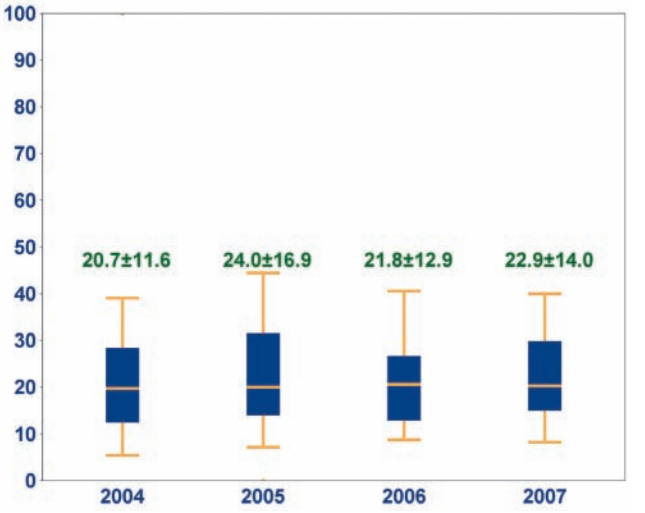
INTERMEDIATE OUTCOME INDICATORS

Patients with HbA1c ≤7%



Although there was an increase in the proportion of persons with target HbA1c values for some centers, there was no substantial reduction in intercenter variability, as shown by the unchanged box widths.

Patients with HbA1c ≥9%



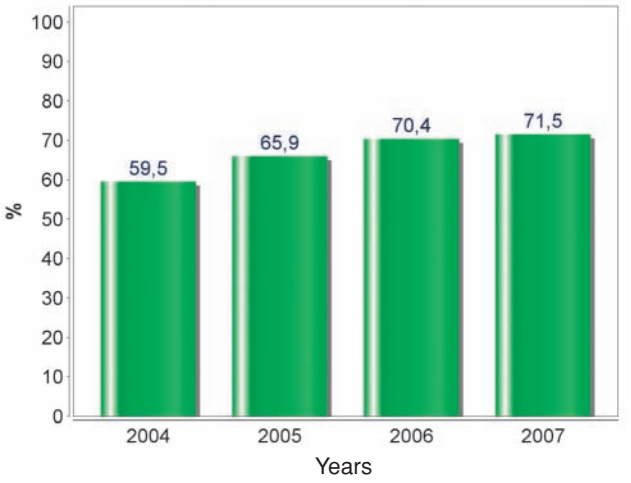
On average, every year about one person in five presented with particularly elevated HbA1c values. However, this value ranged between <10% and >30%, indicating substantial intercenter variability for this negative outcome measure.

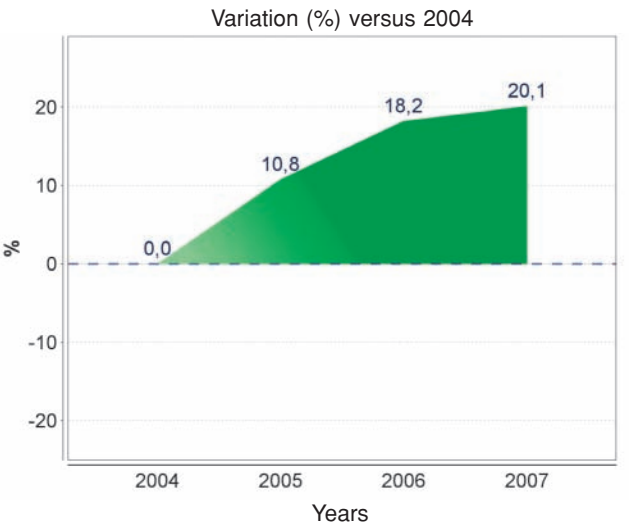
Lipid profile

This section explores the changes in the indicators of lipidic control and takes into consideration process indicators and intermediate outcome indicators (favorable and unfavorable). Also analyzed was whether there was a reduction in intercenter variability, which represents another important aspect of quality of care.

PROCESS INDICATORS

Patients who had their lipid profile measured at least once

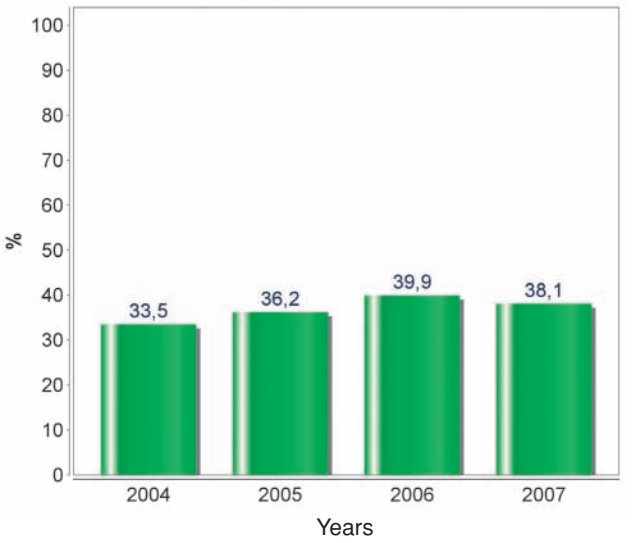


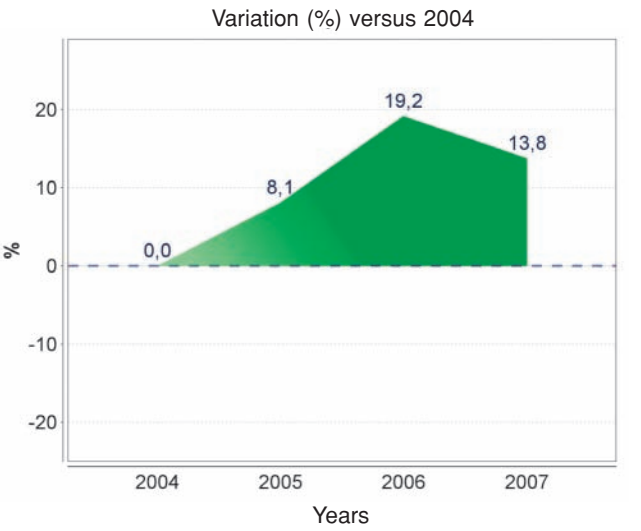


More and more patients had their lipid profile monitored, with a relative increase of 20% over the four-year period.

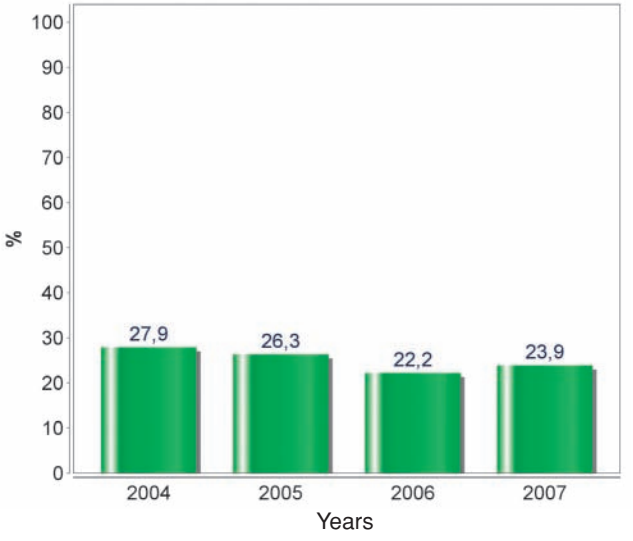
INTERMEDIATE OUTCOME INDICATORS

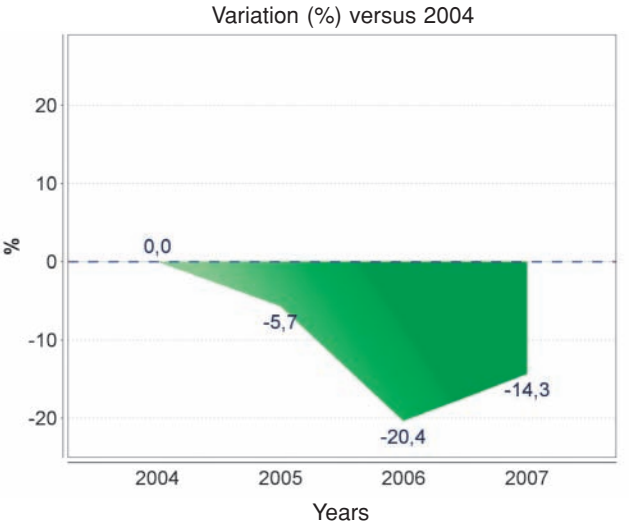
Patients with LDL cholesterol <100 mg/dl





Patients with LDL cholesterol ≥130 mg/dl



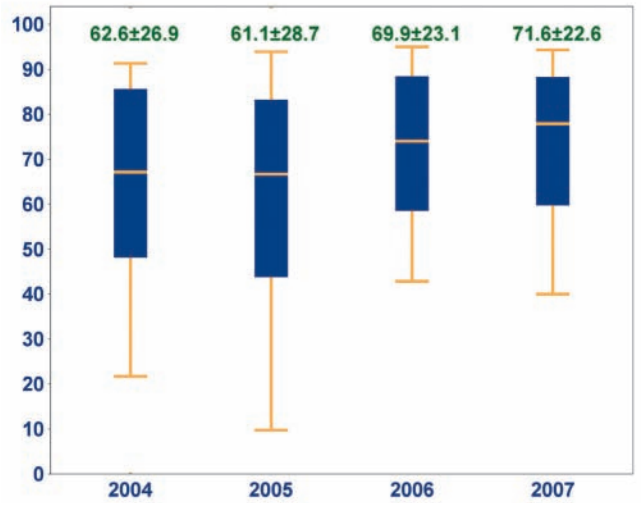


Time analysis of LDL cholesterol values showed an increase in the percentage of patients with target LDL cholesterol values, although slightly less than in 2007. There was also a relative reduction in the proportion of patients with particularly high LDL cholesterol values (20% in 2006 versus 14% in 2007).

Intercenter variability according to year

PROCESS INDICATORS

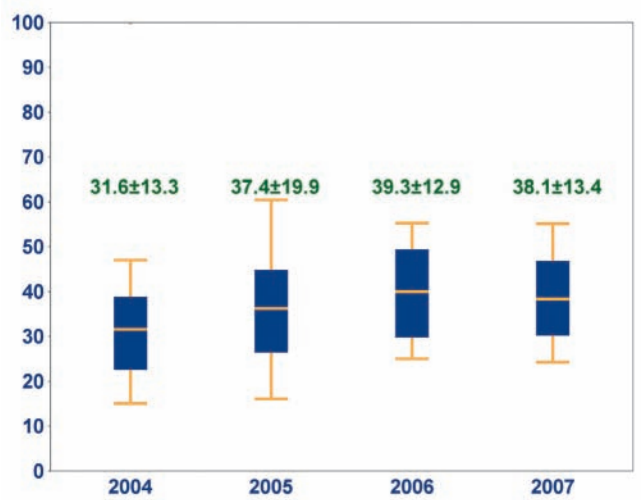
Patients who had their lipid profile measured at least once



Besides the increase in the mean proportion per center of the number of patients undergoing lipid monitoring, there was a clear reduction in inter-center variability for this process indicator, despite the persistence of a wide range of behaviors among centers.

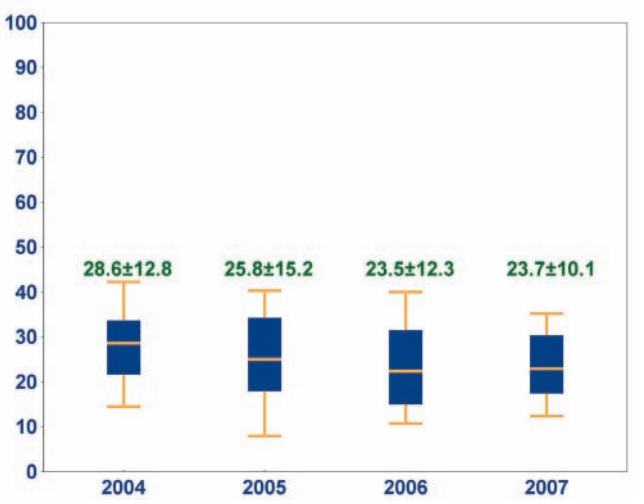
INTERMEDIATE OUTCOME INDICATORS

Patients with LDL cholesterol ≤100 mg/dl



The mean proportion of patients with target LDL cholesterol values per center increased over the four-year period, associated with a limited range of intercenter variability.

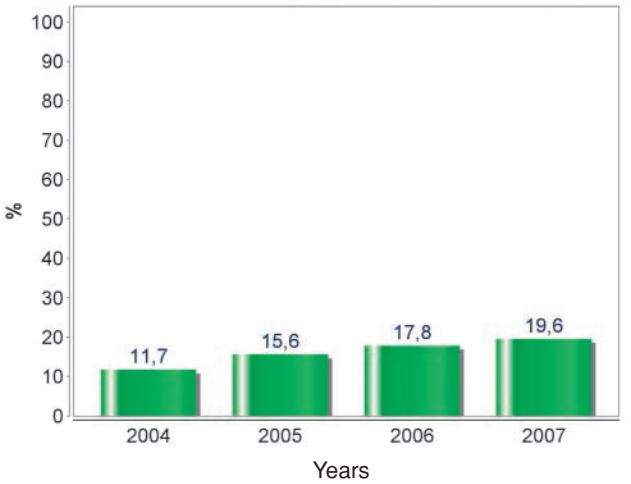
Patients with LDL cholesterol ≥130 mg/dl

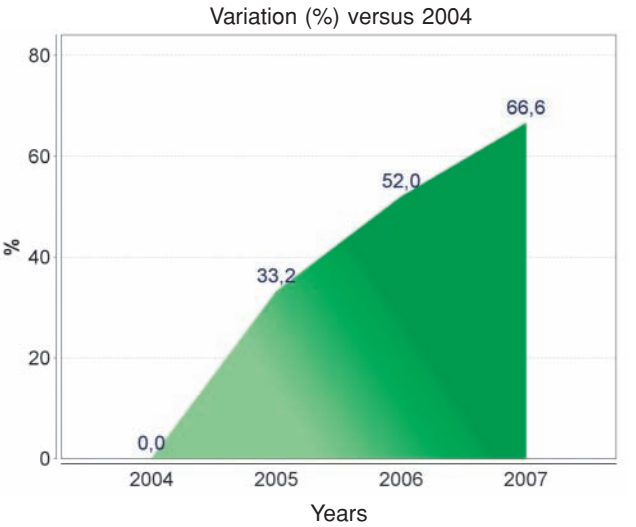


Accordingly, the mean proportion per center of patients with particularly elevated LDL cholesterol levels decreased; here, too, intercenter variability was low.

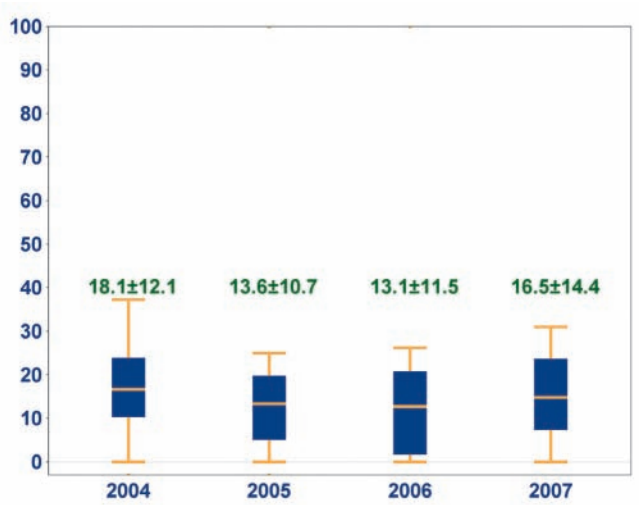
PRESCRIBED MEDICATIONS

Patients treated with statins





Intercenter variability in the rate of statin use according to year



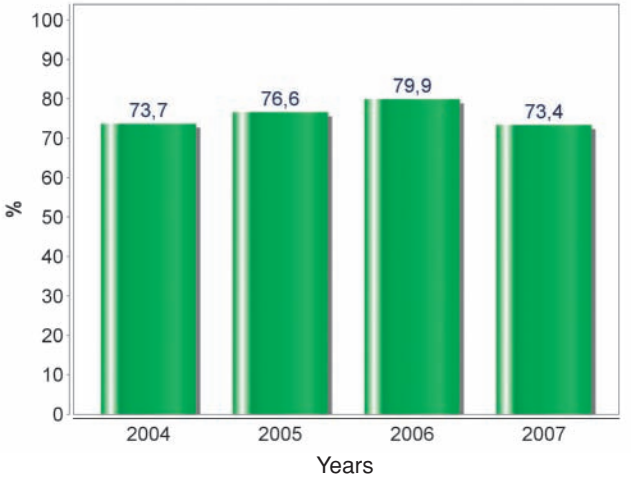
Marked changes were observed in the use of statins during the four-year period. There was a gradual increase in the use of drugs from this class, with a relative increase of 67% between 2004 and 2007. Analysis of intercenter variability showed moderate variability, without marked changes over the years.

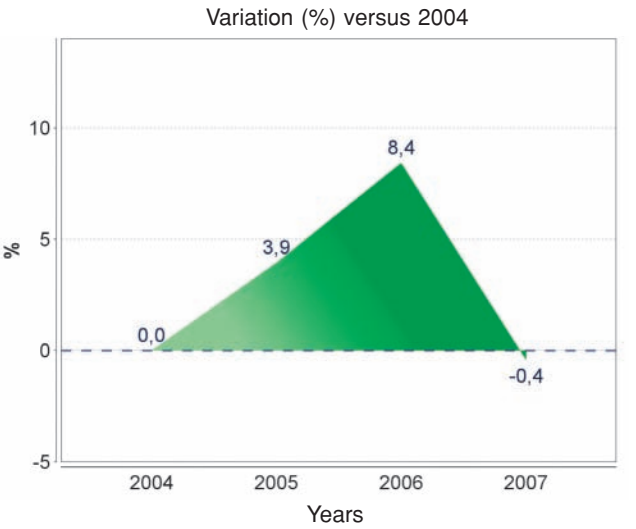
Blood pressure

This section explores the changes in the indicators of blood pressure control and takes into consideration process indicators and intermediate outcome indicators (favorable and unfavorable) of the use of several widely used antihypertensive agents. Also analyzed was whether there was a reduction in intercenter variability, which represents another important aspect of quality of care.

PROCESS INDICATORS

Patients who had their blood pressure measured at least once

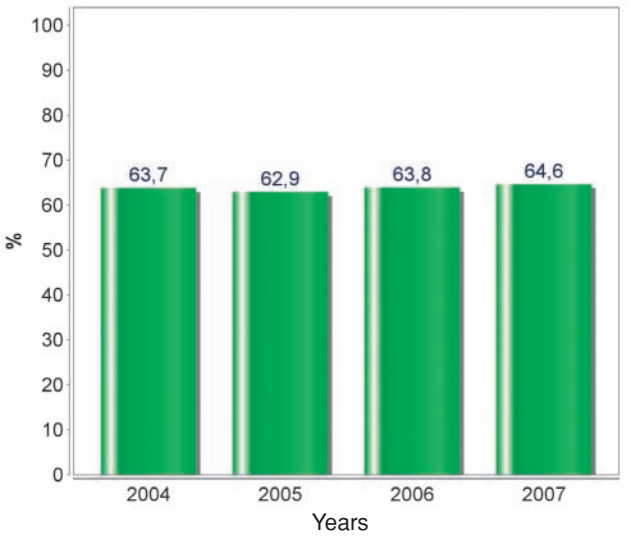


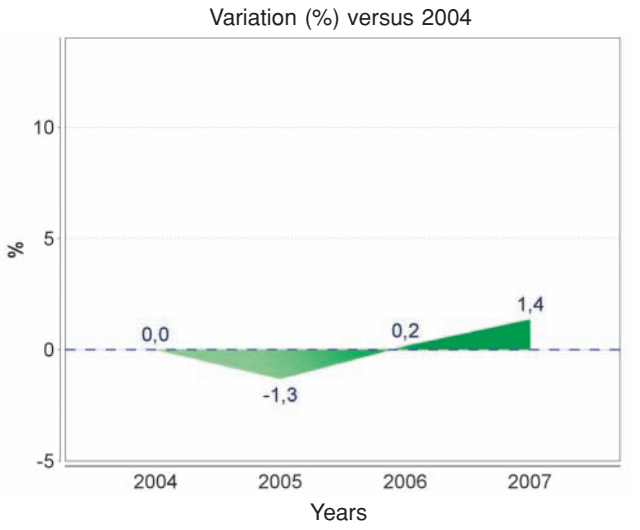


Following a gradual increase in the percentage of patients who had their blood pressure measured at least once between 2004 and 2006, there was a slight drop in 2007.

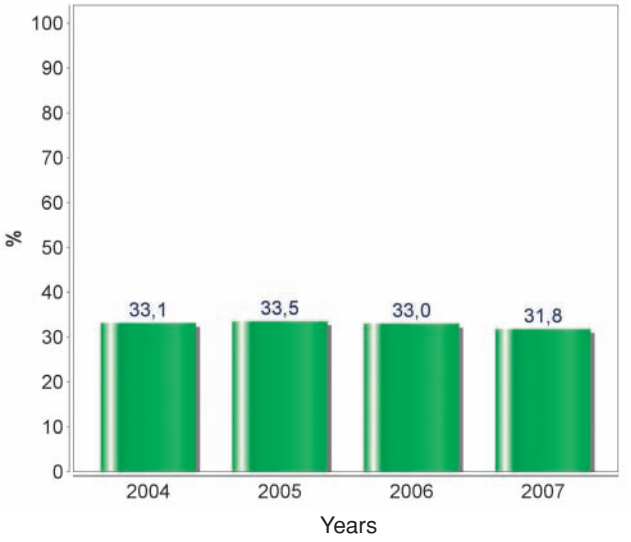
INTERMEDIATE OUTCOME INDICATORS

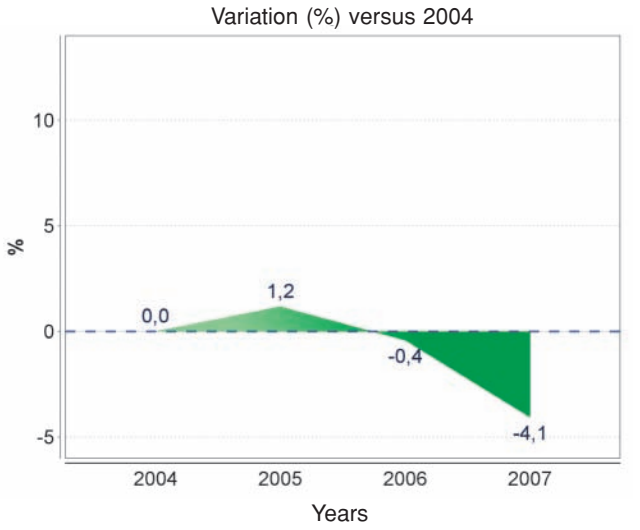
Patients with blood pressure ≤130/85 mmHg





Patients with blood pressure ≥140/90 mmHg



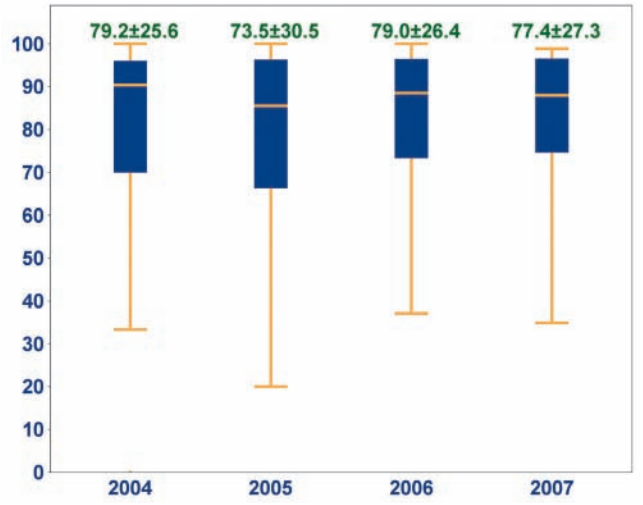


Blood pressure control remained substantially unchanged over the four years. In 2007 there was a slight decrease in the proportion of patients with blood pressure values ≥140/90 mmHg.

Intercenter variability according to year

PROCESS INDICATORS

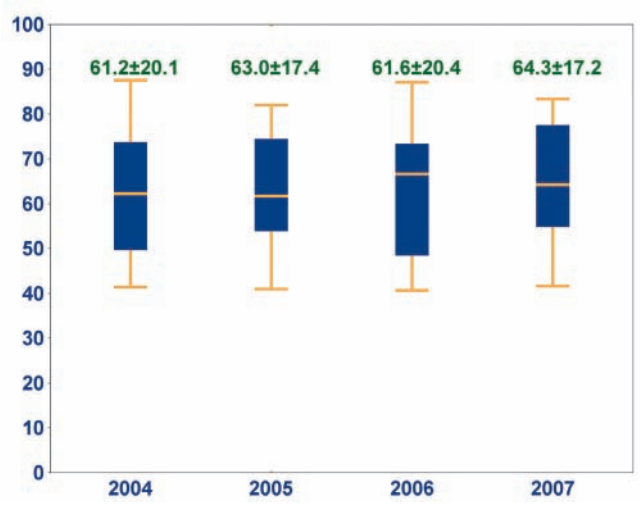
Patients who had their blood pressure measured at least once



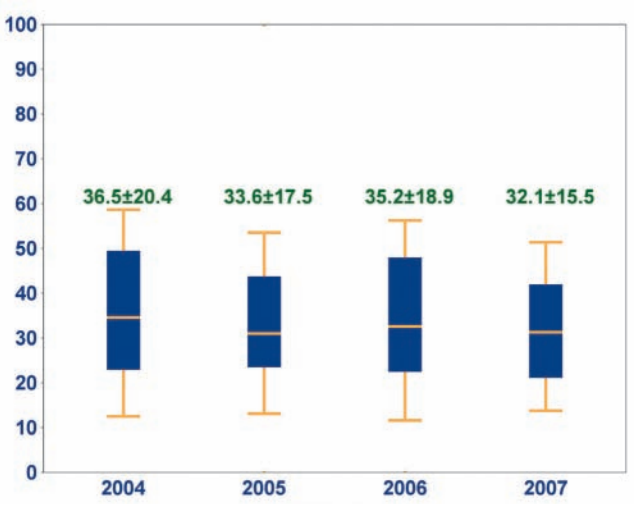
Although intercenter variability narrowed slightly over the four years, there remained a marked variability in the recording of blood pressure values, which was missing in nearly one fourth of patients, with striking differences among centers.

INTERMEDIATE OUTCOME INDICATORS

Patients with blood pressure ≤130/85 mmHg



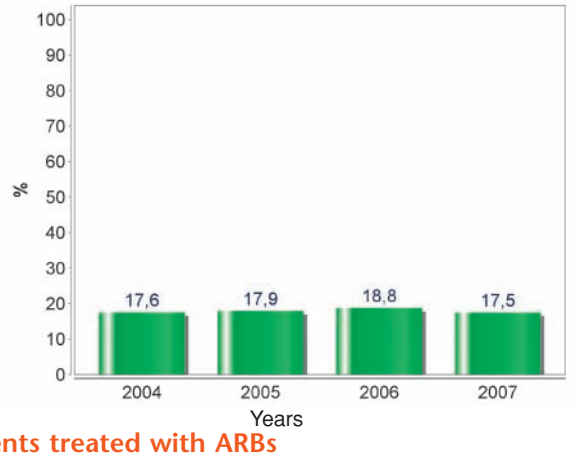
Patients with blood pressure ≥140/90 mmHg

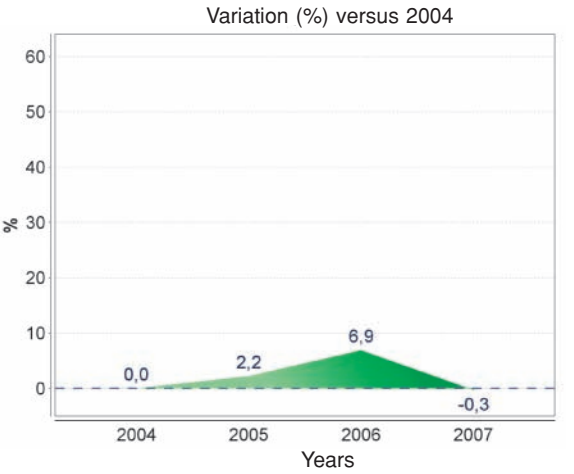


No significant changes were noted in either favorable or unfavorable outcome measures in terms of center performance or of variability.

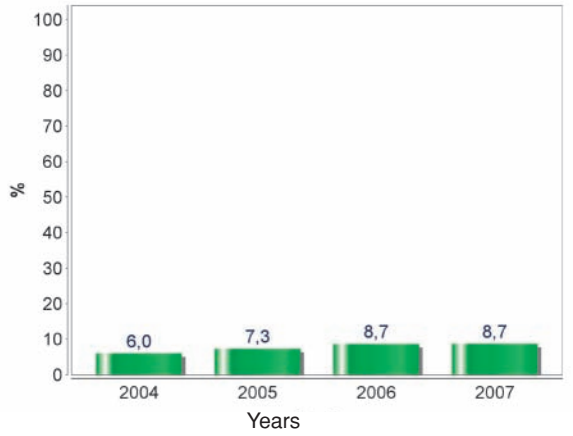
PRESCRIBED MEDICATIONS

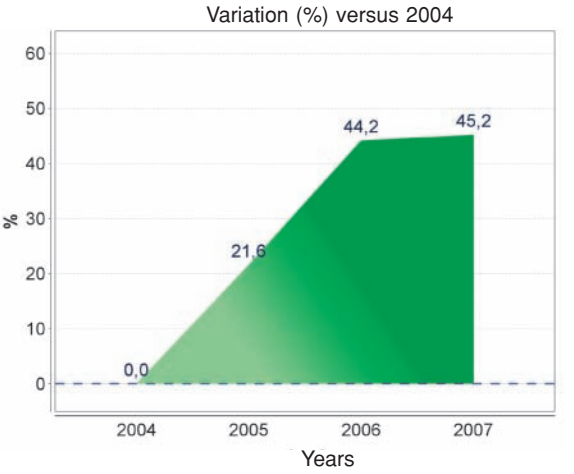
Patients treated with ACE inhibitors



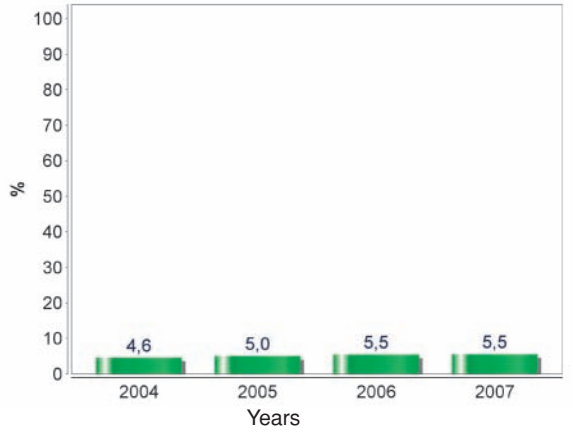


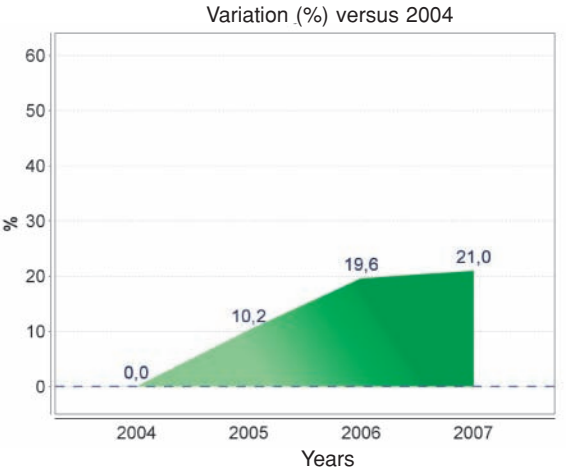
Patients treated with ARBs





Patients treated with beta-blockers

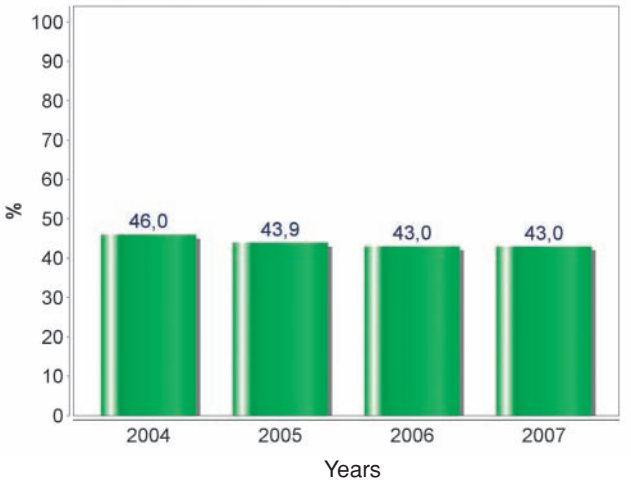


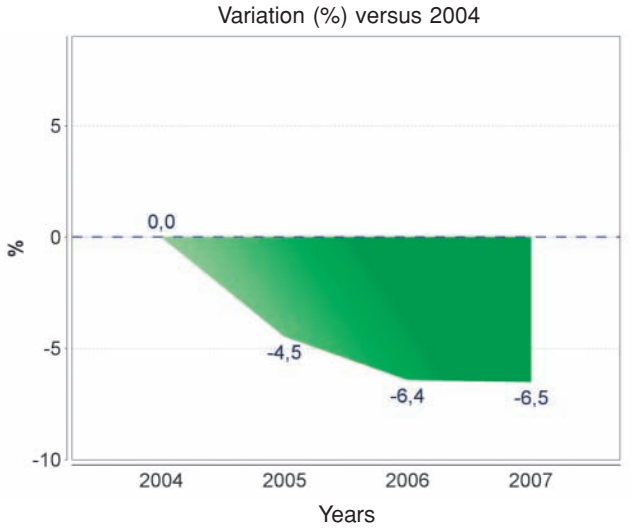


While the proportion of patients treated with ACE inhibitors remained basically unchanged, there was a substantial relative increase in the use of ARBs and beta-blockers.

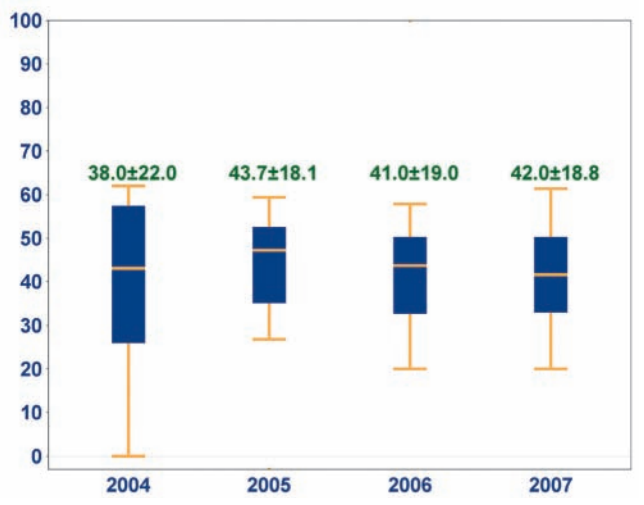
PRESCRIBED MEDICATIONS

Patients treated with ≥2 antihypertensive agents





Intercenter variability in the rate of use of ≥2 antihypertensive agents



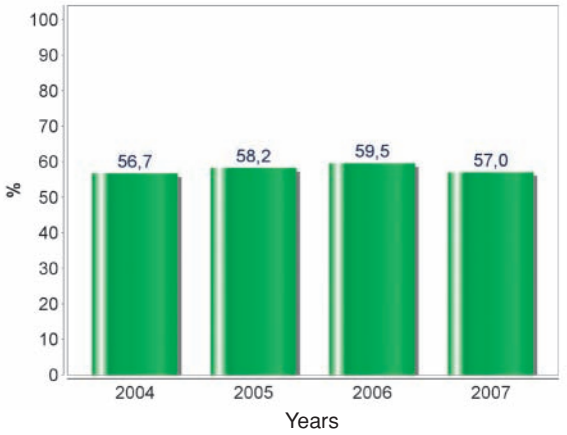
On the whole, the proportion of hypertensive patients treated with two or more antihypertensive agents seems to have decreased. The wide variability among the centers found in 2004 has narrowed since then.

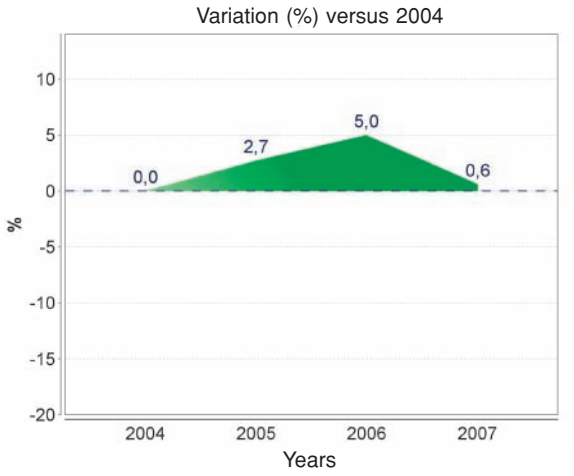
Other indicators

This section explores the changes in the remaining quality indicators ordinarily investigated by the AMD Annals. Taken into the analysis were process indicators such as the proportion of patients monitored for nephropathy and who underwent a foot examination during the four-year period, and as intermediate outcome indicators BMI and the percentage of smokers.

PROCESS INDICATORS

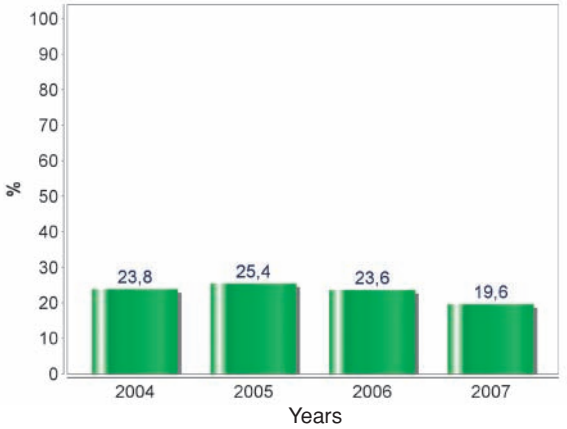
Patients monitored for nephropathy

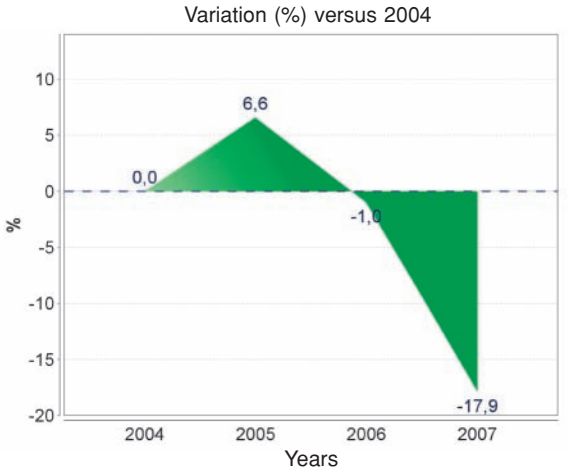




No substantial changes were observed in renal function monitoring over the four-year period. Following a slight rise in 2005-2006, the more recent data reveal a percentage comparable to that of 2004.

Patients monitored for diabetic foot

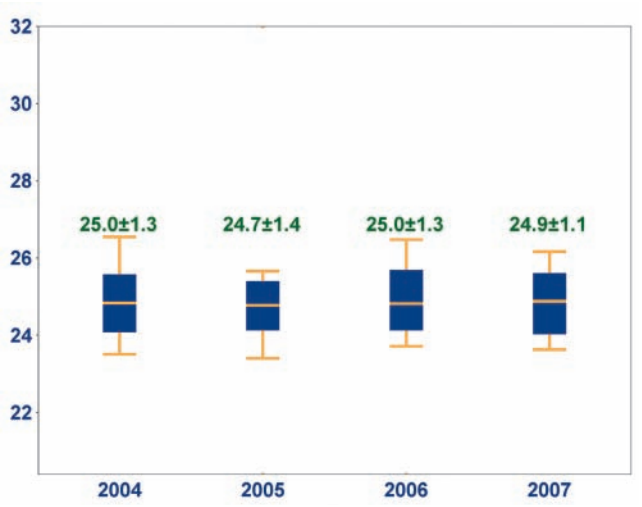




Foot examination remains the least systematically performed or recorded process measure, with a marked drop in 2007.

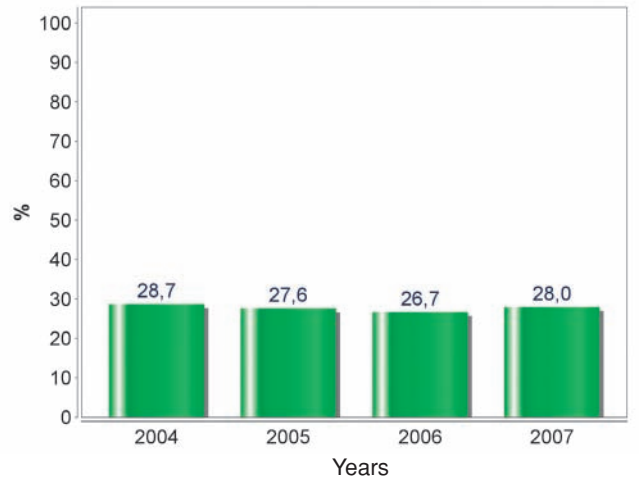
INTERMEDIATE OUTCOME INDICATORS

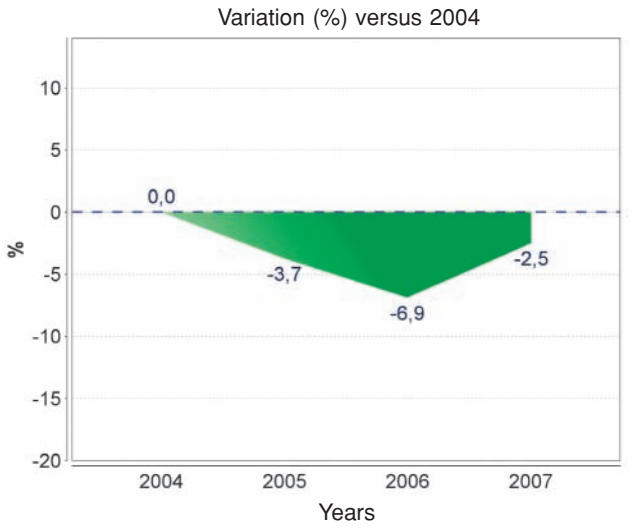
Distribution of mean BMI values according to year and center



No significant changes were found in mean BMI values or in intercenter variability.

Smokers





The percentage of smokers decreased only slightly. The high prevalence of smokers in this high-risk population remains cause for concern.

Commentary

Between 2004 and 2007, the number of patients for which process indicators and intermediate outcome indicators could be analyzed nearly doubled (5647 versus 11,294, respectively). The rate of first visits remained at above 11%.
According to diagnostic-therapeutic health care pathways in diabetes, all persons with T1DM should be followed by a diabetes center.
The reason for the slight but gradual reduction in the mean number of visits per patient over the years might be due to increasing difficulty the centers have in meeting the demand for diabetes care.

GLYCOMETABOLIC COMPENSATION

Glycated hemoglobin

Glycated hemoglobin was measured in nearly all patients at least once yearly and nearly invariably at all centers. According to the *Italian Standards for Diabetes Mellitus*, the objective is to maintain HbA1c <7% (Evidence Level I, Recommendation Strength B). This goal was attained in <30% of patients. Nonetheless, over the four years the number of patients who reached this target value (relative increase of 15.8% versus 2004) rose, and the number of those with HbA1c >9% (relative decrease of 12.4% versus 2004) fell.
Over the four years, the range of intercenter variability remained unchanged as regards the number of patients with target HbA1c values (15-35%) and those with particularly elevated values (10-30%), indicating scope for improvement in this area.

CARDIOVASCULAR RISK FACTORS

LDL cholesterol

The percentage of patients with T1DM who had their LDL cholesterol measured at least once a year rose between 2004 and 2007, increasing from 59.5% to 71.5%, with a relative increase of 20.1%. It appears that in about 30% of patients the lipid profile was not monitored, with a wide range of intercenter variability (60-90%).
Of note is that in order to arrive at this finding, either the LDL cholesterol or the HDL cholesterol or triglyceride value has to be recorded in the Data File in order to calculate the total cholesterol value. Therefore, one problem could be that either the test was not performed or the HDL cholesterol value not recorded.
According to the *Italian Standards for Diabetes Mellitus*, the goal is to reach an LDL cholesterol value <100 mg/dl (Evidence Level I, Recommendation Strength B). Although gradually improving, this objective was achieved in a low percentage of patients. In 2007 only 38.1% of patients were noted to have target values (relative increase of 13.8% versus 2004).
The percentage of patients with elevated LDL cholesterol values (>130 mg/dl) dropped to 23.9% in 2007 (relative reduction of 14.3% versus 2004).
Although there was a relative increase in the use of statins (66.6%), only 19.6% of patients were receiving statin therapy in 2007, with wide intercenter variability.

Blood pressure

The percent of patients who had their blood pressure measured at least once varied between 73% and 80%, with a slight decrease in 2007. The wide intercenter variability (70-95%) may reflect problems with recording this datum.
According to the *Italian Standards for Diabetes Mellitus*, the goal is to reach systolic blood pressure <130 mmHg (Evidence Level III, Recommendation Strength B) and diastolic blood pressure <80 mmHg (Evidence Level II, Recommendation Strength B). For reasons of continuity and data comparability, the threshold of 130/85 mmHg was used in this analysis, as in the 2004 AMD Annals analysis.
The level of blood pressure control remained substantially unchanged over the four years.
The percentage of patients with a blood pressure value ≤130/85 mmHg in 2007 was 64.6%, with a relative increase of 1.4% versus 2004. There was a relative decrease of 4.1% in patients with values ≥140/90 mmHg, or 31.8% in 2007.
The use of ACE inhibitors remained unchanged, whereas the use of ARBs and beta-blockers increased. On the whole, the proportion of hypertensive patients treated with two or more antihypertensive agents decreased slightly.

The wide intercenter variability in reporting found in 2004 narrowed considerably over the following years.

Smoking

The percentage of smokers decreased only slightly; 28% of patients in this high-risk population were smokers.

OTHER INDICATORS

Patients monitored for diabetic nephropathy

Renal function monitoring remained substantially unchanged over the four-year period; following a slight increase in 2005-2006, the more recent data show a percentage comparable to that of 2004. Apparently, only 57% of patients with T1DM were monitored for this complication; however, it cannot be ruled out that monitoring was carried out but not recorded.

Patients monitored for diabetic foot

Foot examination remains the least systematically performed or recorded process measure (19.6% in 2007), with a marked drop of 17.9% in 2007.

Antonino Cimino

TYPE 2
DIABETES MELLITUS

CHARACTERISTICS OF PATIENTS WITH TYPE 2 DIABETES MELLITUS (T2DM)

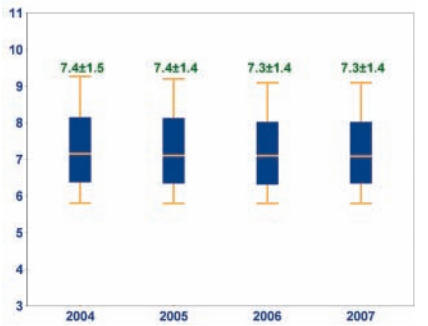
The table illustrates the characteristics of the population according to type of diabetes and year.

	2004	2005	2006	2007
No.	106,319	123,953	151,113	191,967
Males (%)	54.1	54.3	54.8	54.8
Age (%)				
0-35	0.8	0.9	0.8	0.8
35-45	3.2	3.1	3.0	2.8
45-55	10.9	10.6	10.2	9.7
55-65	26.2	25.7	25.4	24.8
65-75	34.2	34.5	34.8	35.2
>75	24.7	25.2	25.8	26.7
First visit (%)	18.3	18.2	18.7	16.6
Treatment (%)				
Diet alone	11.3	11.1	10.5	10.3
OHA*	63.5	62.6	62.1	60.5
OHA* + insulin	11.4	12.0	12.7	13.8
Insulin	13.8	14.3	14.7	15.4
Mean no. of visits				
Diet alone	1.6	1.5	1.5	1.5
OHA*	2.1	2.1	2.0	1.9
Insulin	3.0	3.0	2.9	2.8
OHA* + insulin	3.0	3.0	2.9	2.9

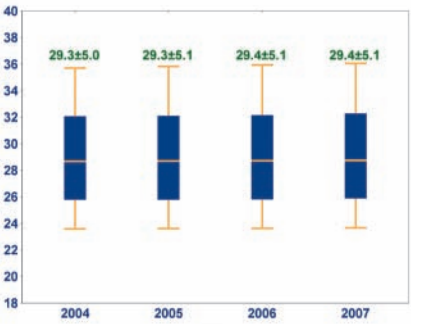
*OHA = oral hypoglicemic agents

Over the four years there was a slight increase in the number of older patients, while the number of younger patients fell slightly. The percentage of first visits appears to have decreased in 2007. The proportion of patients treated with insulin alone or in combination therapy increased steadily over the years, with a parallel decrease in the proportion of those treated with diet alone or with oral hypoglycemic agents.
As in T1DM, there was a slight decrease in the mean number of visits per patient in all treatment categories.

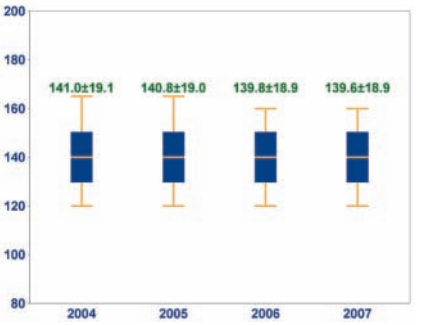
DISTRIBUTION OF MEAN VALUES OF MAIN CLINICAL PARAMETERS



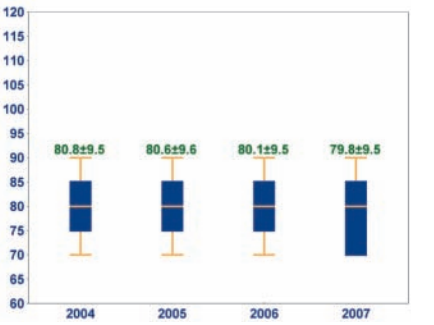
HbA1c



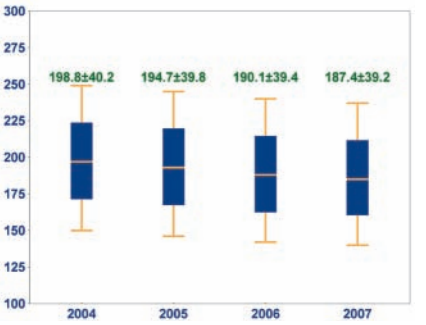
BMI



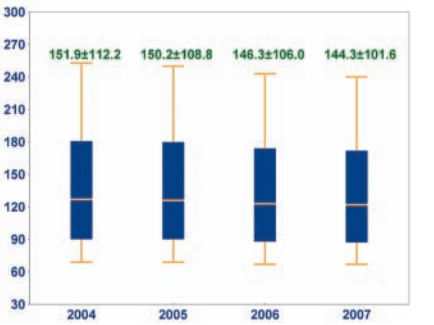
Systolic blood pressure



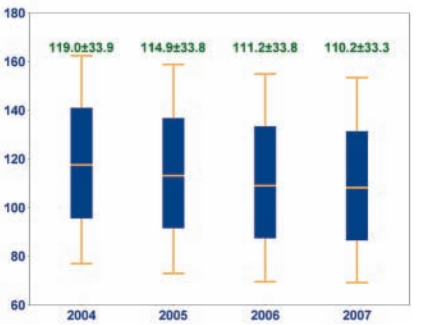
Diastolic blood pressure



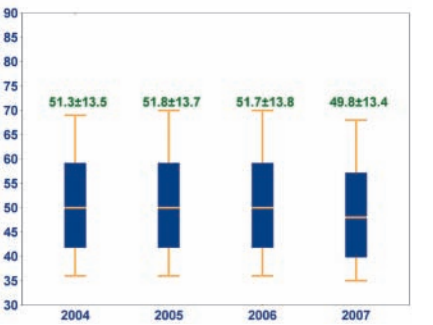
Total cholesterol



Triglycerides



LDL cholesterol



HDL cholesterol

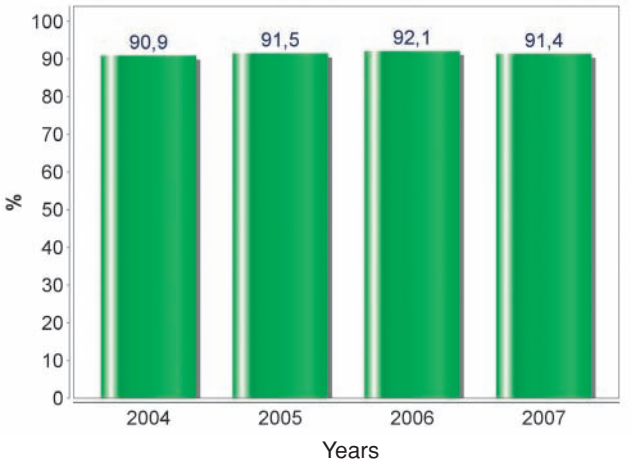
The data on the whole population with T2DM show a slight decrease over time in HbA1c and in lipid levels, while mean blood pressure and BMI values remained unchanged.

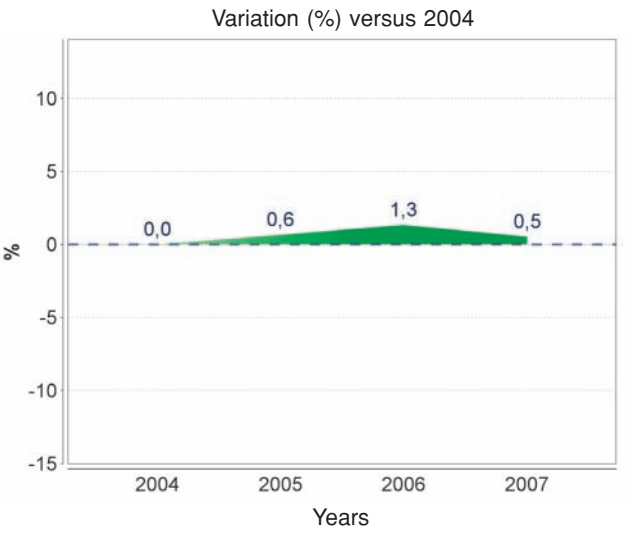
Glycated hemoglobin

This section explores the changes in the indicators of metabolic control and takes into consideration process indicators and intermediate outcome indicators (favorable and unfavorable), the use of insulin and several classes of oral hypoglycemic agents. Also analyzed was whether there was a decrease in intercenter variability, which represents another important aspect of quality of care.

PROCESS INDICATORS

Patients who had their HbA1c measured at least once

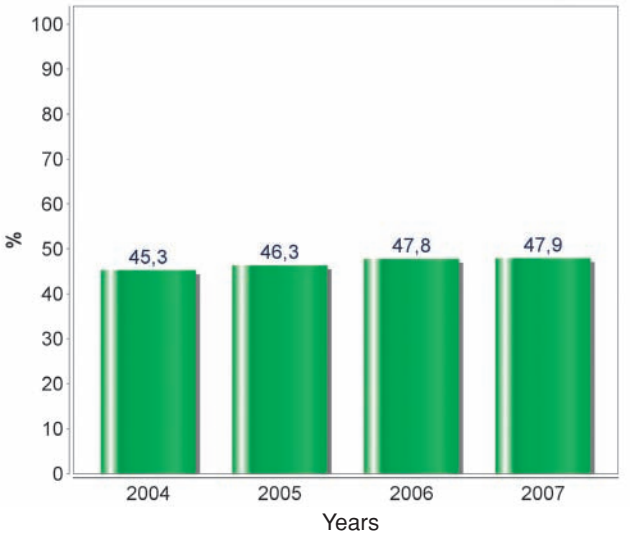


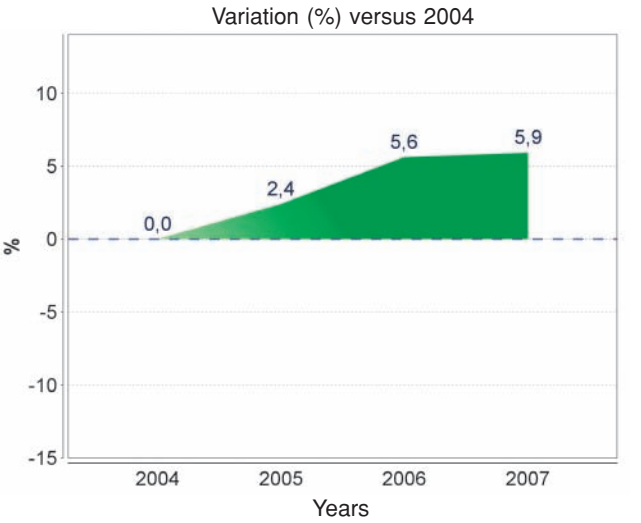


As for T1DM, also for T2DM HbA1c monitoring constituted the most satisfactory process indicator, with over 90% of patients monitored every year since 2004, as shown in the bar graph.
No substantial change was noted in the proportion of subjects who had their HbA1c measured at least once a year, as shown in the mountain graph.

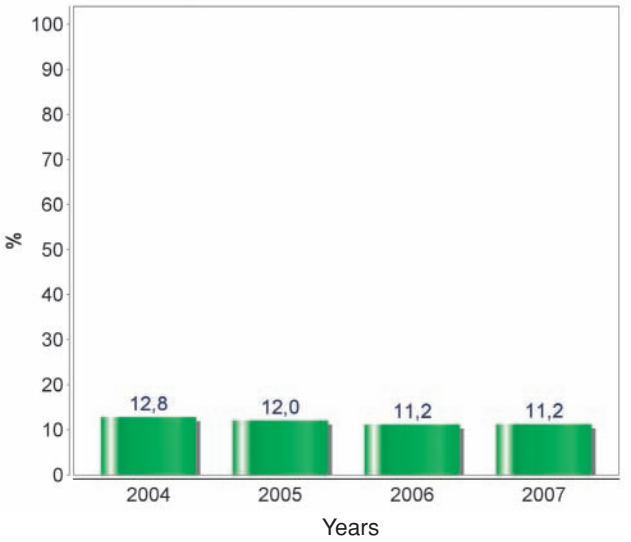
INTERMEDIATE OUTCOME INDICATORS

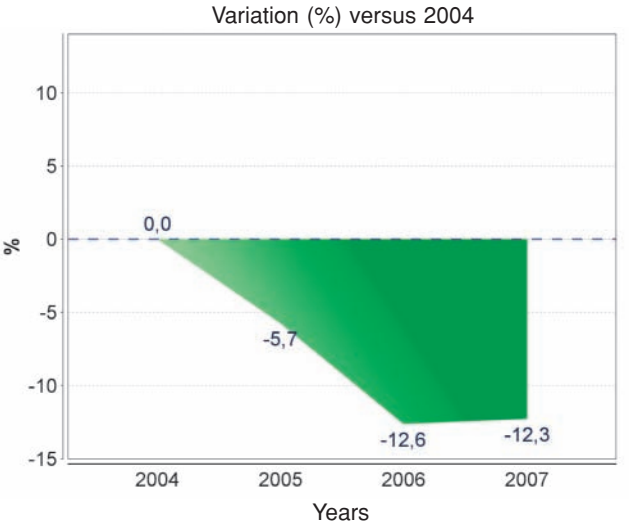
Persons with HbA1c ≤7%





Persons with HbA1c ≥9%



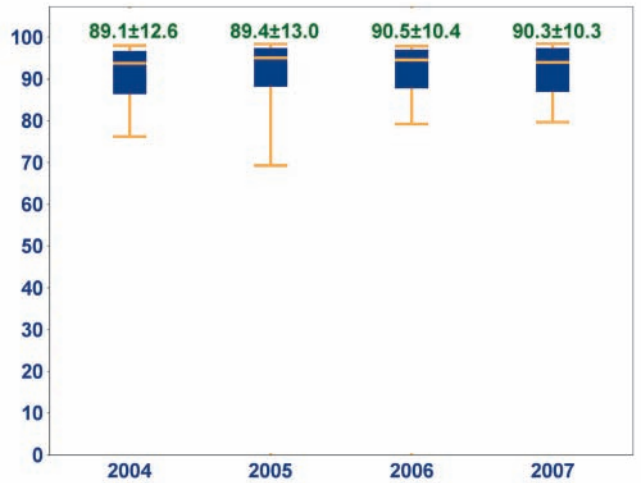


Over the four-year period, there was a constant increase in the proportion of patients with target HbA1c values (from 45% to 48%), with a relative increase of approximately 6%. Parallel to the increase in the percentage of patients with good metabolic control, the proportion of those with HbA1c >9% decreased slightly, with a relative reduction of 12.3%.

Intercenter variability by year

PROCESS INDICATORS

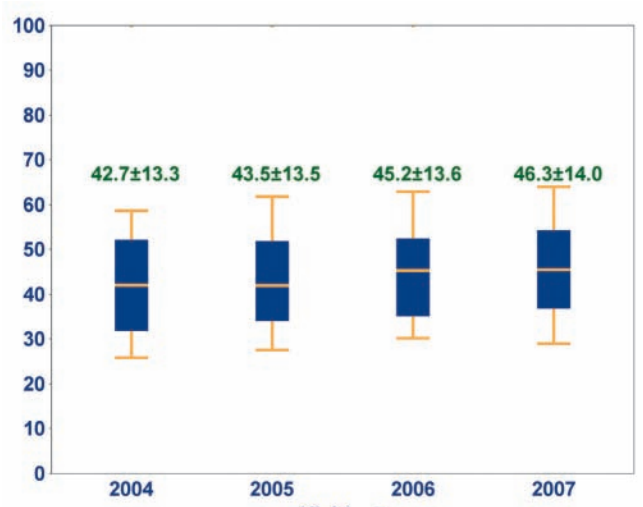
Patients who had their HbA1c measured at least once



Since 2004, HbA1c monitoring has been the process indicator with the least intercenter variability. The narrow range of variability closed further versus 2004.

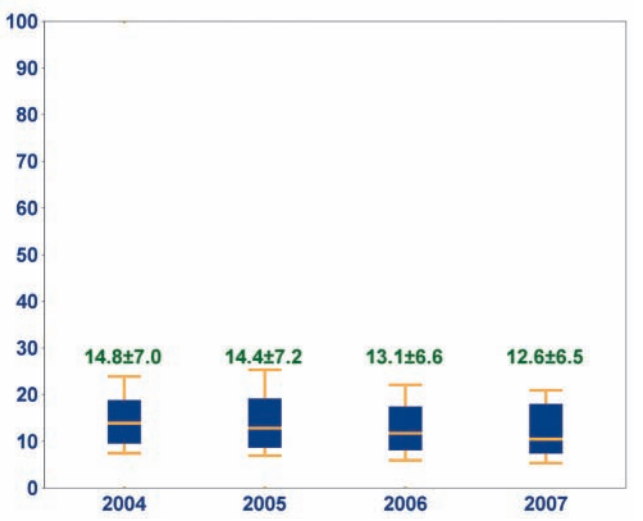
INTERMEDIATE OUTCOME INDICATORS

Patients with HbA1c ≤7%



Although there was an increase in the mean proportion of patients with target values at some centers, intercenter variability did not decrease substantially, as shown by the similar box widths.

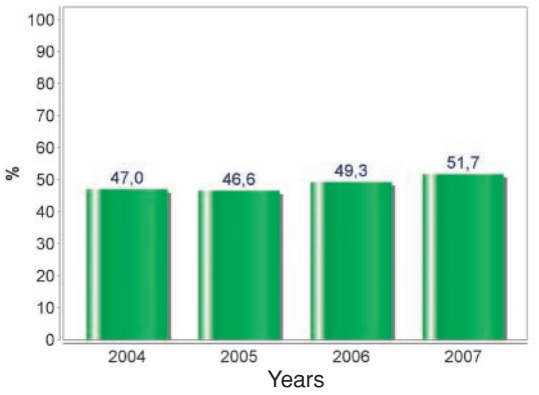
Patients with HbA1c ≥9%

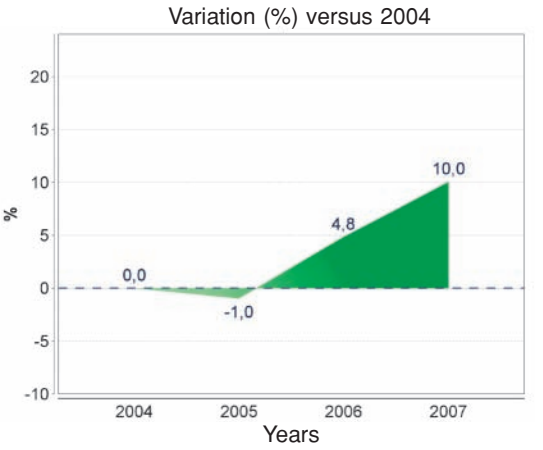


The mean percent of patients with particularly high HbA1c values was moderate and decreased over the years; the range of intercenter variability was also moderate.

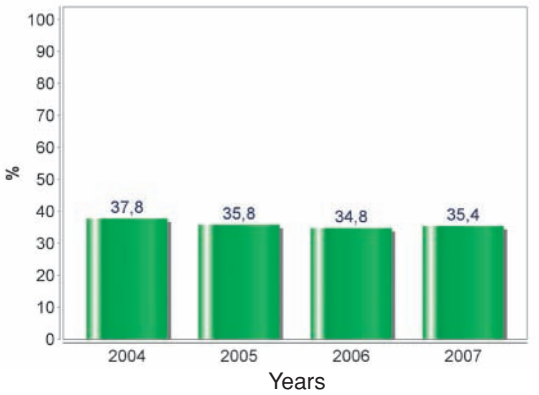
PRESCRIBED MEDICATIONS

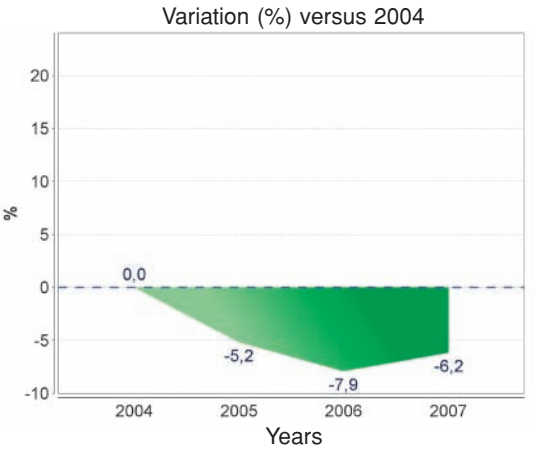
Patients receiving metformin



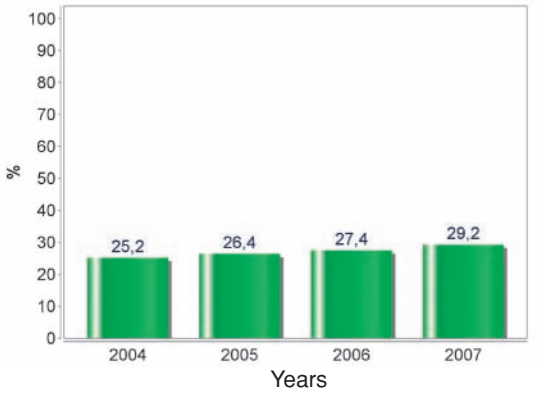


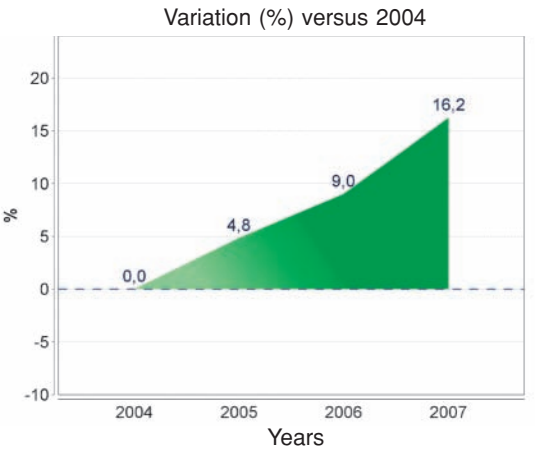
Patients receiving sulfonylureas





Patients receiving insulin

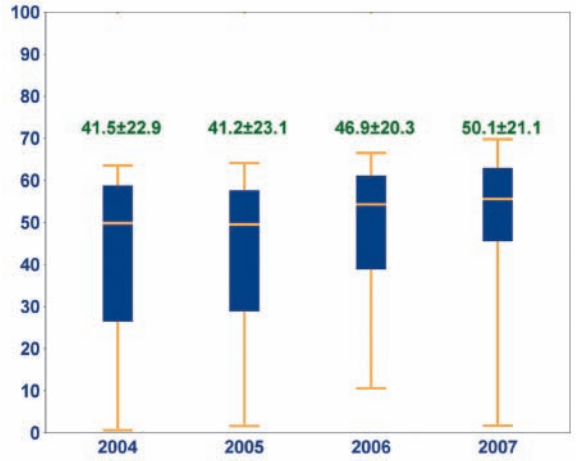




The time trend of the use of antidiabetic drugs showed an increase in the proportion of patients treated with metformin and those treated with insulin, associated with a slight decrease in the percentage of those on sulfonylurea therapy.

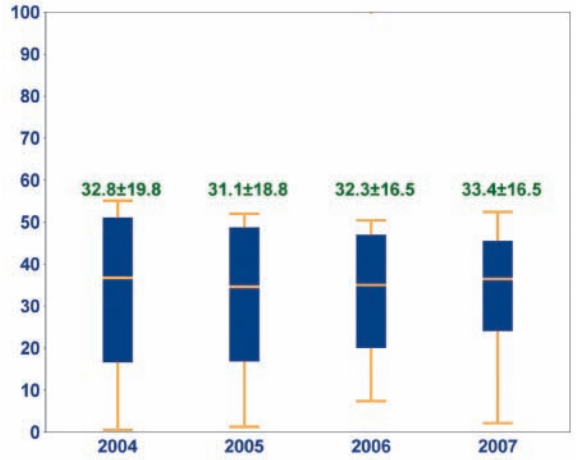
PRESCRIBED MEDICATIONS

Intercenter variability in rate of use of metformin



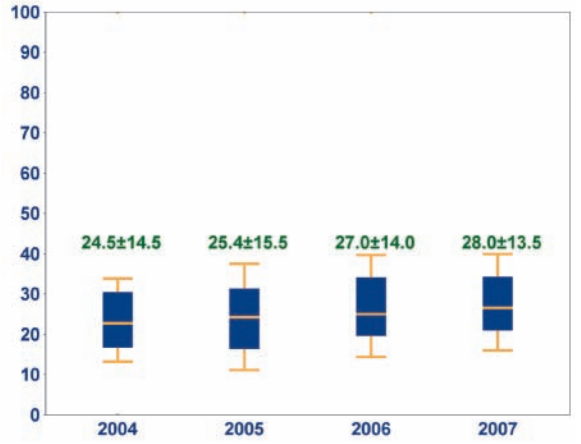
Over the four years there was an increase in the mean number of patients per center treated with metformin, associated with a marked reduction in intercenter variability.
The negative extremes were probably due to the lack of use by some centers of an electronic-medical record for entering drug prescriptions.

Intercenter variability in the rate of use of sulfonylureas



While the mean percentage per center of patients on sulfonylurea therapy remained unchanged, there was a substantial reduction in intercenter variability.

Intercenter variability in the rate of use of insulin



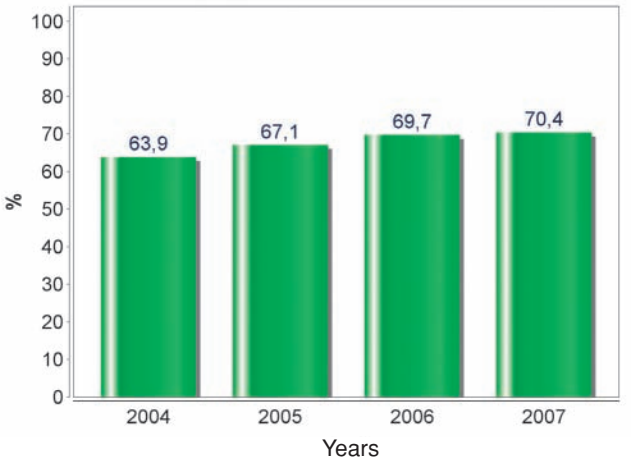
The mean percentage per center of patients on insulin therapy increased over the four-year period, while intercenter variability remained low.

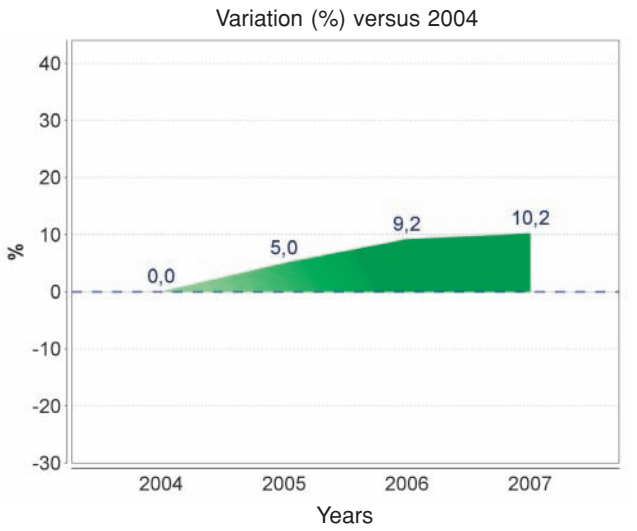
Lipid profile

This section explores the changes in the indicators of lipidic control and takes into consideration process indicators and intermediate outcome indicators (favorable and unfavorable) and the use of statins. Also analyzed was whether there was a reduction in intercenter variability, which represents another important aspect of quality of care.

PROCESS INDICATORS

Patients who had their lipid profile measured at least once

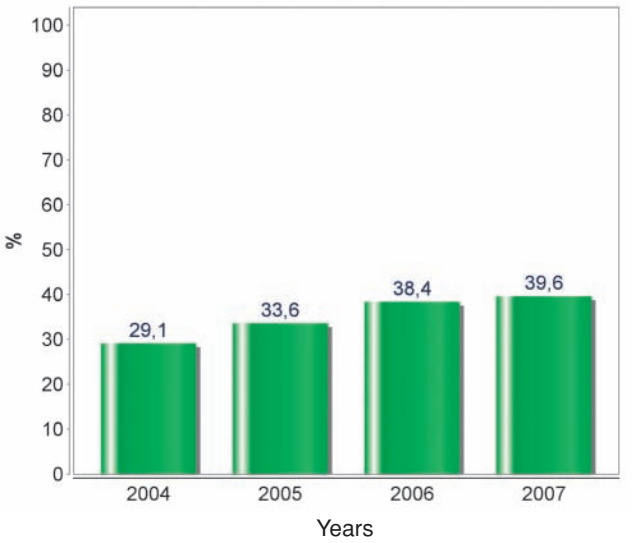


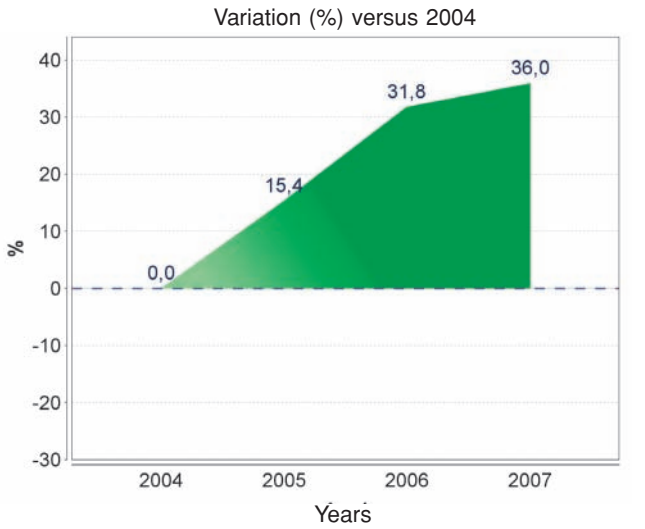


More and more patients had their lipid profile monitored, with a relative increase of 10% over the four-year period.

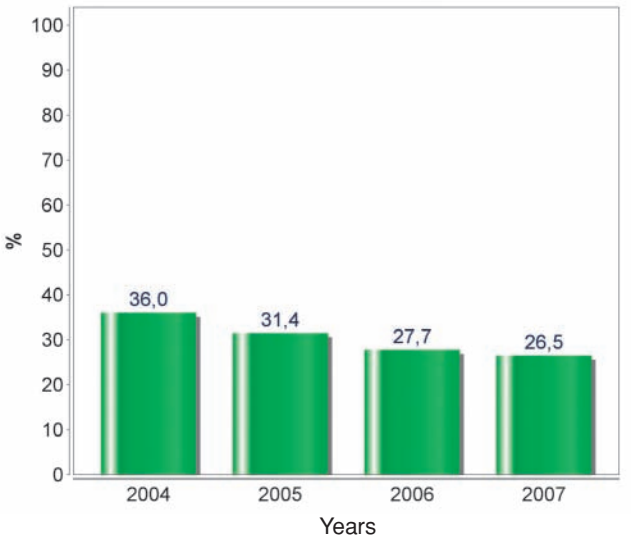
INTERMEDIATE OUTCOME INDICATORS

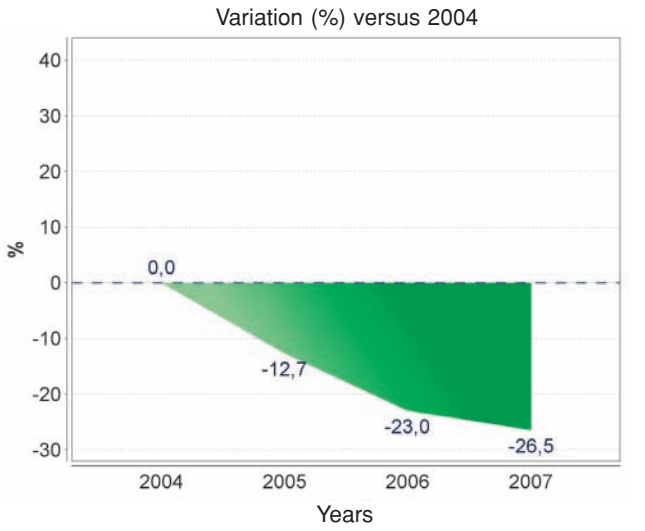
Patients with LDL cholesterol <100 mg/dl





Patients with LDL cholesterol ≥130 mg/dl



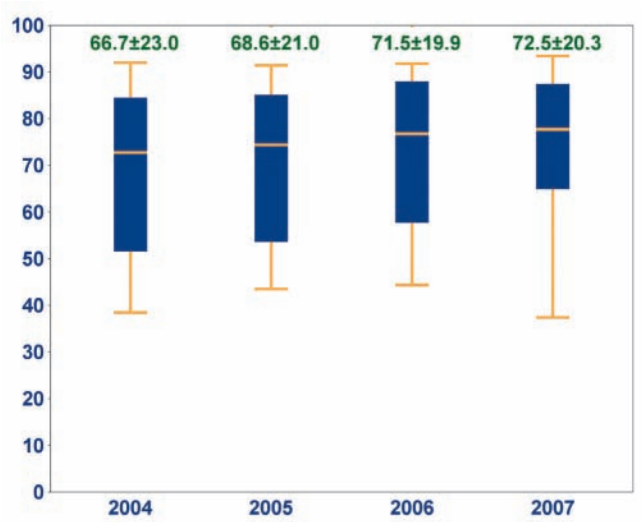


Time analysis of the LDL cholesterol values showed a marked increase in the percentage of patients with target LDL cholesterol values, with a relative increase of 36% between 2004 and 2007. In parallel there was a relative reduction in the proportion of patients with particularly elevated levels (26.5% in 2007).

Intercenter variability according to year

PROCESS INDICATORS

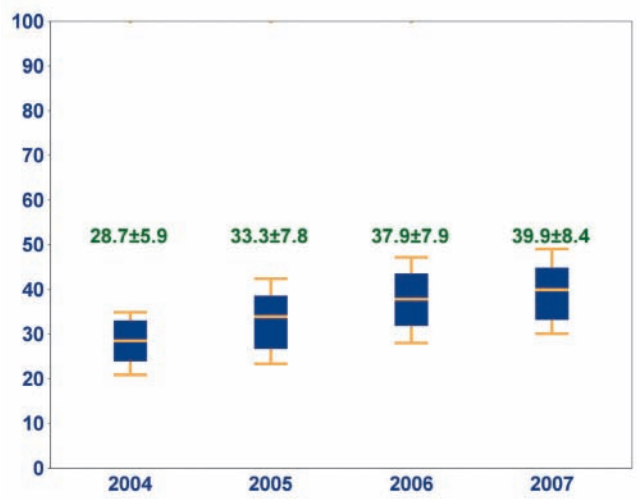
Patients who had their lipid profile measured at least once



Besides the increase in the mean proportion per center of the number of patients undergoing lipid monitoring, there was a clear reduction in intercenter variability for this process indicator, despite the persistence of a wide range of behaviors among the centers.

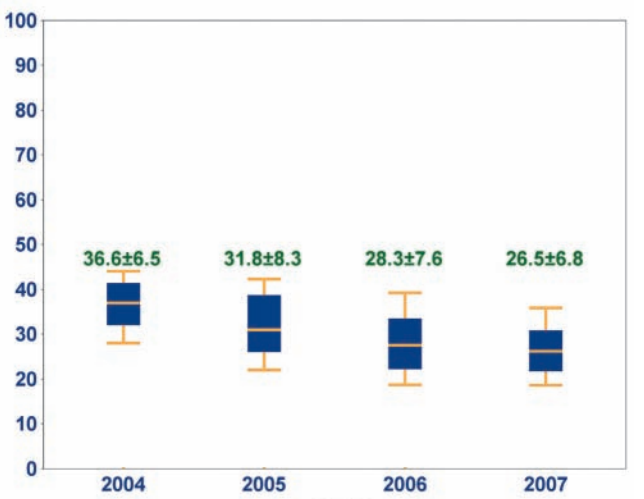
INTERMEDIATE OUTCOME INDICATORS

Patients with LDL cholesterol ≤100 mg/dl



The mean proportion per center of patients with target LDL cholesterol values increased over the four-year period, associated with a slight increase in intercenter variability.

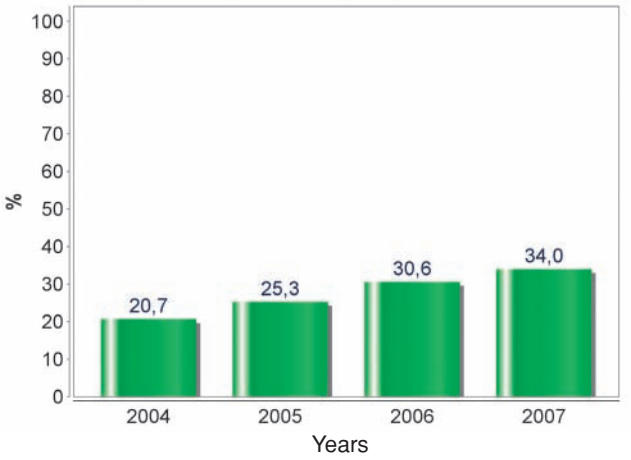
Patients with LDL cholesterol ≥130 mg/dl

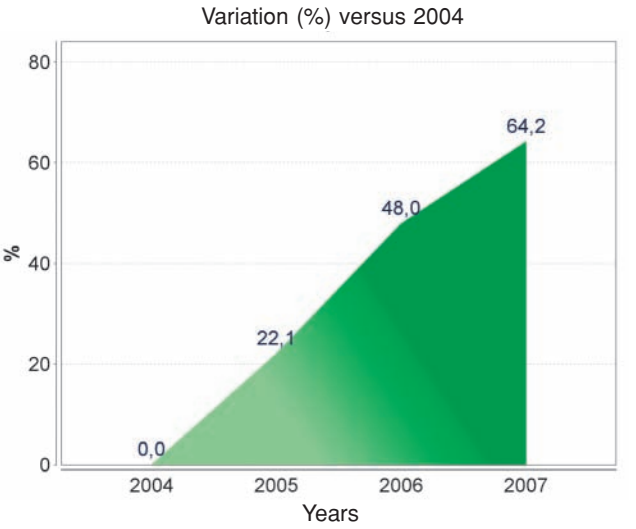


Accordingly, the mean proportion of patients per center with particularly elevated LDL cholesterol levels decreased with the reduction in intercenter variability.

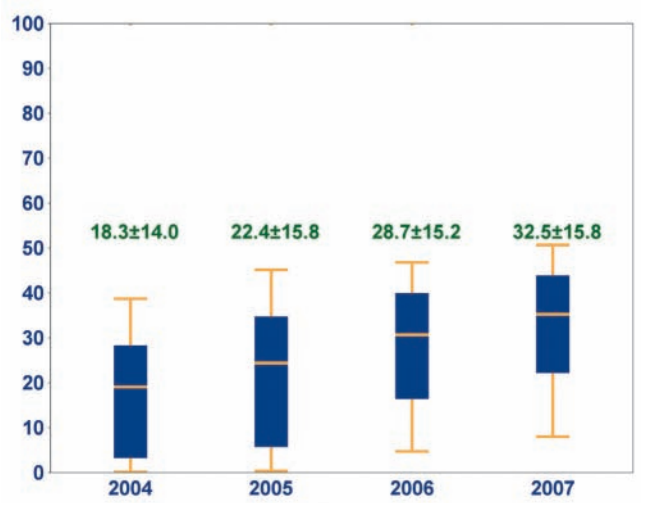
PRESCRIBED MEDICATIONS

Patients treated with statins





Intercenter variability in the rate of statin use by year



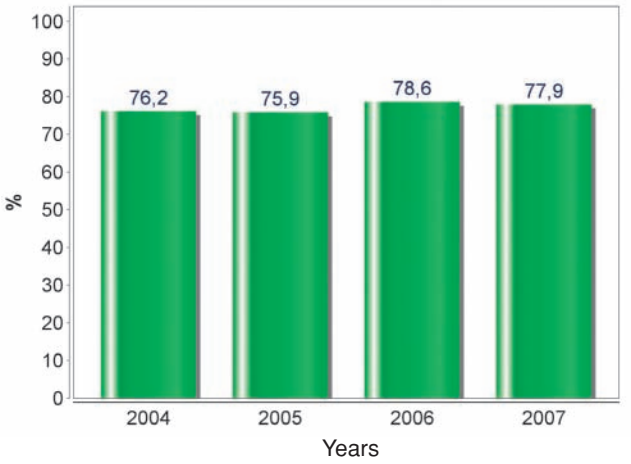
Marked changes were observed in statin use over the four-year period. There was a gradual increase in the use of drugs from this class, with a relative increase of 64% between 2004 and 2007. Analysis of intercenter variability showed an increase in the mean number of patients treated per center, even if the intercenter variability remained high.

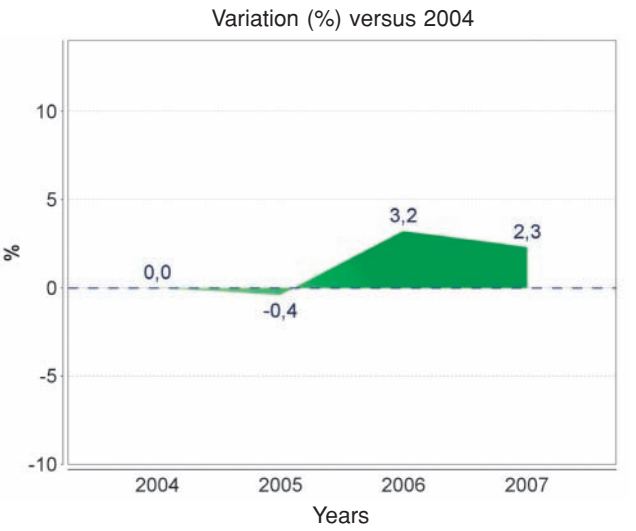
Blood pressure

This section explores the changes in the indicators of blood pressure control and takes into consideration process indicators and intermediate outcome indicators (favorable and unfavorable) of the use of several widely prescribed antihypertensive agents. Also analyzed was whether there was a reduction in intercenter variability, which represents another important aspect of quality of care.

PROCESS INDICATORS

Patients who had their blood pressure measured at least once

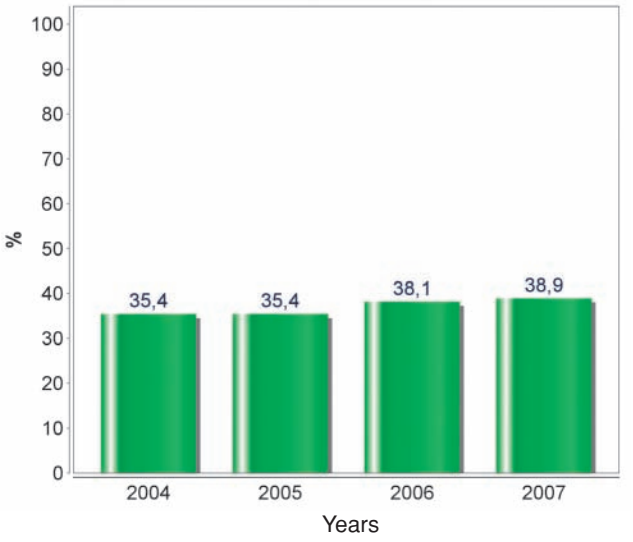


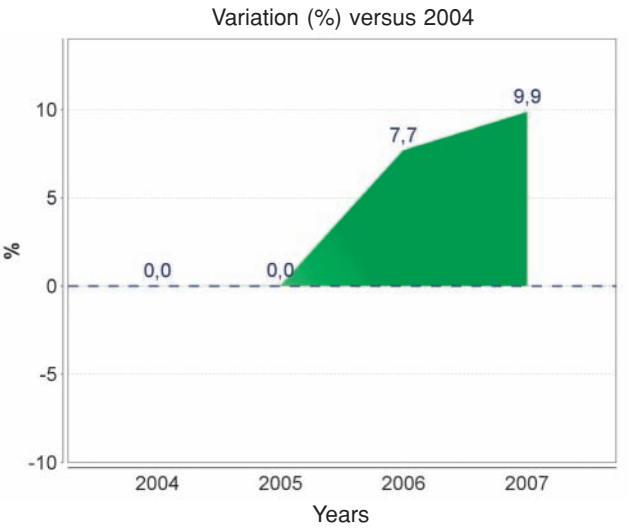


There was no substantial change in the percentage of patients who had their blood pressure measured at least once between 2004 and 2007.

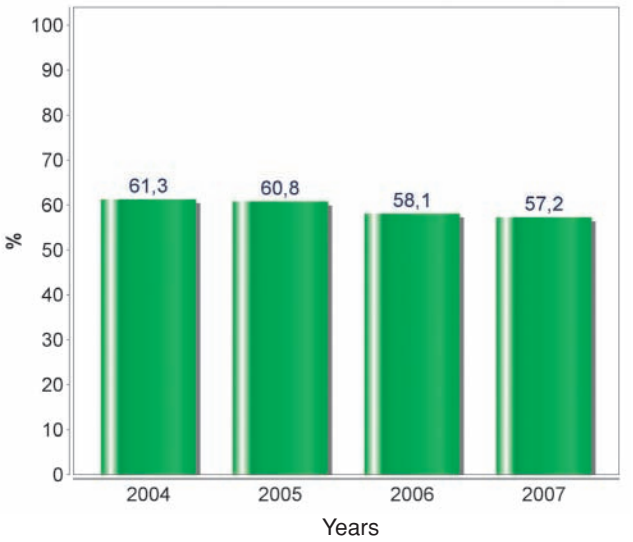
INTERMEDIATE OUTCOME INDICATORS

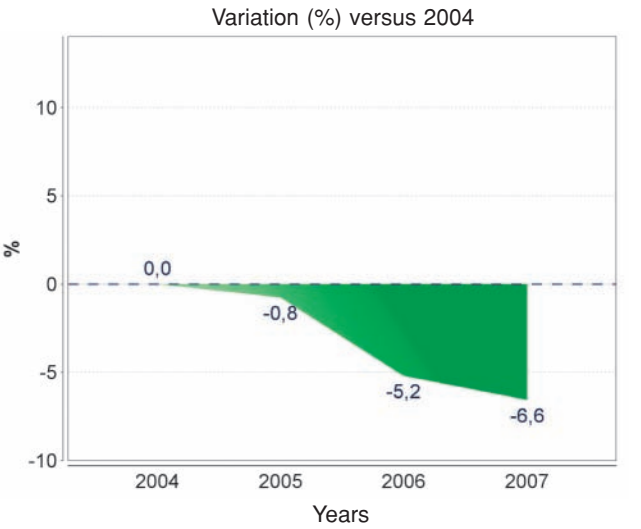
Patients with blood pressure ≤130/85 mmHg





Patients with blood pressure ≥140/90 mmHg



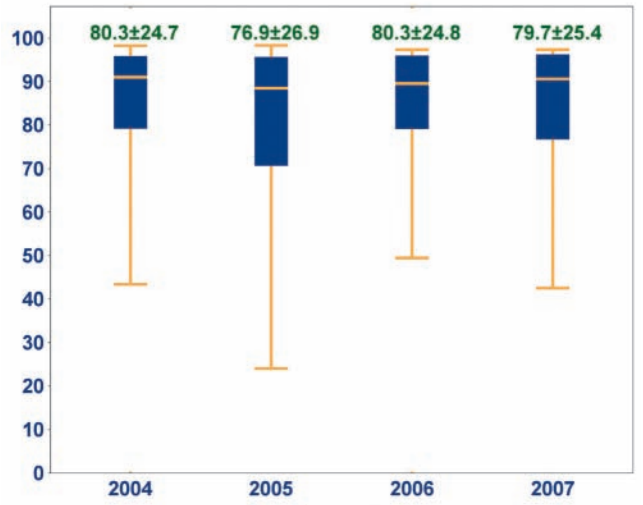


Blood pressure control improved slightly over the four years, with a relative increase of 10% in the number of patients with target values and a concomitant reduction of approximately 7% in the proportion of those with blood pressure values ≥140/90 mmHg.

Intercenter variability according to year

PROCESS INDICATORS

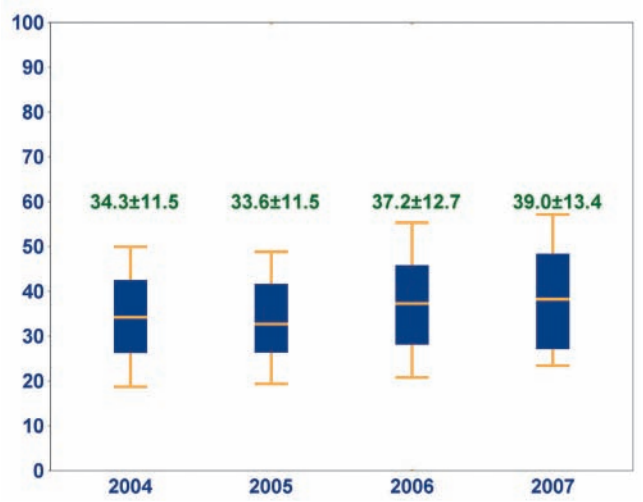
Patients who had their blood pressure measured at least once



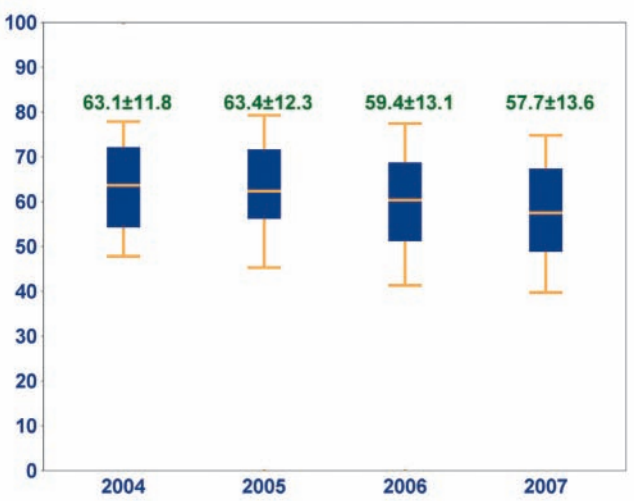
No significant change was observed in the mean proportion of monitored patients, with fluctuations in intercenter variability.

INTERMEDIATE OUTCOME INDICATORS

Patients with blood pressure ≤130/85 mmHg



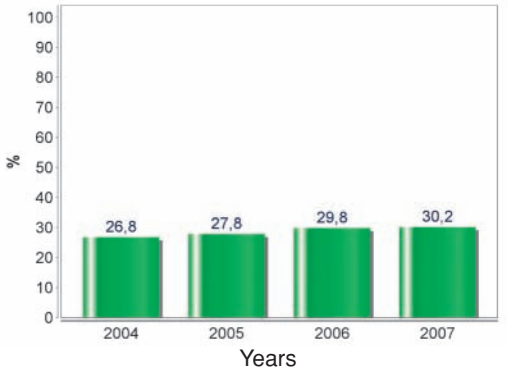
Patients with blood pressure ≥140/90 mmHg

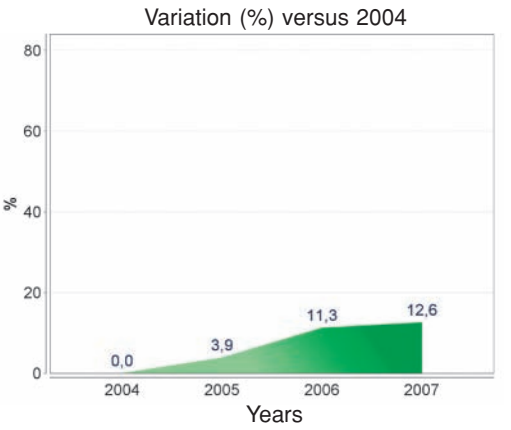


An improvement was observed in the mean number per center of patients with blood pressure values on target, associated with a reduction in those with an unfavorable outcome. This finding was associated with an increase in intercenter variability for both outcomes.

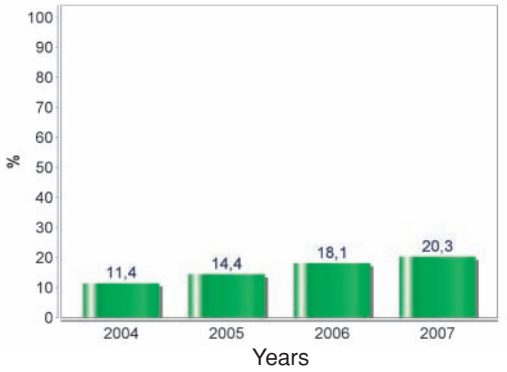
PRESCRIBED MEDICATIONS

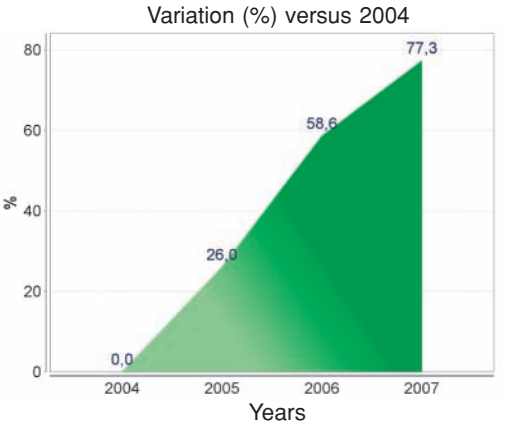
Patients treated with ACE inhibitors



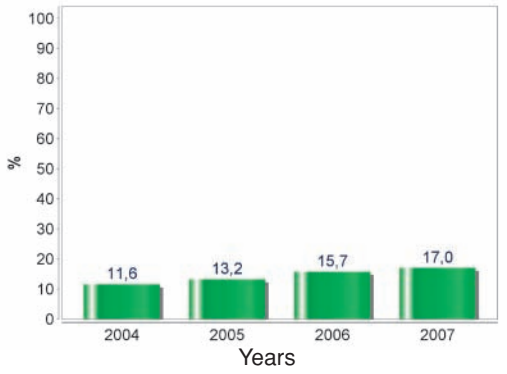


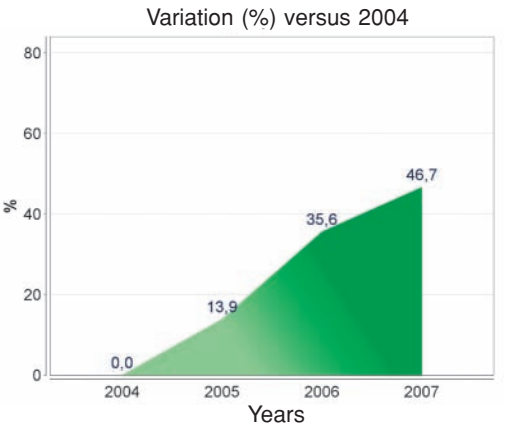
Patients treated with ARBs





Patients treated with beta-blockers

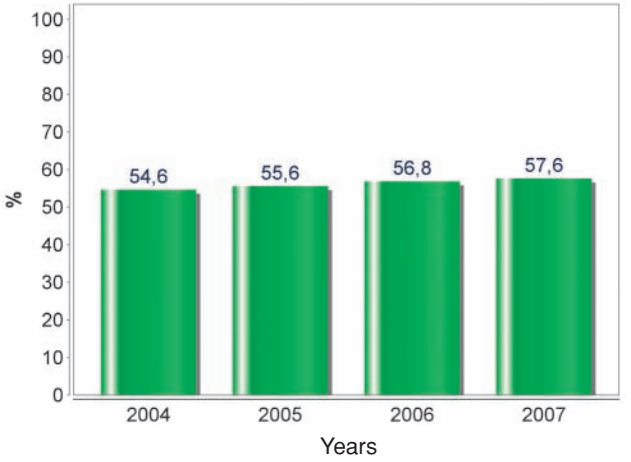


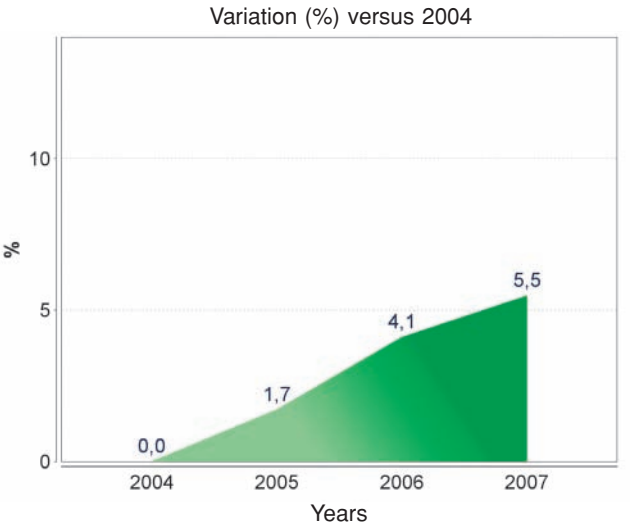


There was an increase in the use of drugs from all three classes, with the highest increase in ARBs and beta-blockers.

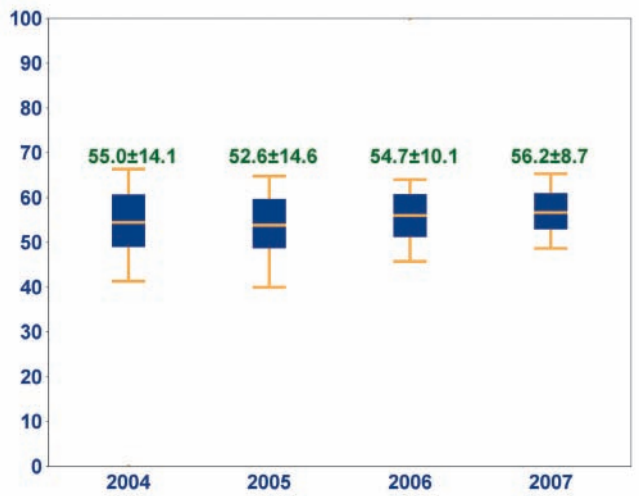
PRESCRIBED MEDICATIONS

Patients treated with ≥2 antihypertensive agents





Intercenter variability in the rate of use of ≥2 antihypertensive agents



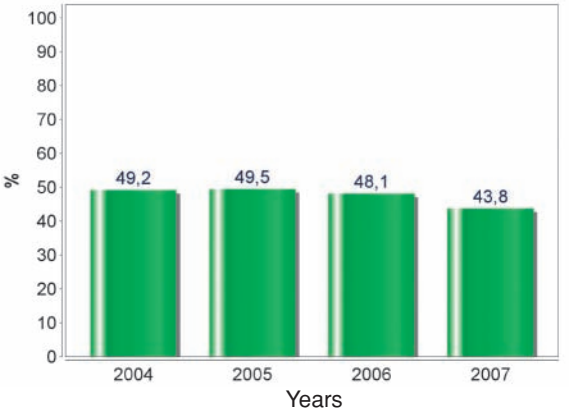
There was an increased use of single classes of antihypertensives, but only a slight increase in the proportion of patients treated with two or more antihypertensive agents, both as regards the total population and the mean values for each center. Of note was the significant reduction in intercenter variability since 2004.

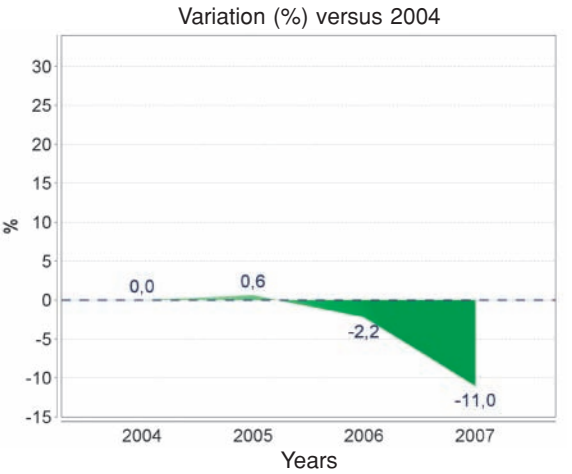
Other indicators

This section explores the changes in the remaining quality indicators ordinarily investigated by the AMD Annals. Taken into the analysis were process indicators such as the proportion of patients monitored for nephropathy and who underwent a foot examination during the index period, and BMI and the percentage of smokers as intermediate outcome indicators.

PROCESS INDICATORS

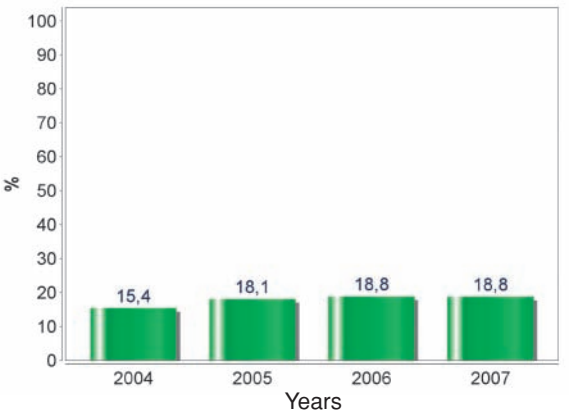
Patients monitored for nephropathy

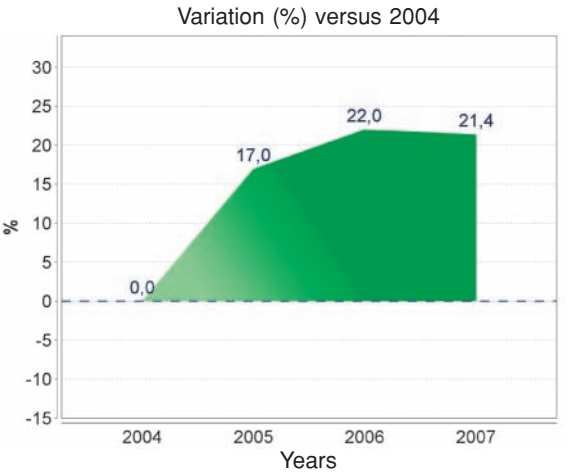




A slight decrease in renal function monitoring was observed over the four-year period, with a relative decrease of 11% in 2007 versus 2004.

Patients monitored for diabetic foot

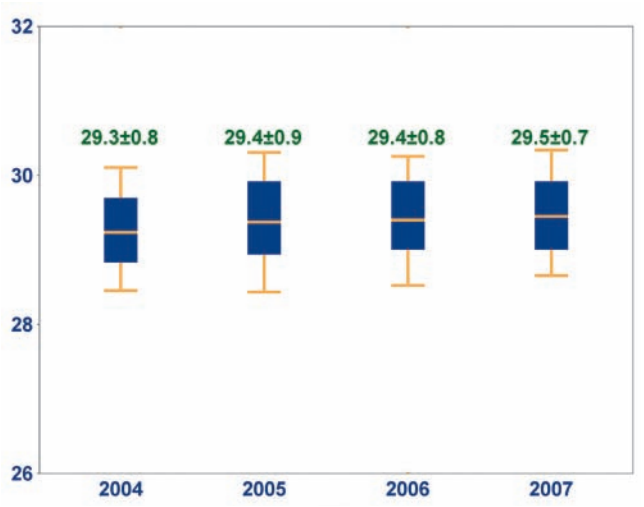




Foot examination remained the least systematically performed or recorded process measure; nevertheless, it improved slightly since 2004.

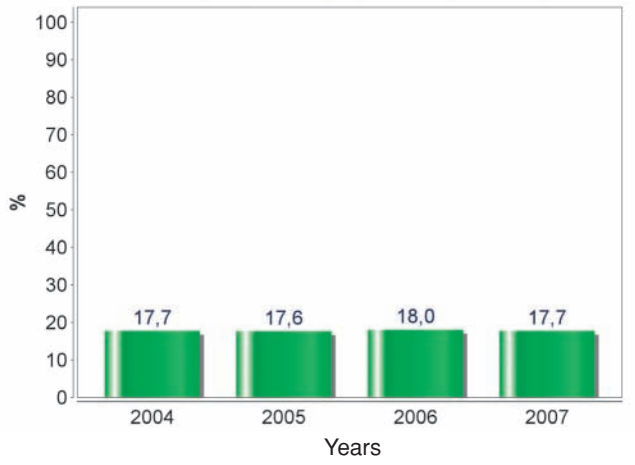
INTERMEDIATE OUTCOME INDICATORS

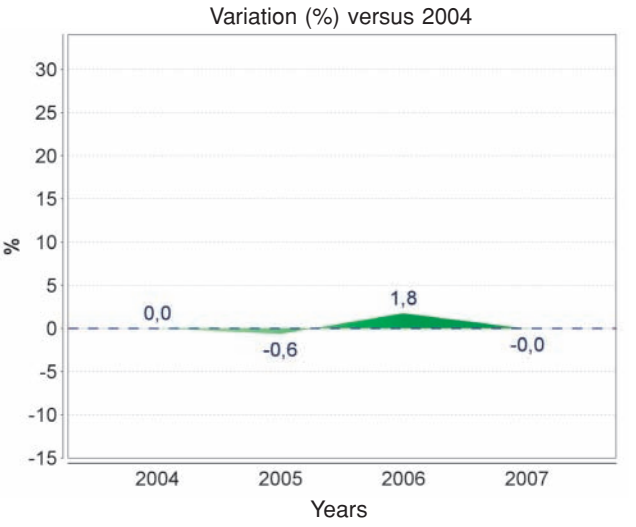
Distribution of mean BMI values according to year and center



No significant changes were found in mean BMI values or in intercenter variability.

Smokers





The percentage of smokers remained unchanged, testifying to the difficulty with intervening on this risk factor.

Commentary

Between 2004 and 2007 there was an increase in the percentage of older patients seeking diabetes care, with an increase from 58.9% to 61.9% among the over-65s. There was a decrease in the number of patients treated with diet alone and with oral hypoglycemic agents, whereas the percentage of those treated with insulin, both alone and in combination with hypoglycemic agents increased.
There was a slight decrease in the mean number of visits per patient in all treatment classes, perhaps owing to the difficulty of centers to meet the increased number of patients seeking diabetes care.

GLYCOMETABOLIC COMPENSATION

Glycated hemoglobin

Italian Standards for Diabetes Mellitus: the goal is to maintain HbA1c <7% (Evidence Level I, Recommendation Strength B).

The percentage of patients who had their glycated hemoglobin measured at least once a year remained unchanged between 2004 and 2007 (just over 90%). The goal of maintaining a target value ≤7% was reached by a growing number of patients: 47.9% in 2007 with a relative increase of 5% versus 2004. Also the percentage of patients with elevated values (≥9%) decreased steadily: 11.2% in 2007, with a relative reduction of 12.3% versus 2004.
Intercenter variability for all three parameters remained unchanged: a fairly narrow range in the percentage of patients monitored and the percentage of patients with elevated HbA1c levels; more marked was the percentage of patients with target levels.
In brief, the results for glycated hemoglobin were fairly satisfactory and improved compared with international series.
Between 2004 and 2007 the percentage of patients treated with metformin increased by 10% and those with insulin by 16%; there was a relative decrease of 6% in those treated with sulfonylurea.
Intercenter variability in the use of these drugs did not change significantly.

CARDIOVASCULAR RISK FACTORS

LDL cholesterol

Italian Standards for Diabetes Mellitus: the objective is to reach an LDL cholesterol value <100 mg/dl in patients with diabetes and one or more cardiovascular risk factors (Evidence Level I, Recommendation Strength B).
In persons with diabetes and heart disease and multiple unmodifiable risk factors for cardiovascular disease, LDL cholesterol values <70 mg/dl may represent a therapeutic objective (Evidence Level VI, Recommendation Strength B).

Between 2004 and 2007 the percentage of patients who had their LDL cholesterol measured at least once a year rose to 70.4%, with a relative increase of 10%. The recommended value of <100 mg/dl was reached by a growing number of patients: nearly 40% in 2007, with a relative increase of 36% versus 2004.
The percentage of patients with elevated values (≥130 mg/dl) fell to 26.5% in 2007, with a relative reduction of 26.5% versus 2004.
Intercenter variability gradually narrowed in both monitoring and objectives attained.
In brief, both LDL cholesterol monitoring and attainment of objectives as indicated by the guidelines improved, although the results still remain far from satisfactory.
The use of statins increased markedly: 34% of patients in 2007, with a relative increase of over 60%. Intercenter variability in the use of statins remained wide.

Blood pressure

Italian Standards for Diabetes Mellitus: the goal is to reach systolic blood pressure values <130 mmHg (Evidence Level III, Recommendation Strength B) and diastolic blood pressure values <80 mmHg (Evidence Level II, Recommendation Strength B).
N.B. For reasons of continuity, the threshold value of 130/85 mmHg has been maintained since 2004.

During the four-year period, the percentage of patients who had their blood pressure measured at

least once a year remained substantially unchanged at nearly 80%.
The percentage of patients with blood pressure values ≤130/85 mmHg rose: 36.9% in 2007, with a relative increase of 10% versus 2004.
The percentage of patients with blood pressure values ≥140/90 mmHg fell: 57.2% in 2007, with a relative reduction of 7% versus 2004.
Intercenter variability remained moderately high for this process indicator, which, however, increased for favorable and unfavorable intermediate outcome measures.
The use of prescribed medications increased, and more so for ARBs and beta-blockers than for ACE inhibitors.
Between 2004 and 2007 there was a slight relative increase of 10% in the percentage of patients treated with more than one antihypertensive agent.
On the whole, although the situation improved, the percentage of patients with optimal blood pressure control is still insufficient.

Obesity

The BMI values did not change between 2004 and 2007: the mean BMI value per center remained 29.5 (indicating marked overweight in persons with T2DM); intercenter variability remained unchanged.

Smoking

Between 2004 and 2007 the percentage of smokers (17.7%) remained high in a population burdened with other cardiovascular risk factors.

OTHER INDICATORS

Patients monitored for diabetic nephropathy

In 2004 the percentage of patients monitored for diabetic nephropathy was nearly 50%, with a relative reduction of about 11% in 2007, indicating diminished attention to screening and follow-up for diabetic nephropathy.

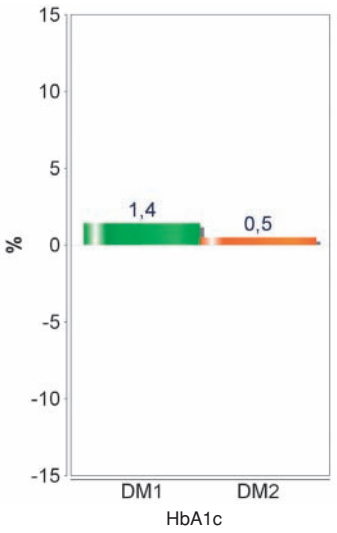
Patients monitored for diabetic foot

Between 2004 and 2007 there was a marked relative increase (21%) in monitoring for diabetic foot, but in absolute terms too little attention was given to this process indicator: only 18.8% of patients were examined during 2007.

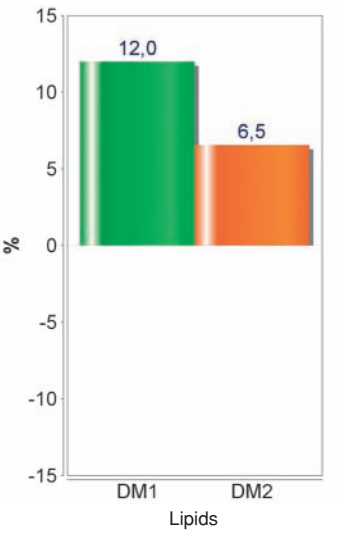
Illidio Meloncelli

SYNOPSIS OF CHANGES BETWEEN 2004 AND 2007

PROCESS INDICATORS

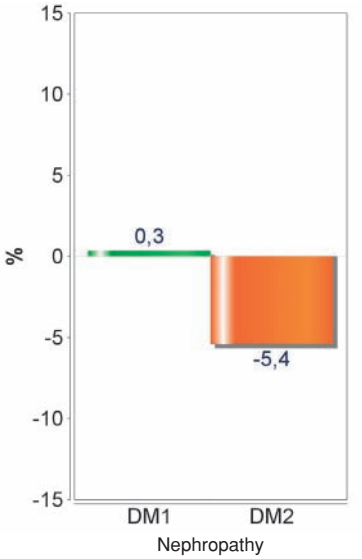


HbA1c

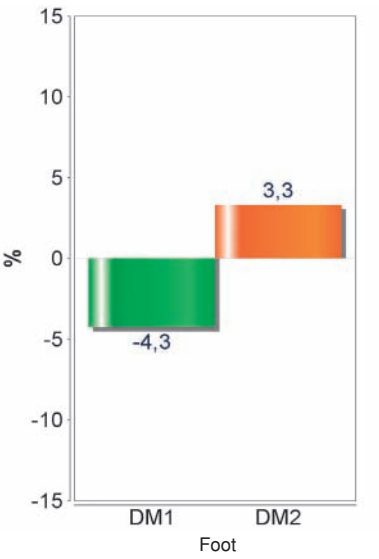


Lipids

Blood pressure



Nephropathy

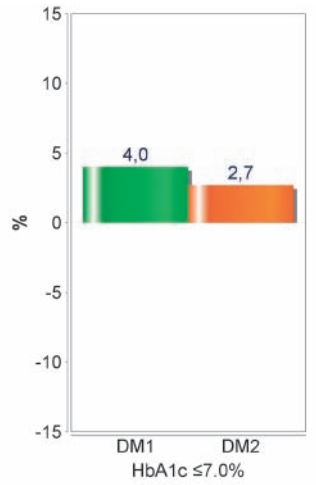


Foot

The graphs illustrate the percent changes in the process indicators for T1DM and T2DM between 2004 and 2007. Slight changes in HbA1c and blood pressure values were observed for both T1DM and T2DM; an improvement in lipid profile monitoring can be noted for T1DM and T2DM, with 12% and 6.5% more patients monitored, respectively.

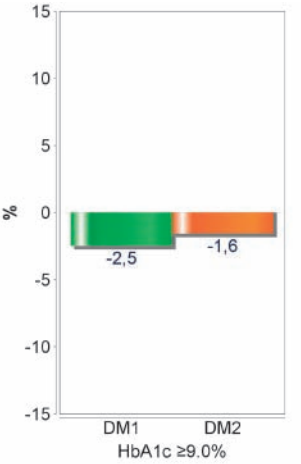
Some 5.4% fewer patients with T2DM had their renal function monitored, while the proportion of those with T1DM who underwent renal function monitoring remained unchanged. Monitoring for diabetic foot decreased by 4.3% in patients with T1DM but increased by 3.3% in those with T2DM.

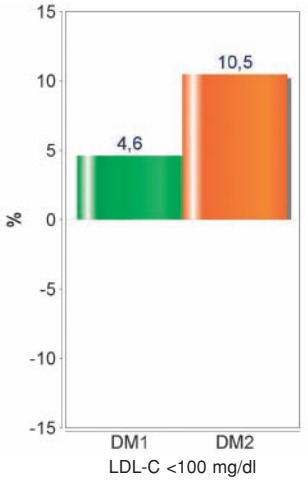
FAVORABLE OUTCOME MEASURES



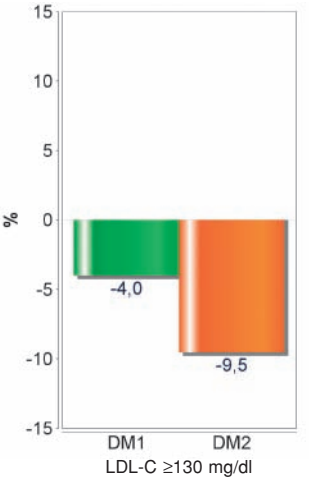
Metabolic control in both T1DM and T2DM produced a slight increase in favorable outcomes associated with a reduction in the proportion of patients with elevated HbA1c values.

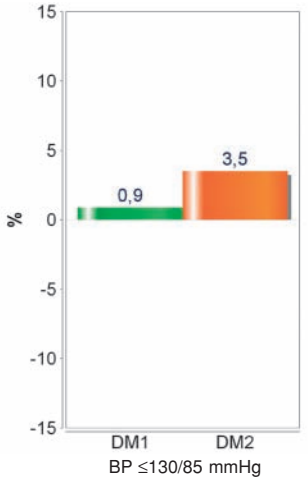
UNFAVORABLE OUTCOME MEASURES



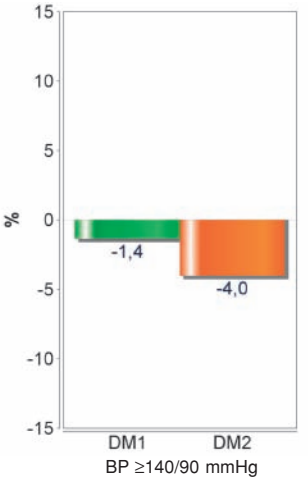


Data on lipid profile control showed an improvement, especially in patients with T2DM, with a substantial increase in the proportion of those with target values and a parallel reduction in those with elevated LDL cholesterol values.

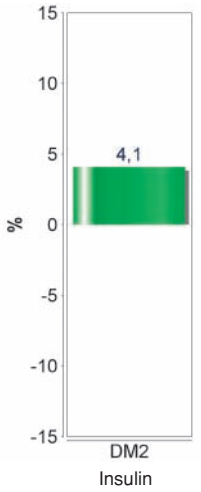




Blood pressure data showed a slight improvement, particularly for favorable and unfavorable measures in T2DM.

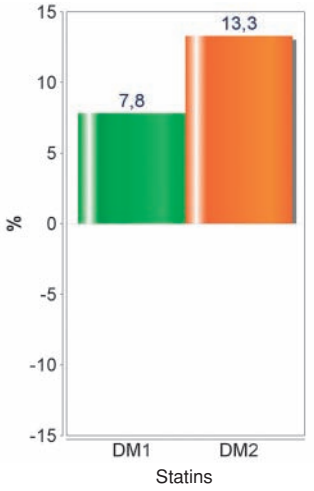


PRESCRIBED MEDICATIONS



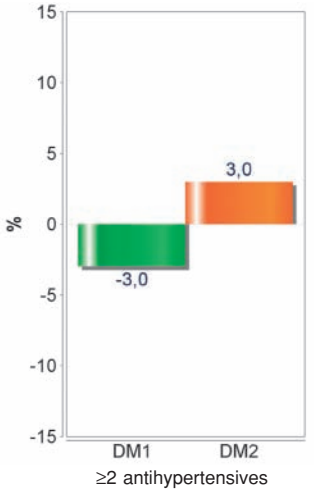
Insulin

There was an absolute increase of 4% in the proportion of persons with T2DM treated with insulin, reflecting increased intensive therapy between 2004 and 2007.



Statins

Statin use increased the most among the antidiabetic drugs prescribed for both types of diabetes.



≥2 antihypertensives

The use of more than one antihypertensive agent in combination therapy, a sign of increased therapeutic intensity, increased slightly in persons with T2DM and decreased in those with T1DM.

Commentary

The 2009 AMD Annals offer a new perspective on the quality of diabetes care with an analysis of the changes in the main process and intermediate outcome indicators at the end of a four-year period. The picture is positive because in this period there was an improvement in the care the collaborating centers delivered for both types of diabetes.

An example is the data on metabolic and blood pressure control which showed an increase in the proportion of T1DM and T2DM patients with target values, without a commensurate increase in annual monitoring of these parameters. This means that diabetologists have improved the quality of care, expressed as intermediate outcome indicators, making more effective use of the clinical data, which had been recorded in a high percentage of patients. Specifically, in 2007 HbA1c was measured in 95.1% of patients with T1DM, with a 1.4% increase versus 2004, and in 91.4% of those with T2DM, with a 0.5% increase versus 2004; blood pressure was controlled in 73.4% of patients with T1DM, with a decrease of 0.3% versus 2004, and in 77.9% of those with T2DM, with an increase of 1.8% versus 2004. As regards HbA1c ≤7% there was a 4% increase in the proportion of patients with T1DM and a 2.7% increase in those with T2DM, whereas as regards blood pressure value ≤130/85 mmHg the proportion of patients with T1DM increased by 0.9% and by 3.5% in those with T2DM.

Another positive finding derives from the data on lipid control, which showed an increase of 12% in patients with T1DM and of 6.5% in those with T2DM, yielding an annual control of lipid profile in nearly 70% of patients with diabetes examined in 2007. This reflects an improvement in the correlated intermediate outcome indicator: the proportion of patients with target LDL cholesterol values increased by 4.6% and 10.5% for those with T1DM and T2DM, respectively.

Supporting this positive trend in the quality of care was the increase in all favorable outcome measures and the simultaneous reduction in the corresponding unfavorable measures. In addition, the increased intensity of intervention on cardiovascular risk factors was demonstrated by the greater use of insulin in patients with T2DM, increased statin prescription in both types of diabetes, and the changes in the use of more than one antihypertensive agent in patients with T2DM.

A disappointing picture is that of monitoring of renal function and diabetic foot; specific interventions are clearly needed to improve these parameters in terms of provider-order entry on the electronic-medical record and actual performance of these examinations.

A final consideration is the degree of changes revealed in this longitudinal analysis. Expressed as absolute percent variations, the phenomenon could appear modest, but since the sample size is extraordinarily large, the absolute number of patients who benefited from the change is relevant. In 2007, for example, 21,000 more persons with diabetes than in 2004 presented with optimal LDL cholesterol values, which translates into a reduction in cardiovascular risk. The important thing is to view these results not as small percentage points but rather as significant changes in the life expectancy of thousands of persons with diabetes and in the related socioeconomic impact.

These results reflect a cultural paradigm shift in diabetes care over the last four years in Italy which, thanks to a more correct and wider use of electronic-medical records and the ability to examine in real time the results of health care, there was an incentive to put into practice the recommendations of good clinical practice promulgated and discussed by our association.

Danila Fava, Gualtiero de Bigontina

ANALYSIS OF QUALITY INDICATORS BY GEOGRAPHIC MACRO-AREA

Premise

This section explores the trends of quality care indicators by geographic macro-area.
The macro-areas are:

- **North**: Piemonte, Liguria, Lombardia, Trentino-Alto Adige, Veneto, Friuli-Venezia-Giulia, Emilia-Romagna
- **Center**: Toscana, Lazio, Umbria, Marche
- **South and the islands**: Abruzzo, Campania, Puglia, Basilicata, Calabria, Sicilia and Sardegna.

Valle d'Aosta and Molise were not included in the analysis.
The table below illustrates the descriptive data on the number of centers and the level of acceptable completeness of data.

	2004	2005	2006	2007
NORTH				
No. of centers	46	53	55	64
No. of centers with minimum acceptable completeness (gold)	25	26	34	43
% gold/ total no. of centers	54.3%	49.1%	61.8%	67.2%
CENTER				
No. of centers	20	22	23	23
No. of centers with minimum acceptable completeness (gold)	4	10	10	12
% gold/ total no. of centers	20%	45.5%	43.5%	52.2%
SOUTH				
No. of centers	19	22	24	29
No. of centers with minimum acceptable completeness (gold)	4	5	5	9
% gold/ total no. of centers	21.1%	22.7%	20.8%	31.0%

The table shows that the majority of centers are located in the North, with a marked increase in those collaborating in the North and the South macro-areas.
Of note is that the quality of the data entered on the electronic-medical records improved, as shown by the increase in the percentage of centers that met the minimal criteria for completeness applied to define the gold standard (cf. Methods section).
Also in 2007 there remained a north-south gradient in the number of centers and in the percentage of centers with minimum acceptable completeness of data.

CHARACTERISTICS OF PATIENTS WITH T1DM

	2004	2005	2006	2007
No. of patients				
North	3171	3572	4659	6292
Center	1671	2043	2407	2796
South	805	997	1389	2853
First visit (%)				
North	10.5	13.1	12.6	11.7
Center	12.8	15.1	16.7	11.9
South	9.2	14.0	17.9	9.6
Males (%)				
North	54.2	54.8	55.7	55.8
Center	56.5	55.3	56.0	55.3
South	51.3	51.8	52.1	53.0
Age (yr)				
North	46.0 ± 17.1	46.2 ± 16.6	46.6 ± 16.3	46.5 ± 15.9
Center	46.4 ± 16.9	46.6 ± 16.8	46.4 ± 16.2	46.4 ± 16.1
South	43.2 ± 17.4	42.9 ± 16.5	43.2 ± 16.4	44.9 ± 15.8
Duration of diabetes (yr)				
North	18.1 ± 12.3	18.1 ± 12.6	18.2 ± 12.7	18.5 ± 12.6
Center	18.6 ± 12.6	18.7 ± 12.6	18.7 ± 12.8	19.1 ± 12.9
South	16.1 ± 12.2	15.1 ± 11.7	16.6 ± 12.0	19.2 ± 12.3

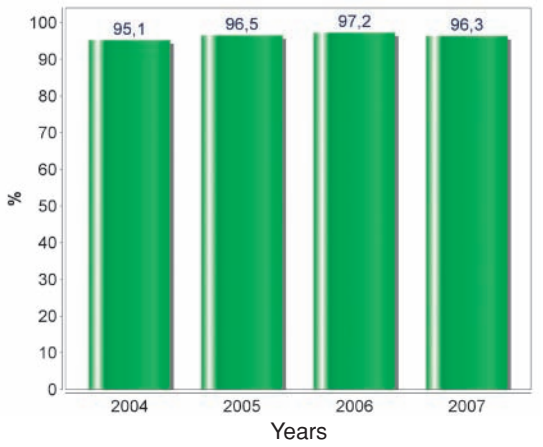
CHARACTERISTICS OF PATIENTS WITH T2DM

	2004	2005	2006	2007
No. of patients				
North	52,784	62,230	79,083	102,159
Center	36,907	41,410	46,672	52,066
South	16,628	20,313	25,358	37,742
First visit (%)				
North	20.3	19.9	19.2	17.8
Center	14.9	15.4	17.0	15.2
South	19.5	18.7	20.3	15.3
Males (%)				
North	55.6	56.0	56.4	56.3
Center	53.3	53.4	54.1	54.3
South	50.7	50.9	50.9	51.3
Age (yr)				
North	66.7 ± 11.3	66.8 ± 11.3	67.1 ± 11.1	67.5 ± 11.1
Center	67.5 ± 11.3	67.6 ± 11.4	68.0 ± 11.4	68.2 ± 11.3
South	65.1 ± 11.7	65.4 ± 11.7	65.8 ± 11.7	66.6 ± 11.4
Duration of diabetes (yr)				
North	10.4 ± 9.1	10.4 ± 9.1	10.7 ± 9.1	11.0 ± 9.1
Center	11.2 ± 9.5	11.6 ± 9.6	11.7 ± 9.6	12.1 ± 9.6
South	9.3 ± 8.6	9.5 ± 8.5	10.2 ± 8.6	11.3 ± 8.8

Glycated hemoglobin

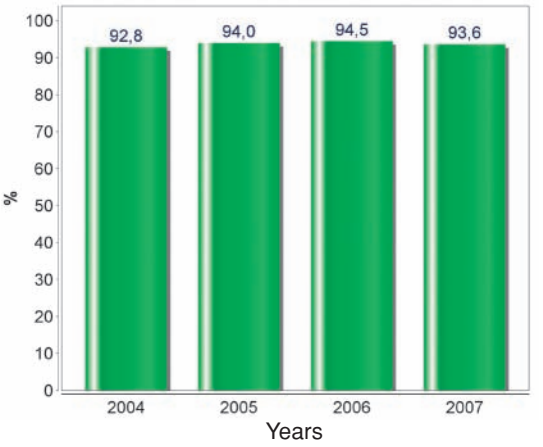
Patients who had their HbA1c measured at least once

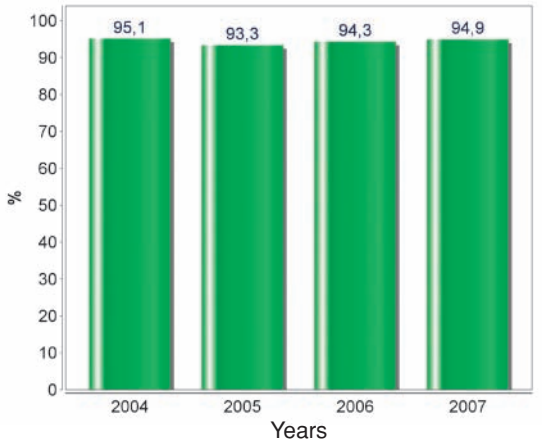
T1DM



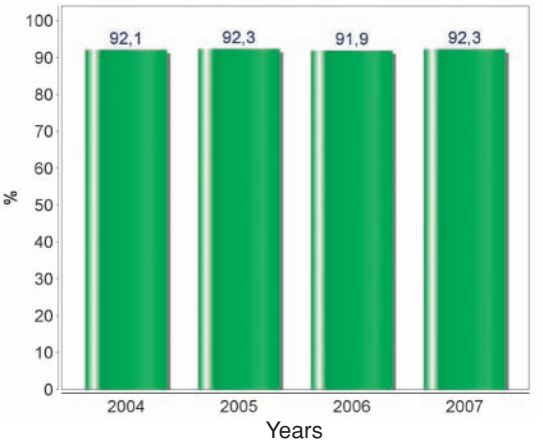
NORTH

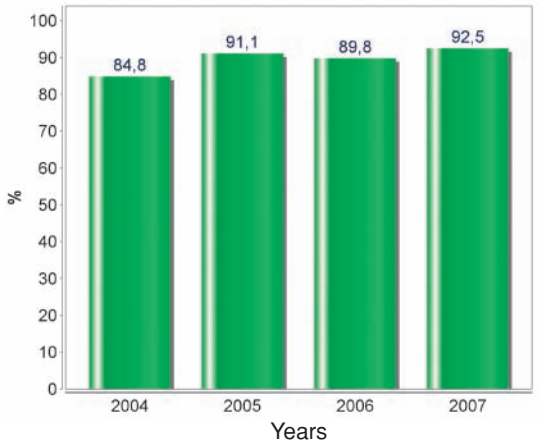
T2DM



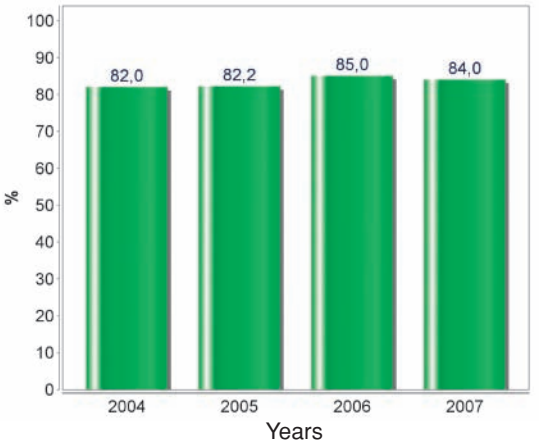


CENTER





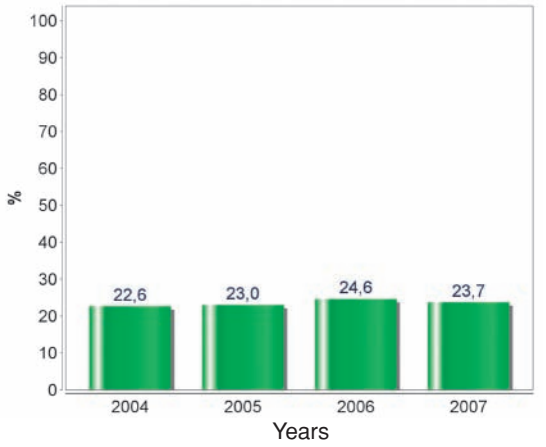
SOUTH



In the North and Center macro-areas, HbA1c monitoring was consistently high for both types of diabetes over the four-year period; in the South the percentage of monitoring in patients with T1DM increased steadily, while it remained unchanged at under 90% in those with T2DM.

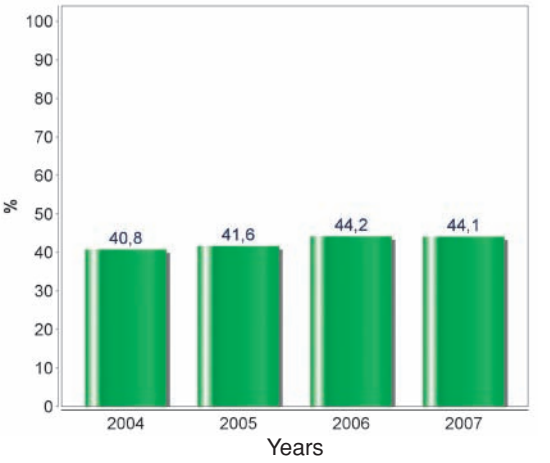
Patients with HbA1c ≤7%

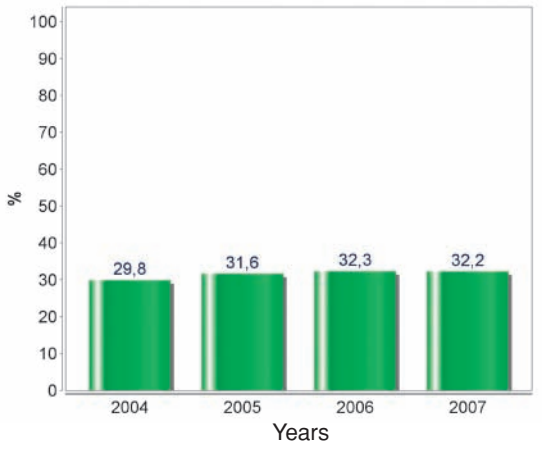
T1DM



NORTH

T2DM





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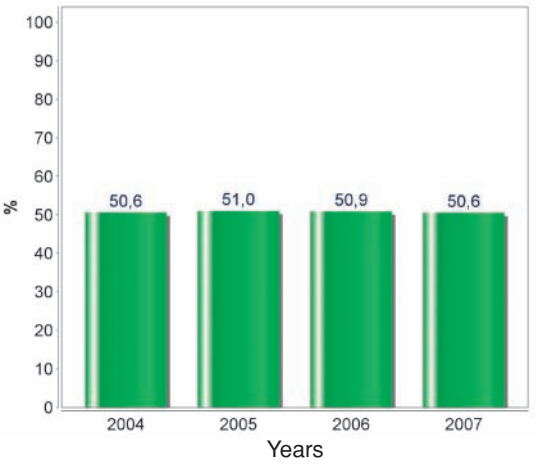

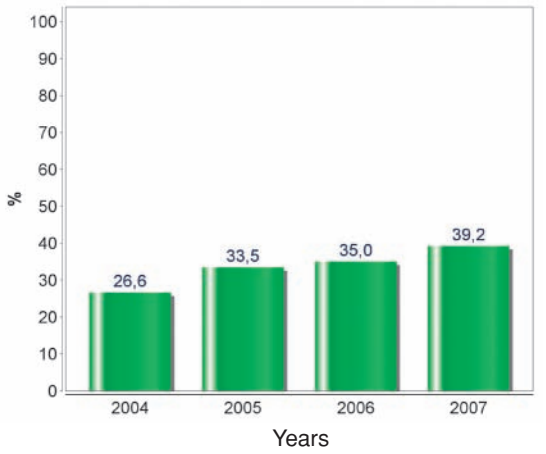

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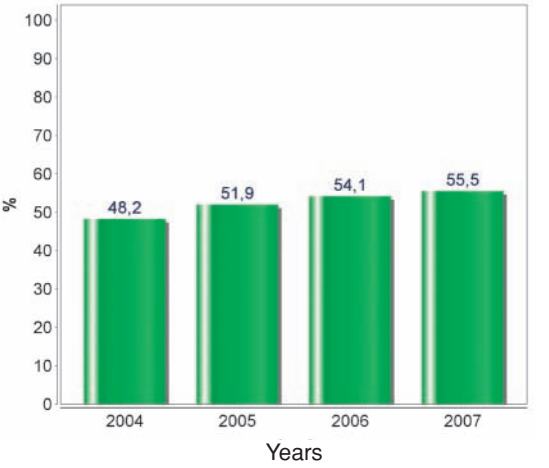
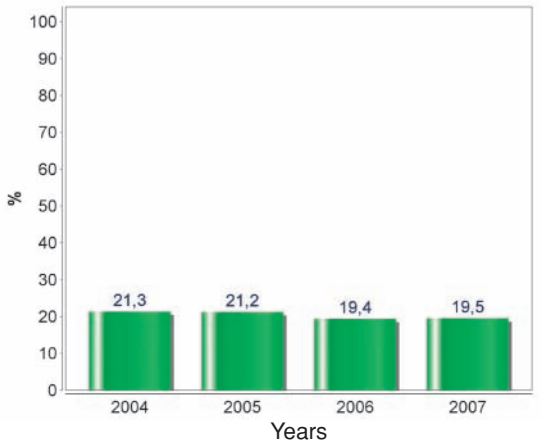


Adequate metabolic control in both T1DM and T2DM was observed more often in the South, where higher growth rates can be noted.

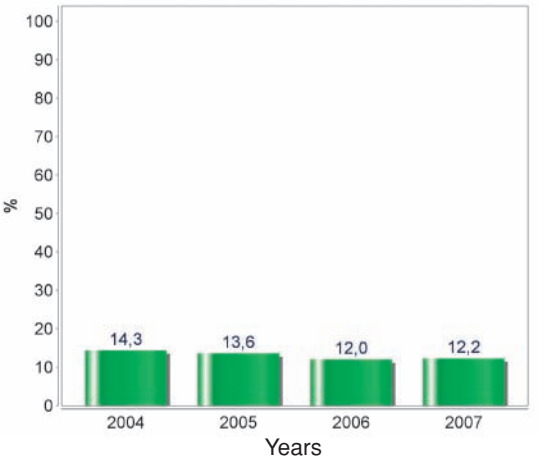
Patients with HbA1c ≥9%

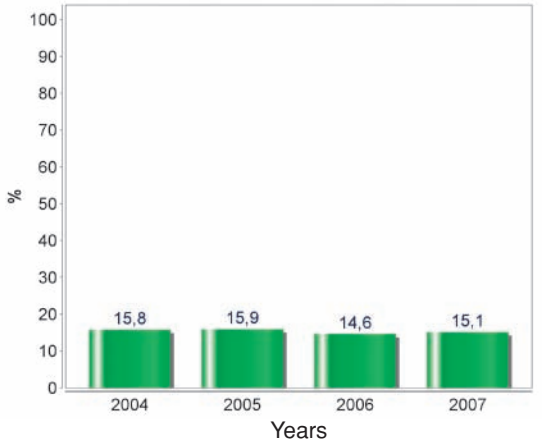
T1DM



NORTH

T2DM





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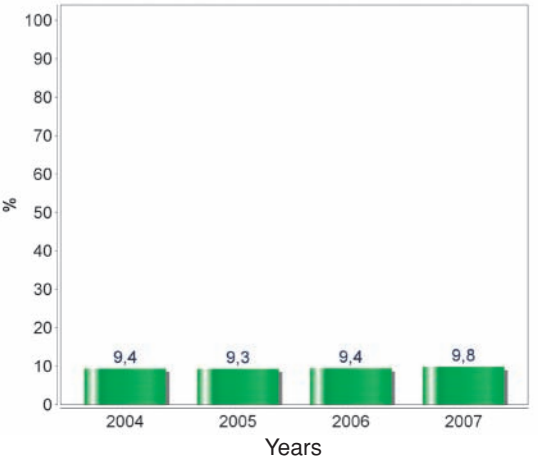

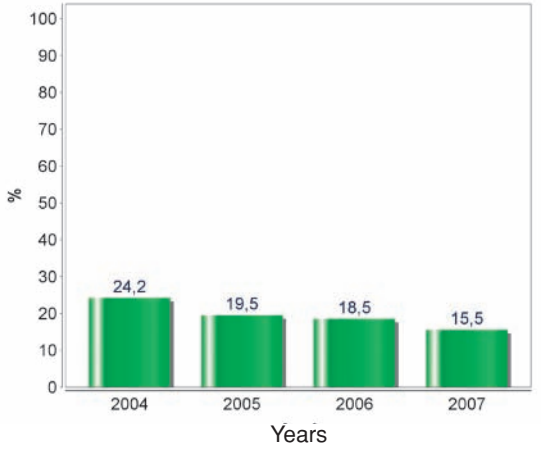

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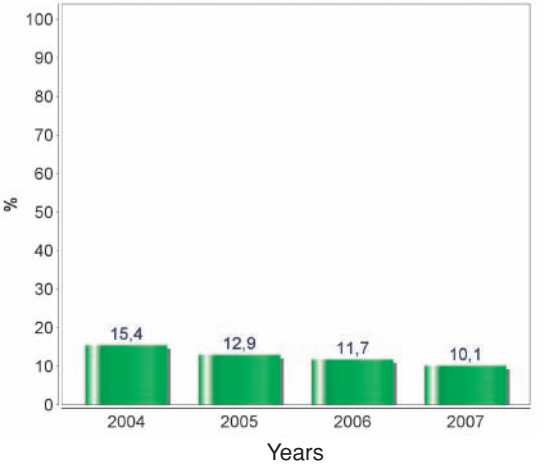


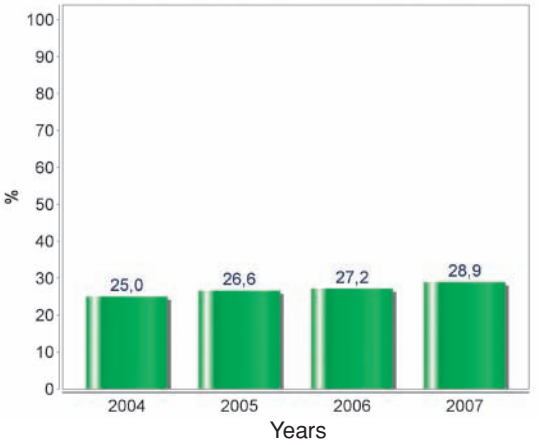
The percentage of patients with an unfavorable outcome measure for both T1DM and T2DM, which was higher in the South, decreased markedly there, and remained substantially unchanged in the other two macro-areas.

Patients treated with insulin

T2DM

The percentage of patients treated with insulin increased steadily in all three macro-areas, reaching nearly 30% in 2007.

NORTH



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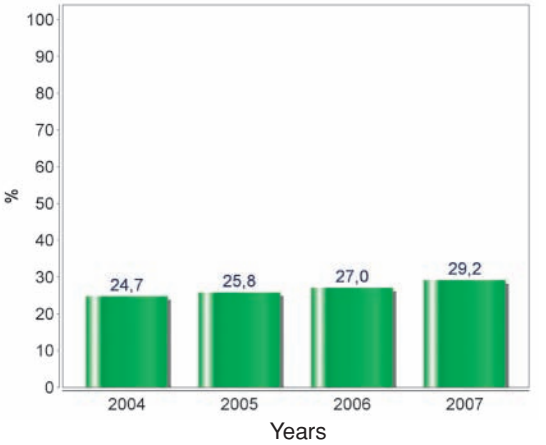

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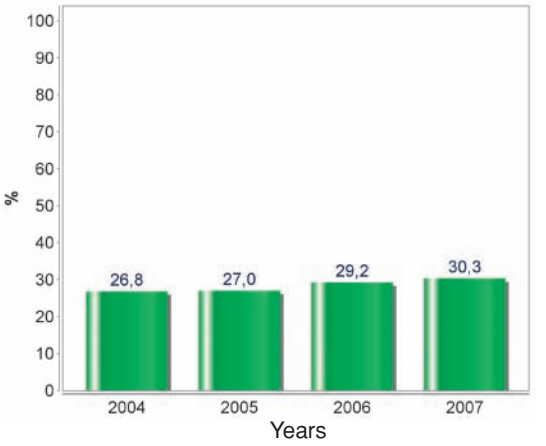
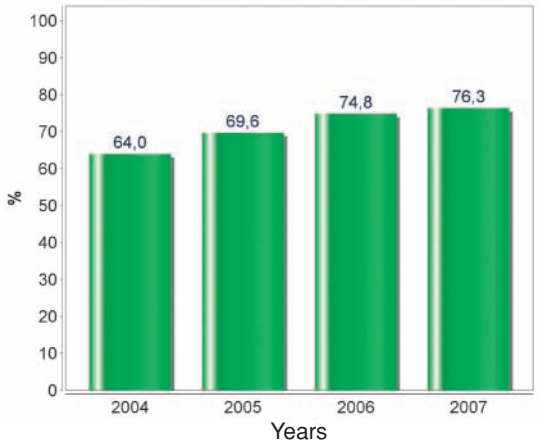


Lipid profile

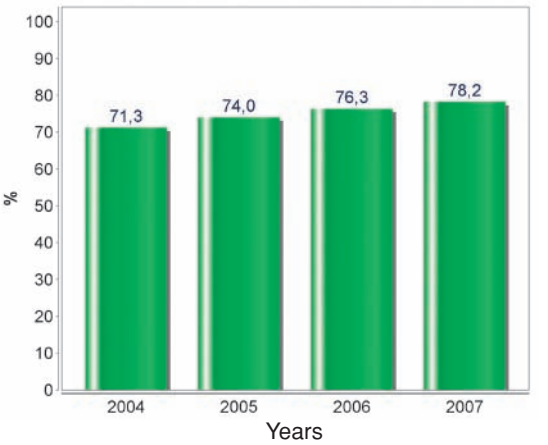
Patients who had their lipid profile measured at least once

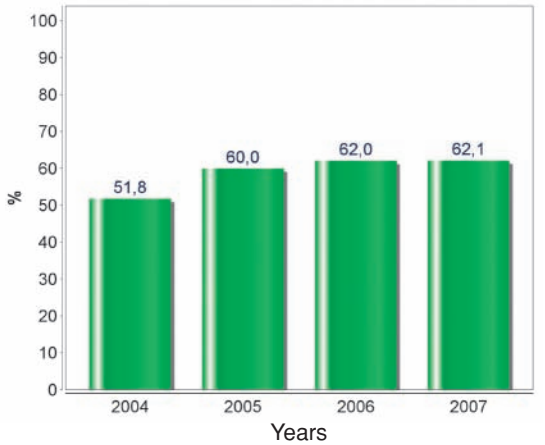
T1DM



NORTH

T2DM





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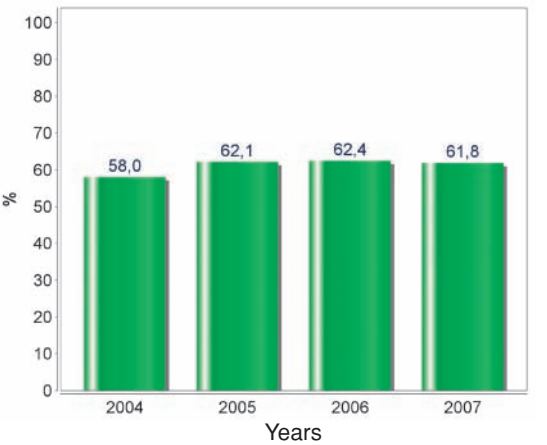

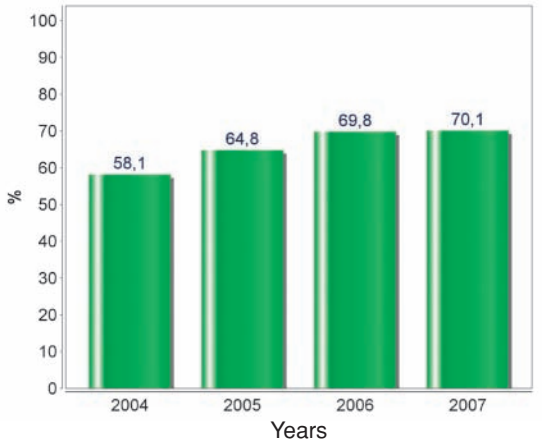

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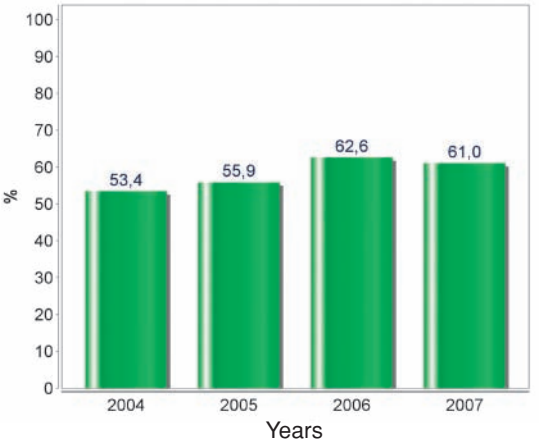
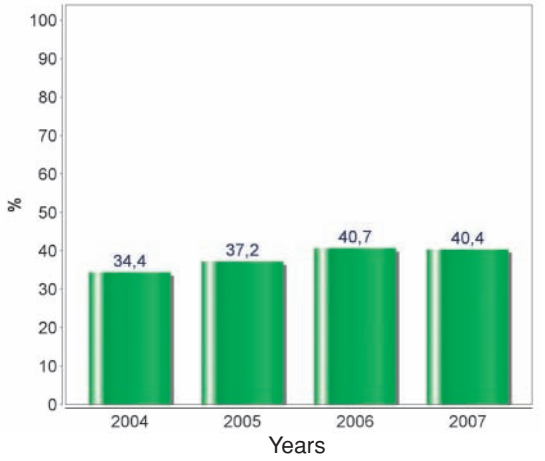


Lipid profile measurement in T1DM and T2DM was increasingly performed, and more often in the North than in either of the other two macro-areas.

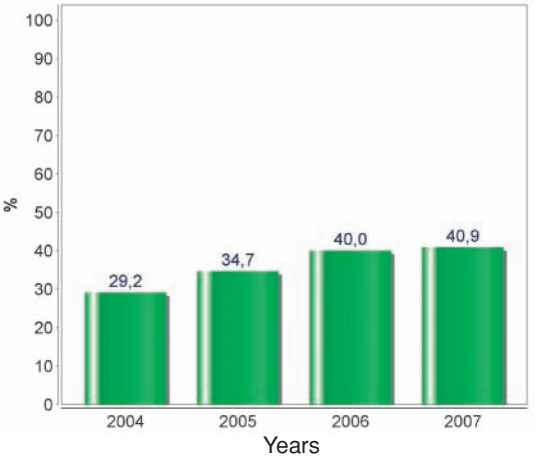
Patients with LDL cholesterol <100 mg/dl

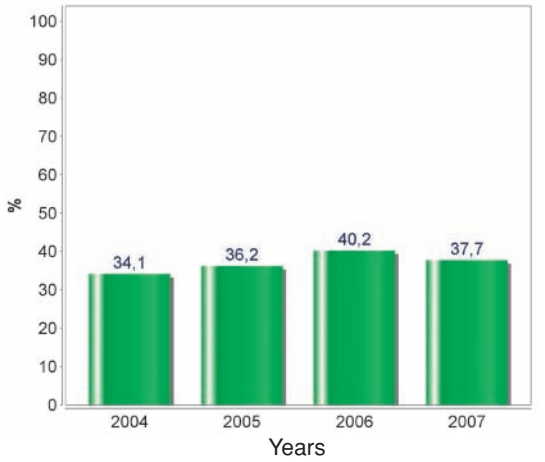
T1DM



NORTH

T2DM





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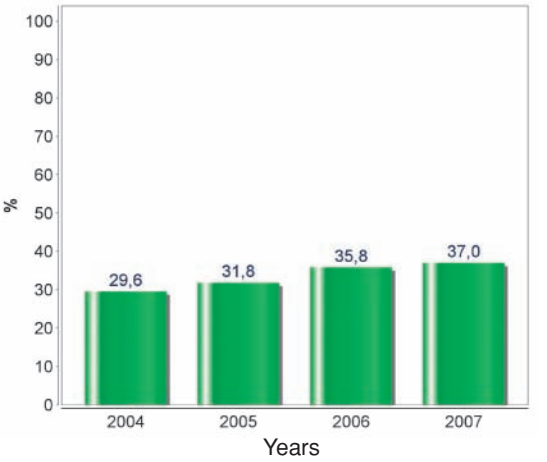

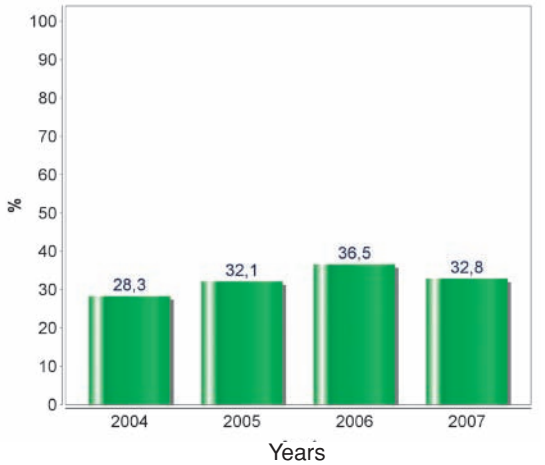

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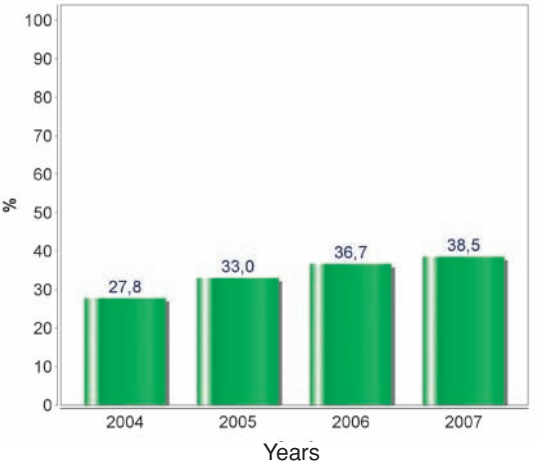
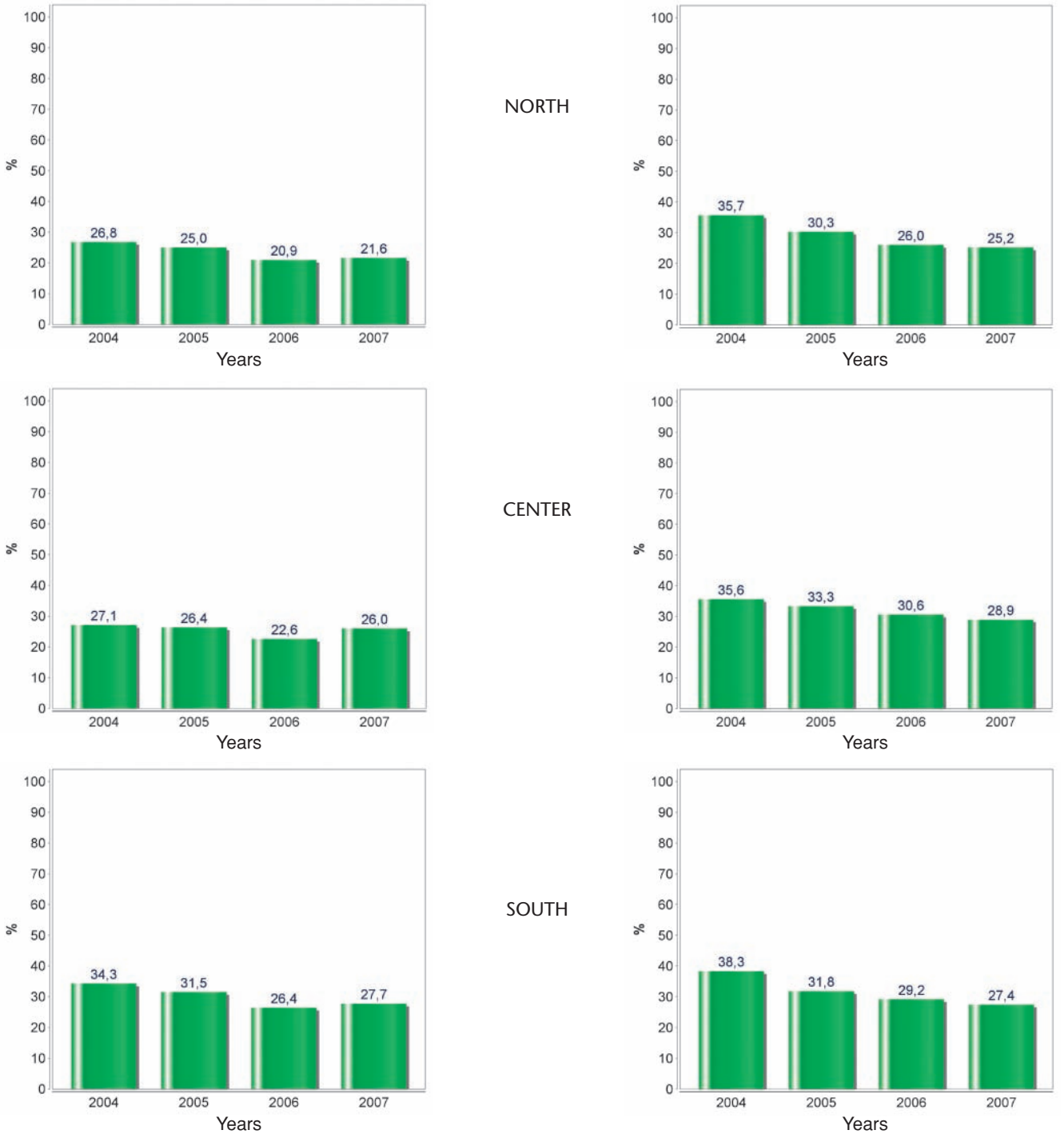


This indicator generally improved in both T1DM and T2DM, with slightly better results reported for the North.

Patients with LDL cholesterol ≥130 mg/dl

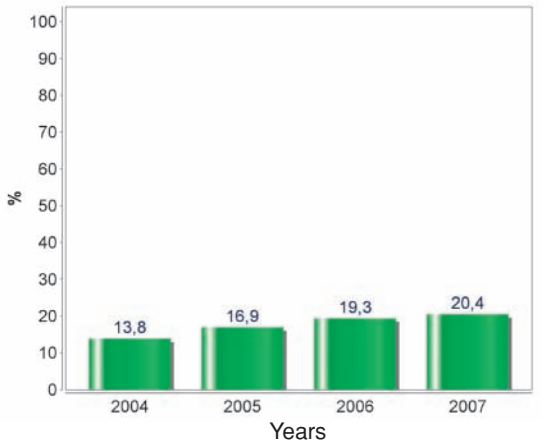
T1DM T2DM



The steady reduction in this unfavorable outcome measure was more marked in the North and the South than in the Center, especially in patients with T2DM.

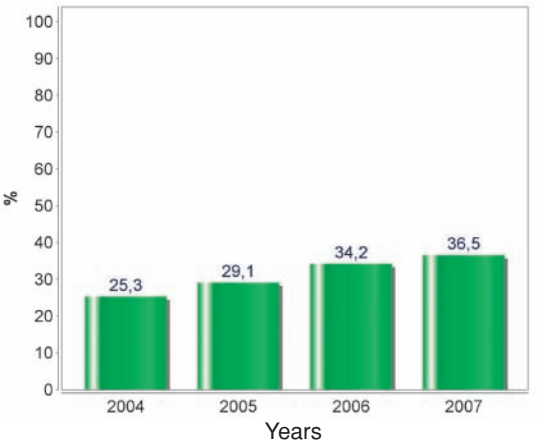
Patients treated with statins

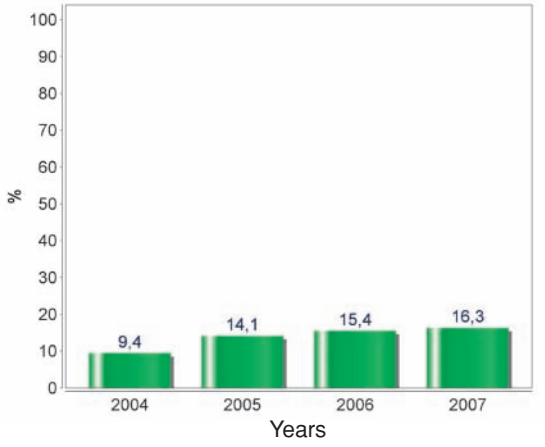
T1DM



NORTH

T2DM





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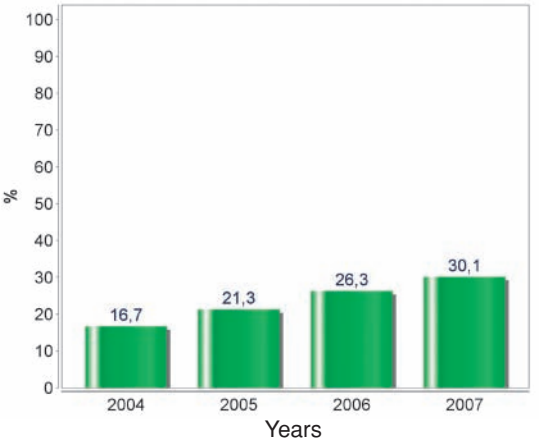

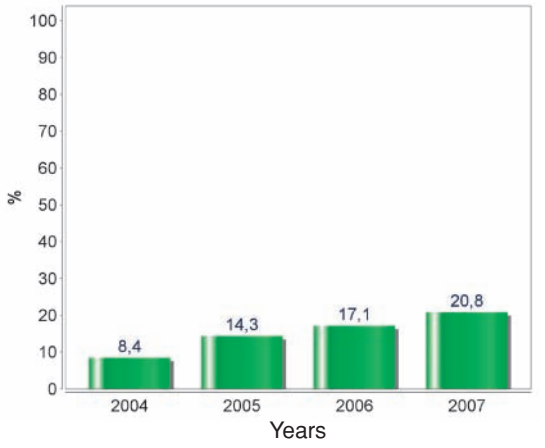

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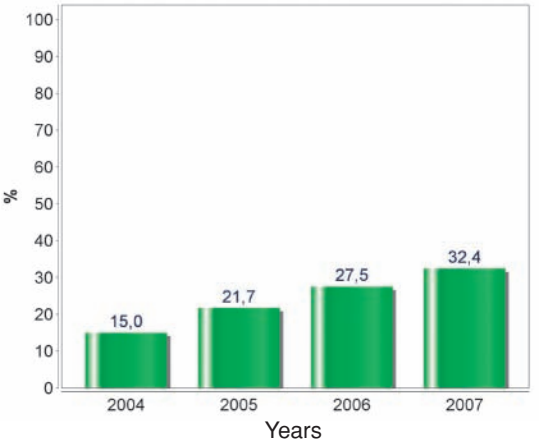
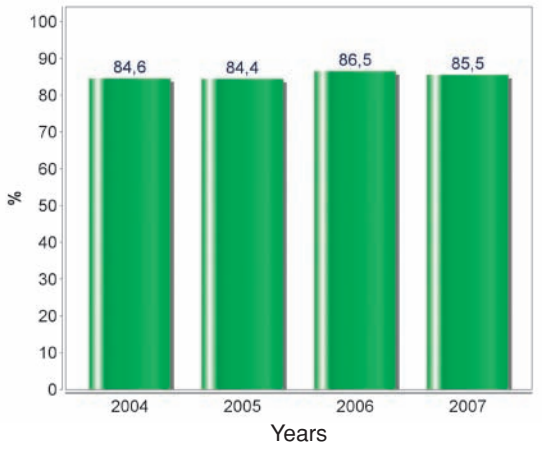


In all three macro-areas and in both types of diabetes there was a steady increase in the proportion of patients treated with statins; higher percentages in those with T2DM were observed in the North.

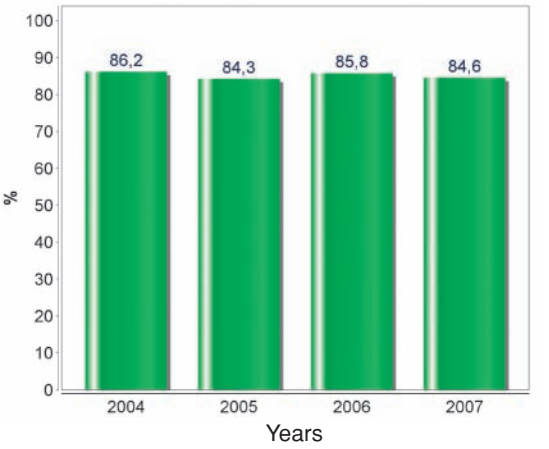
Blood pressure

Patients who had their blood pressure measured at least once

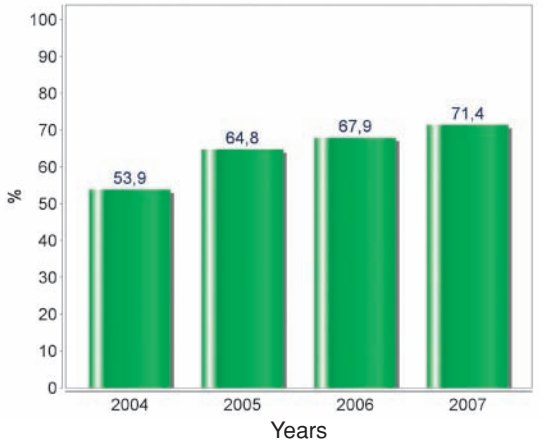
T1DM



T2DM



NORTH



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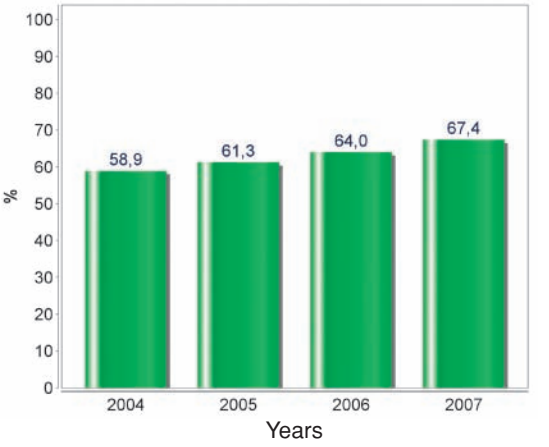

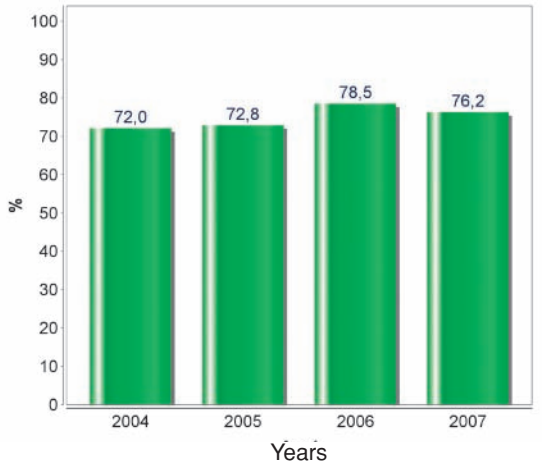

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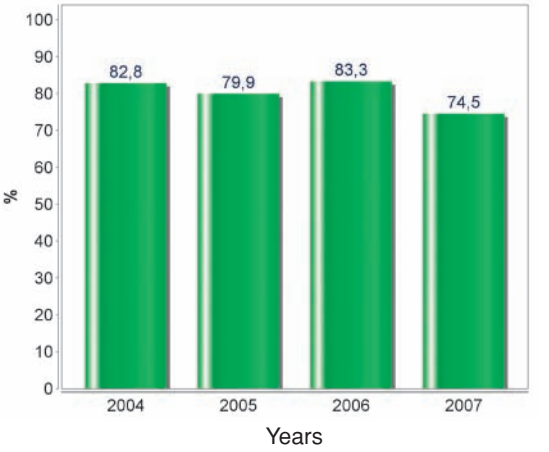
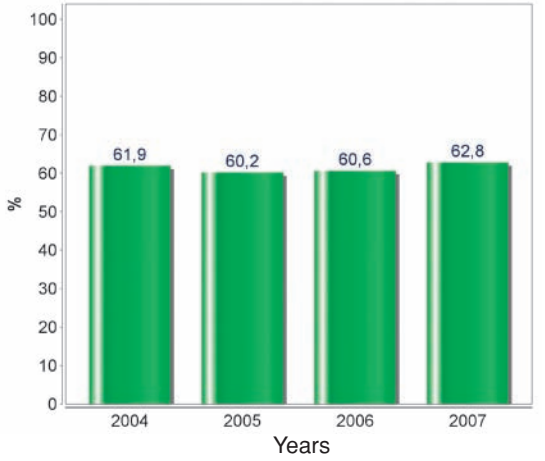


Reporting rates of blood pressure control were high in the North, rose in the Center and declined in the South.

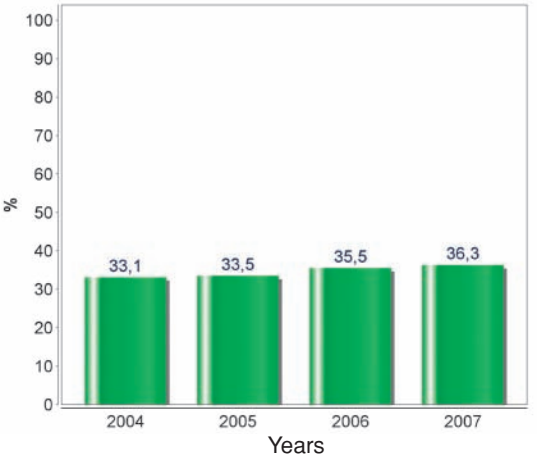
Patients with blood pressure ≤130/85 mmHg

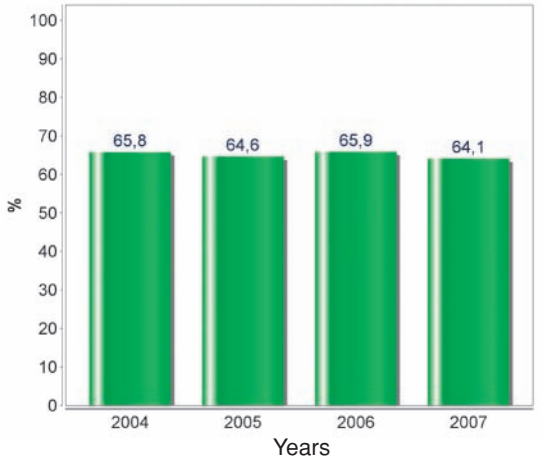
T1DM



NORTH

T2DM





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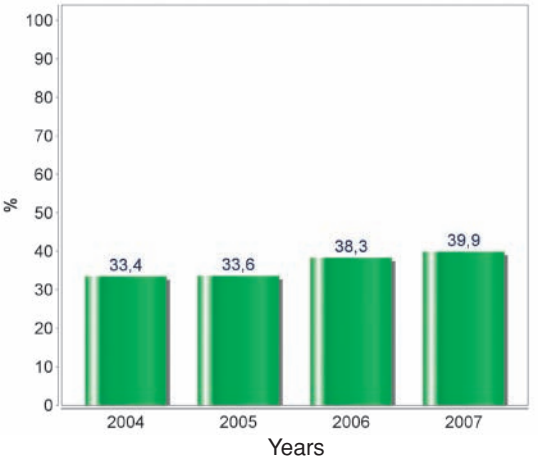

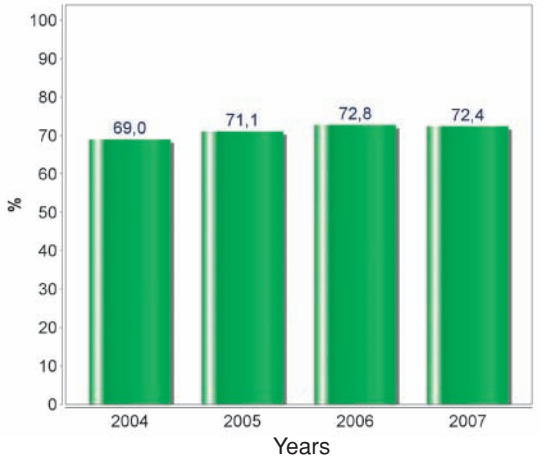

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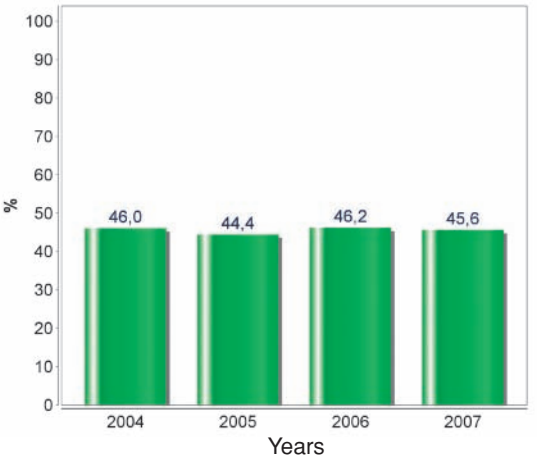
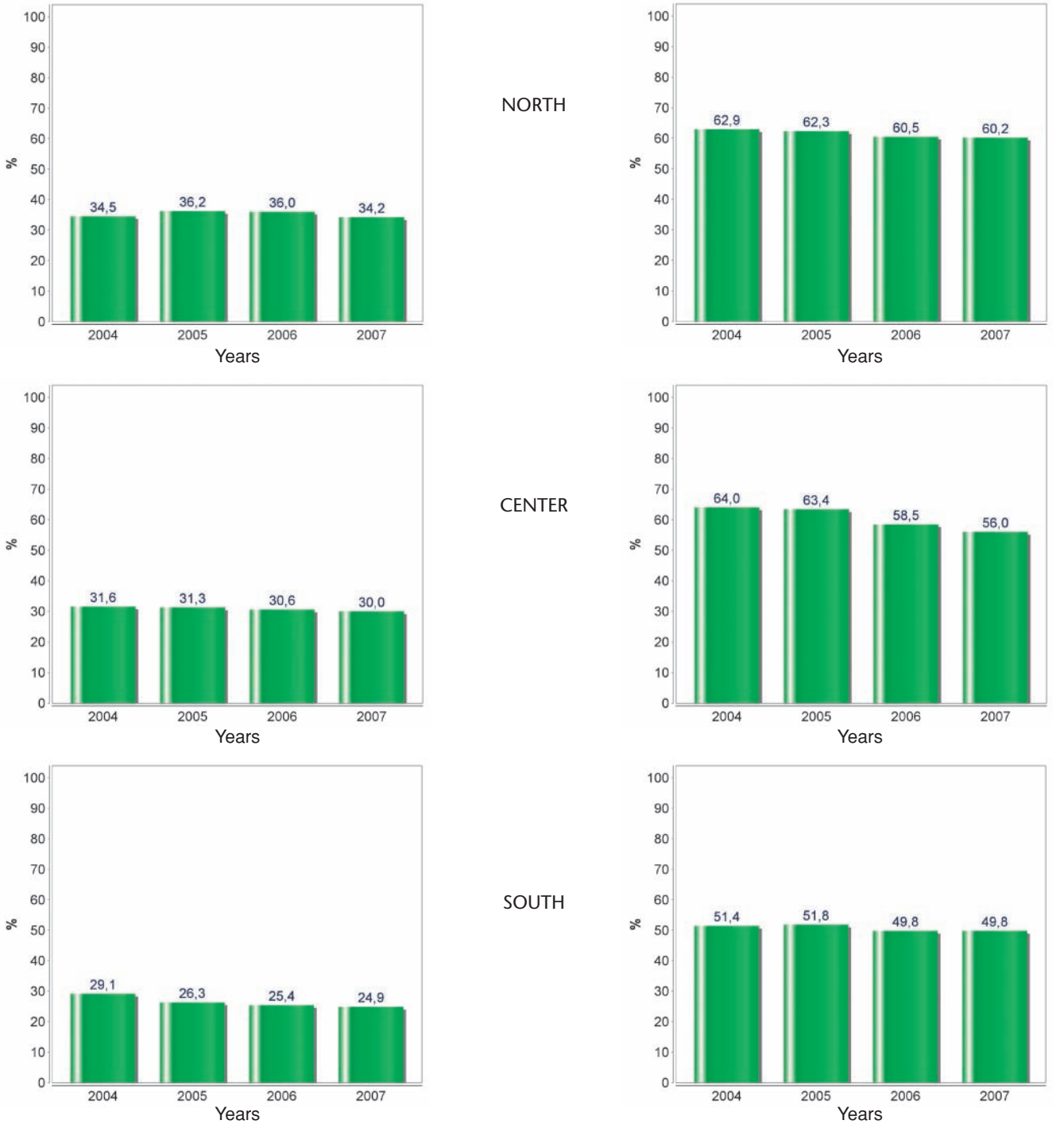


In the absence of marked temporal changes, adequate blood pressure control was more frequently reported in the South for both types of diabetes.

Patients with blood pressure ≥140/90 mmHg

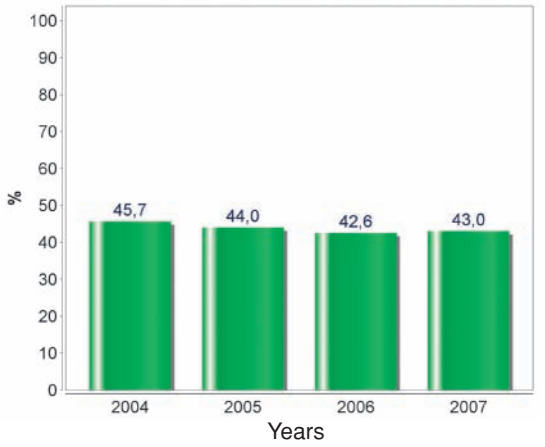
T1DM T2DM



A reduction in this unfavorable outcome measure was observed only in the South for T1DM; the trend appears to be present for T2DM in all three macro-areas, although more pronounced in the Center. A decreasing north-south gradient in the proportion of patients with elevated blood pressure values persisted.

Patients treated with ≥2 antihypertensive agents

T1DM T2DM



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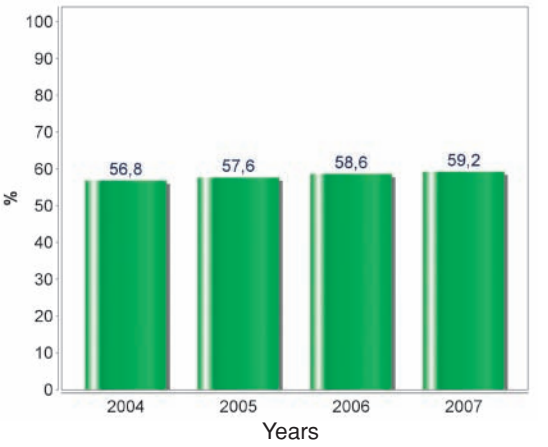

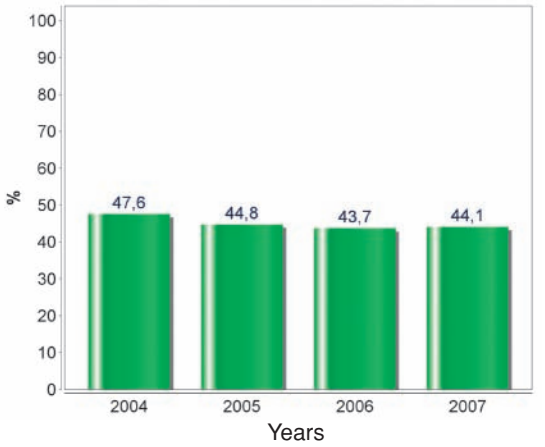

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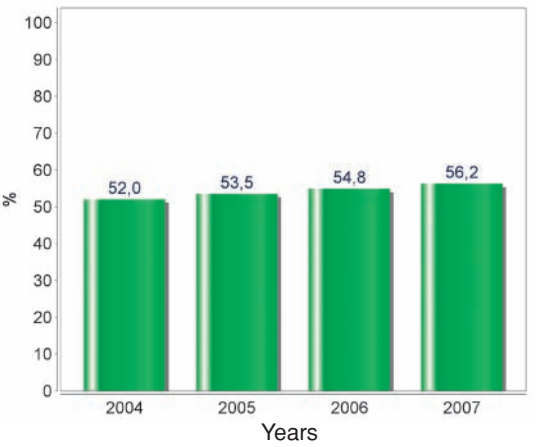
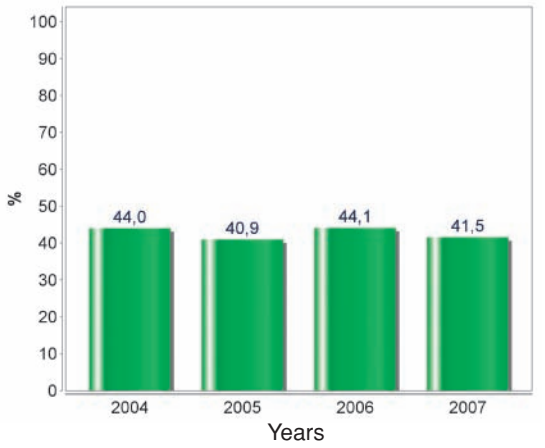
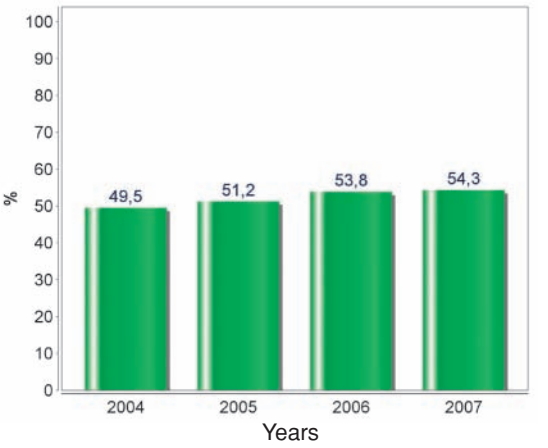




SOUTH

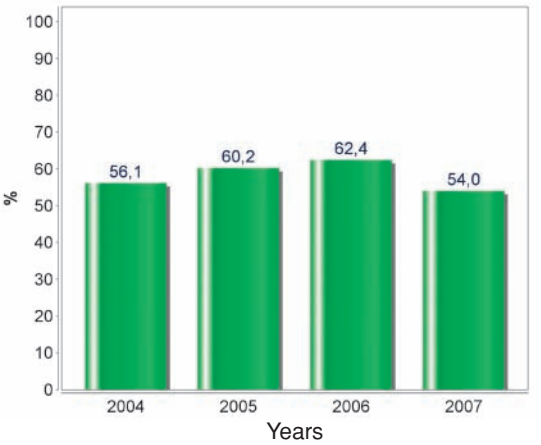


In all three macro-areas the proportion of patients treated with two or more antihypertensive agents declined slightly in those with T1DM but increased in those with T2DM.

Other indicators

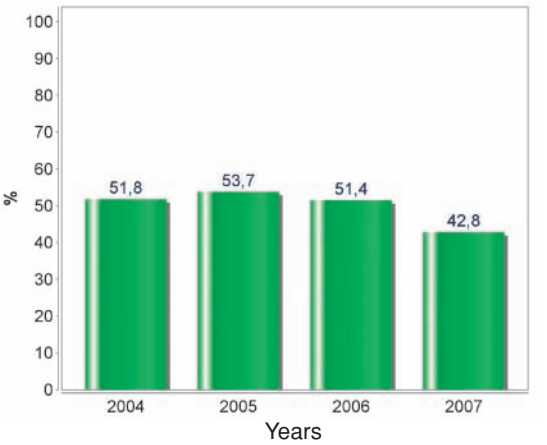
Patients monitored for nephropathy

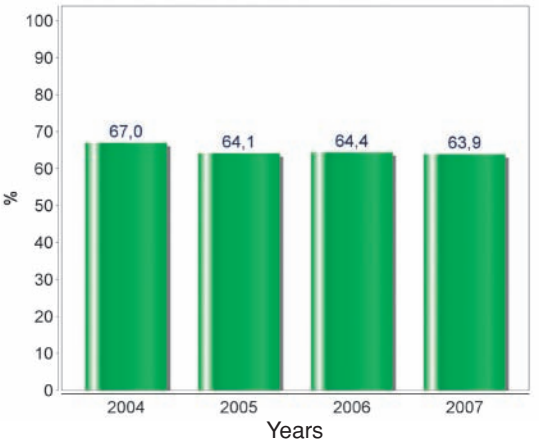
T1DM



NORTH

T2DM





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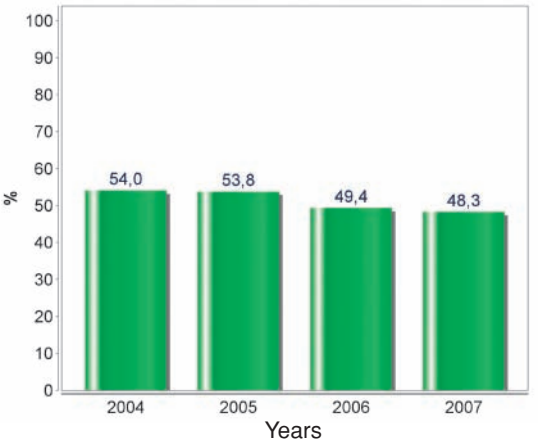

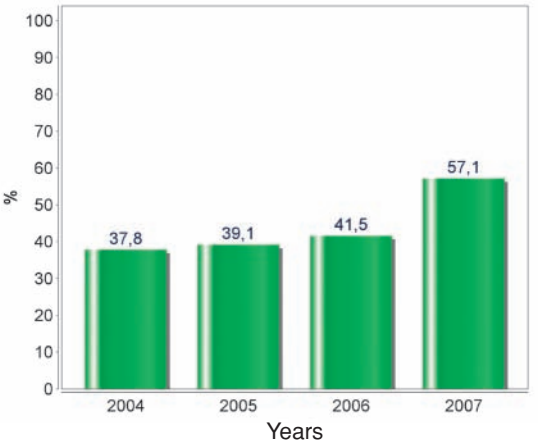

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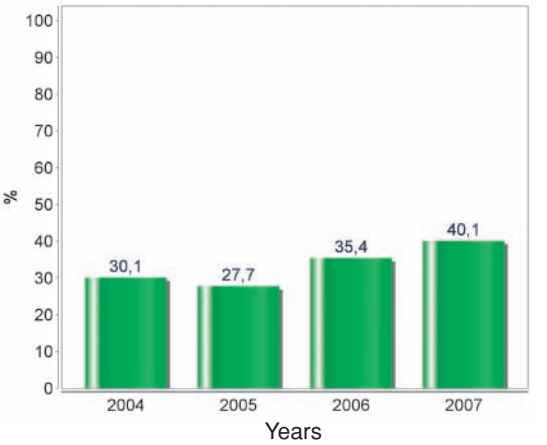
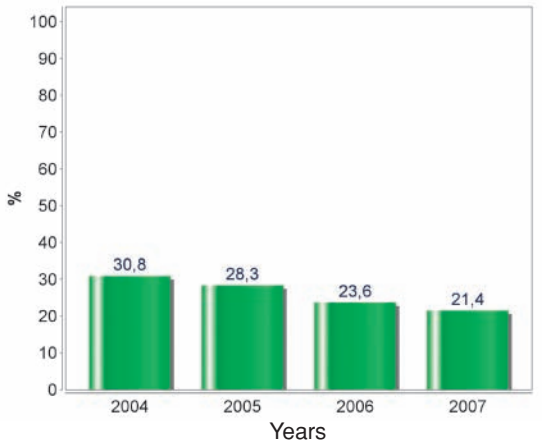


There was a downward trend in the North and the Center, whereas in the South, where monitoring for nephropathy was comparatively less frequent, the percentage increased to approximately the levels reported in the other two macro-areas.

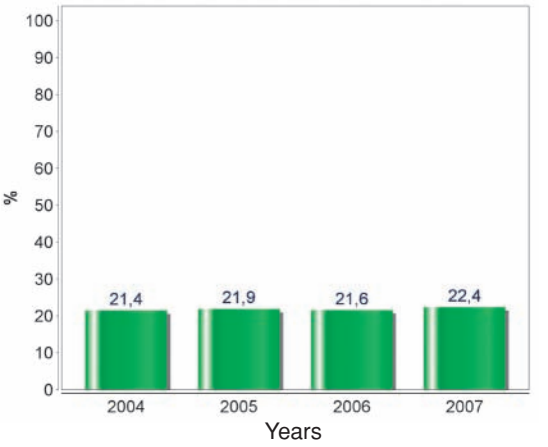
Patients monitored for diabetic foot

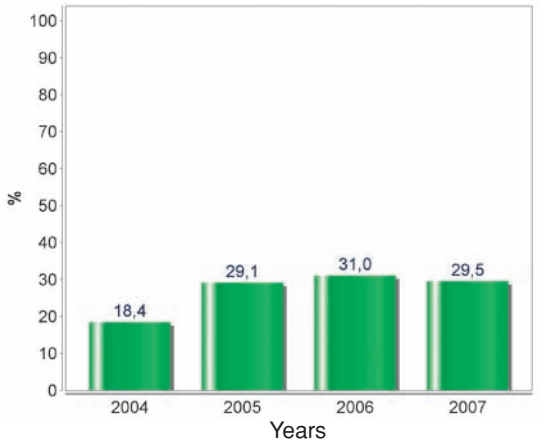
T1DM



NORTH

T2DM





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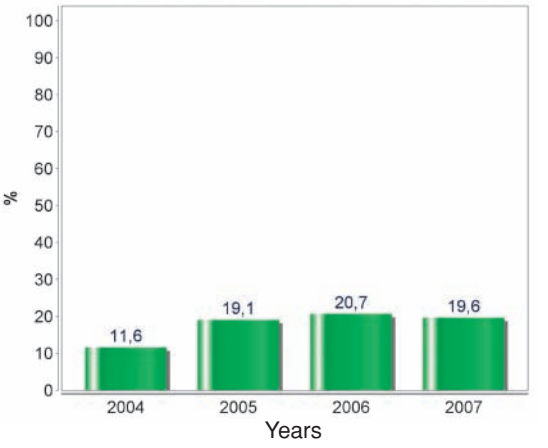

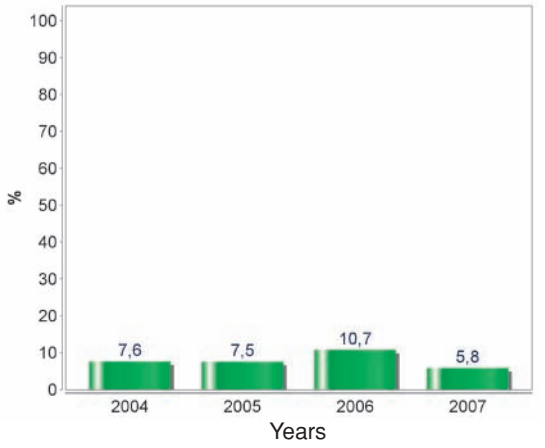

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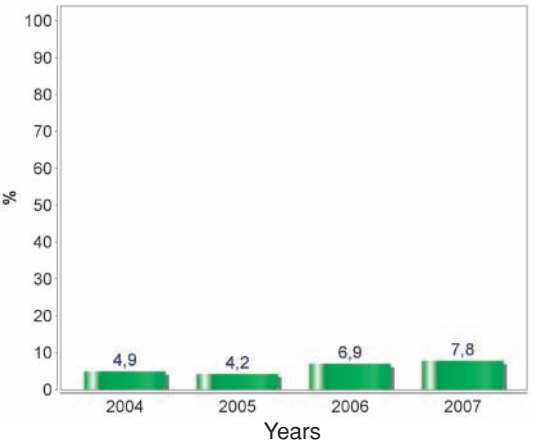


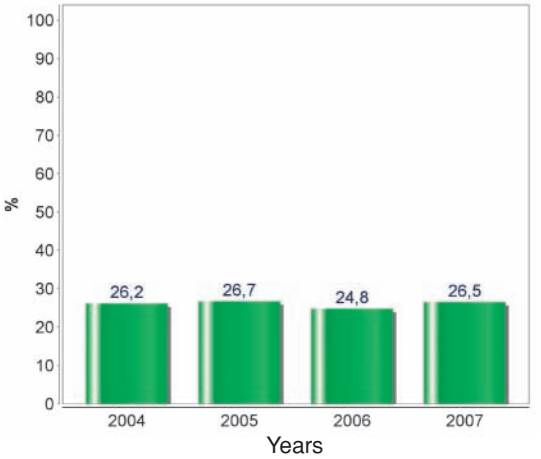
Monitoring for diabetic foot was generally low, with fairly uneven data according to macro-area and type of diabetes, resulting in no clear trend of improvement.

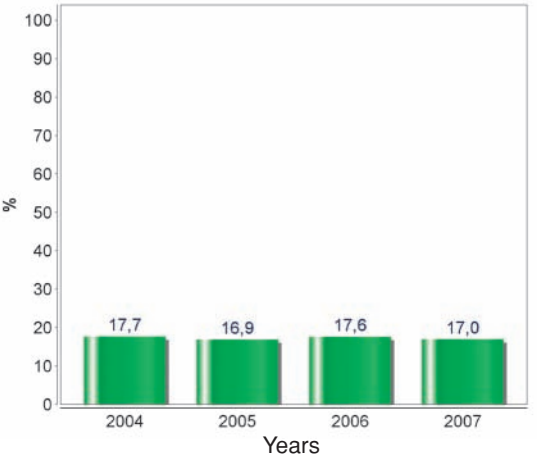
Smokers

T1DM

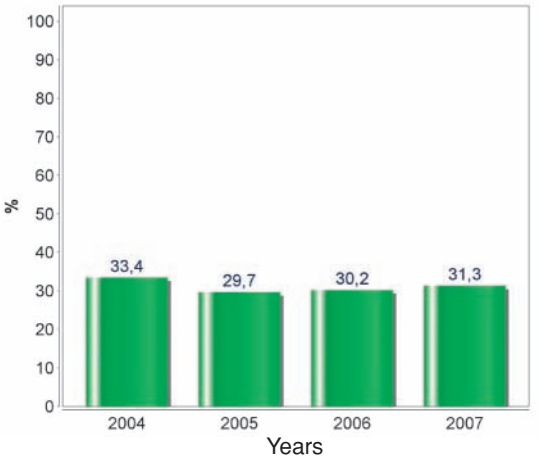
T2DM

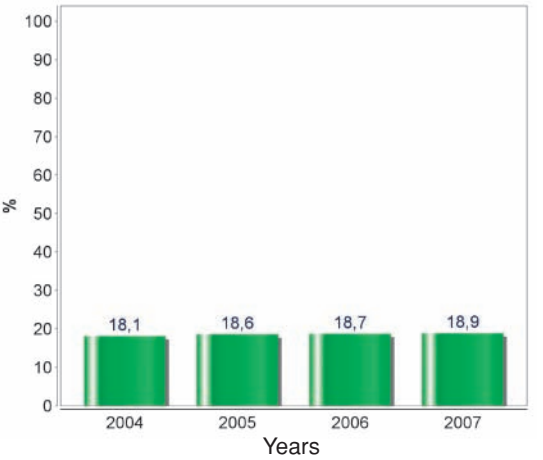
NORTH



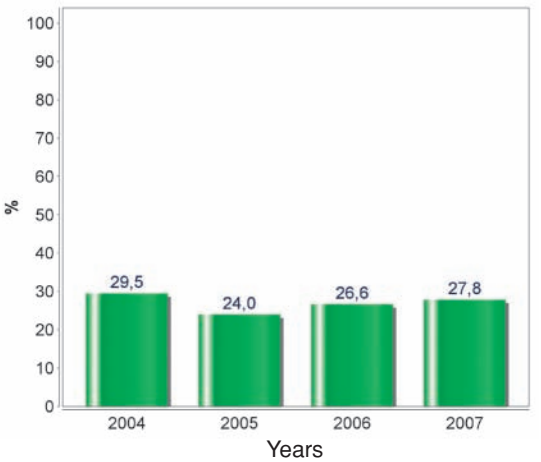


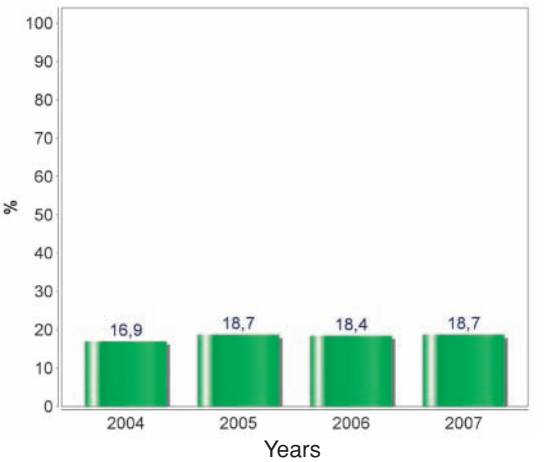
CENTER





SOUTH





The proportion of smokers remained substantially unchanged over the four years and across all three macro-areas.

Commentary

Besides providing a broad national picture of diabetes care, the AMD Annals reveal whether, in an era of increased mandating to the regional administrations and health care devolution, the health care models operated in the various different geographic areas manage to deliver a fairly similar level of services, ensuring equality of access and elevated quality of care. Analysis by macro-area is important for documenting whether and to what extent there exist geographic and temporal trends in the improvement of quality of care. Documentation of what has been done and of the results thereby obtained can, in fact, represent the knowledge basis that informs reflection and deeper analysis at the regional level, as can a comparative evaluation between different organizational models. Given these premises, the analysis of four years of activity has highlighted several important issues that may be summarized as follows:

1. Ever wider participation in the AMD Annals is accompanied by a continuing improvement in the quality of data entered on the electronic-medical records. Not only has the number of centers collaborating in the initiative grown, but also the percentage of those that met the criteria for minimum acceptable data completeness for defining the gold standard. It should be stressed, however, that the diabetes centers in the Center and South macro-areas need to be more involved. Over 50% of the sample comes from centers located in the North. In addition, efforts need to be stepped up so that the completeness of the collected data reach the gold standard level in all collaborating centers, thus closing the current north-south gap.

2. As regards metabolic control, given the elevated performance levels in all three macro-areas for HbA1c monitoring (slightly lower in the South), there remain considerable differences in the targets reached. Specifically, the proportion of patients with HbA1c ≤7% in T1DM and in T2DM increased markedly from north to south, with a percentage difference of over 15 points for T1DM and over 10 points for T2DM. Also as concerns the time trends, an improvement was observed especially in the South, where it was more evident for T1DM. Although underlying these differences may be differing demographic characteristics (lifestyle, socio-economic status, referral of patients with more or less severe diabetes to diabetes centers), it is also possible that in the South there is a greater propensity to treat aggressively, as seems to emerge from the data on T1DM and the slightly higher percentage of patients with T2DM treated with insulin.

3. In lipid profile control there was a general trend toward improved performance as measured by process and intermediate outcome indicators. In the generally positive picture there remains a markedly higher monitoring rate of lipid profile for both types of diabetes, with the highest percentage of patients with target LDL cholesterol values in the North. This finding is associated with a greater use of statins in the North, although there was an upward trend in all three macro-areas.

4. The blood pressure data paint a variegated picture. While blood pressure values were more often measured and recorded in the North for both types of diabetes, target values were more often reported in the South. Of note is the extremely high proportion of persons with elevated blood pressure (≥140/90 mmHg), especially among those with T2DM in the North (60%) and the Center (56%) and the South (just under 50%). Similarly for patients with T1DM, one out of three in the North and the Center and one out of four in the South presented with elevated blood pressure values. This negative finding persists, despite the elevated and increasingly growing proportion of persons treated with two or more antihypertensive agents, and calls attention to the need to examine the reasons for this failure.

5. The other indicators show a substantial lack of monitoring or recording of data for two important complications of diabetes: nephropathy and diabetic foot. The data show a reduction in the

frequency of monitoring for nephropathy in the North and the Center, whereas the situation has improved in the South, approaching the performance levels of the other two macro-areas in 2007. Such cannot be said, however, for diabetic foot monitoring, which was reported in about one fifth of patients in the North and the Center but in far fewer in the South. As concerns T1DM, there was a drop in performance in the North and an improvement in the Center. The prevalence of smokers continues to be a cause for concern. The consistently high number of smokers testifies to the inefficacy of anti-smoking campaigns (or lack thereof) in reducing one of the most important risk factors as regards microvascular and macrovascular complications. In conclusion, the analysis by macro-area revealed modest variability across all geographic areas, without a common trend for any indicators. While the process indicators are more systematically performed/recorded in the North, the intermediate outcome indicators are more positive in the South as regards metabolic and blood pressure control, and are fairly even across all macro-areas as regards LDL cholesterol, especially among persons with T2DM. Lastly, within a general trend of improvement, there remained negative results concerning monitoring for diabetic foot and renal function, and smoking cessation. The documentation of still unmet care needs that emerged from the AMD Annals will be more useful the more these data are exploited for regional or national initiatives focused singly on finding solutions to a problem among those perceived as more relevant to a specific care context. Initiatives targeting specific objectives could surely enhance the positive impact of the AMD Annals on diabetes care beyond that documented in the first four years of this initiative.

Antonio Nicolucci

CHARACTERISTICS OF PATIENTS WITH T2DM AT FIRST VISIT TO A DIABETES CENTER

Premise

This analysis evaluates the characteristics of patients with T2DM who first visited a diabetes center in the last four years. In light of recent evidence underscoring the need for prompt and intensive intervention on metabolic control and cardiovascular risk factors, which contrasts with the frequent documentation of therapeutic inertia, it appeared important to characterize the clinical profile of first-time patients.

The finding is initially presented aggregated by year to determine whether the characteristics of patients referred to specialist services had somehow changed over time. The information is presented by region (new cases examined between 2004 and 2007), in order to see whether and to what extent the different care settings influenced the specialist referral process.

CHARACTERISTICS OF PATIENTS WITH T2DM AT FIRST VISIT, ACCORDING TO YEAR

	2004	2005	2006	2007
No. patients	19,478	22,515	28,226	31,917
Age (yr)	64.3±11.5	64.4±11.7	64.8±11.7	64.9±11.9
Males (%)	56.1	56.4	56.7	57.7
BMI (body weight in kg/height in m^2)	29.6±5.2	29.6±5.3	29.7±5.3	29.7±5.3
Duration of diabetes (yr)	7.4±8.1	6.9±8.1	7.4±8.3	7.4±8.2
HbA1c (%)	7.3±1.6	7.4±1.6	7.4±1.6	7.4±1.7
Diabetes treatment (%)				
Diet alone	17.9	18.6	16.5	15.8
OHA*	67.0	62.3	62.9	63.2
Insulin	9.2	12.5	12.3	12.7
Insulin + OHA*	5.9	6.6	8.3	8.3
Diastolic BP (mmHg)	81.7±9.8	81.6±10.0	81.1±9.9	80.8±9.8
Systolic BP (mmHg)	140.5±19.6	140.1±19.4	139.6±19.1	139.1±19.1
Antihypertensive treatment (%)	50.1	54.1	58.0	57.4
Total cholesterol (mg/dl)	202.0±41.9	198.6±42.3	194.4±42.0	193.5±42.3
HDL cholesterol (mg dl)	50.6±13.3	51.0±13.5	50.6±13.3	48.9±13.2
LDL cholesterol (mg/dl)	122.2±35.2	118.4±35.5	115.0±35.7	115.3±35.8
Triglycerides (mg/dl)	157.6±121.1	158.5±119.6	155.8±128.3	155.7±116.6
Lipid-lowering treatment (%)	21.1	25.8	29.8	29.6

*OHA = oral hypoglicemic agents

The analysis of first-time visits in the entire sample shows that the characteristics of patients with T2DM seen for the first time by a diabetologist remained substantially unchanged over the last four years. These patients presented elevated BMI, a duration of diabetes of over 7 years, fair metabolic control, and were generally treated with oral hypoglicemic agents and/or insulin.
The elevated percentage of antihypertensive and lipid-lowering treatments indicates that these persons are at high cardiovascular risk.

CHARACTERISTICS OF PATIENTS WITH T2DM AT FIRST VISIT, ACCORDING TO REGION

	ITALY	ABRUZZO	BASILICATA	CALABRIA	CAMPANIA	EMILIA ROMAGNA	FRIULI VENEZIA GIULIA	LAZIO	LIGURIA
No. patients	102,136	1705	823	1068	4896	8886	4465	5877	580
Age (yr)	64.6±11.7	65.0±11.8	61.2±11.3	62.3±11.6	62.1±11.1	65.9±12.2	64.5±11.8	64.7±12.2	67.6±10.3
Males (%)	56.9	53.5	65.6	52.1	52.5	56.9	59.5	57.6	59.7
BMI	29.6±5.3	30.9±5.4	29.9±4.9	29.8±5.0	30.5±5.8	29.7±5.3	29.5±5.0	29.1±5.3	28.9±4.9
Duration of diabetes (yr)	7.3±8.2	8.0±8.2	6.0±5.9	8.2±8.3	8.7±8.7	7.1±8.0	6.1±6.4	10.4±10.1	8.3±8.8
HbA1c (%)	7.4±1.7	6.6±1.7	7.1±1.7	8.0±1.8	7.6±1.7	7.4±1.6	7.6±1.8	7.9±1.7	7.8±1.8
Diabetes treatment (%)									
Diet alone	17.0	16.7	1.2	10.7	9.2	22.8	21.0	9.2	1.0
OHA	63.6	63.4	81.4	63.1	67.7	52.2	67.8	66.0	70.7
Insulin	11.9	10.2	10.1	13.1	15.7	18.4	5.3	12.6	22.0
Insulin + OHA	7.5	9.7	7.3	13.1	7.4	6.6	5.9	12.2	6.3
Diastolic BP (mmHg)	81.2±9.9	78.3±10.4	80.8±7.4	82.6±8.6	80.0±10.0	81.6±8.3	82.6±10.5	82.6±10.7	84.9±13.1
Systolic BP (mmHg)	139.7±19.3	135.5±19.3	135.1±14.7	135.8±13.1	136.5±19.4	138.7±17.8	144.2±21.1	141.3±20.5	143.3±23.0
Antihypertensive treatment (%)	55.5	59.4	42.4	37.2	40.9	66.2	64.9	57.3	68.4
Total cholesterol (mg/dl)	196.6±42.3	200.2±42.8	192.2±43.1	194.4±40.9	195.9±42.2	197.8±41.7	202.2±42.5	190.9±41.5	196.8±44.2
HDL cholesterol (mg/dl)	50.1±13.3	48.2±11.5	46.6±12.1	48.9±14.1	48.6±12.0	51.7±14.1	50.7±13.0	49.3±13.4	49.8±12.0
LDL cholesterol (mg/dl)	117.3±35.7	120.5±36.4	113.1±34.5	115.3±33.7	117.9±35.1	118.6±35.6	121.0±35.4	111.6±35.1	120.8±36.0
Triglycerides (mg/dl)	156.7±121.4	165.3±102.1	175.4±131.0	160.2±116.0	159.3±133.9	158.7±121.9	159.9±125.3	151.6±100.1	154.6±118.7
Lipid-lowering treatment (%)	27.2	23.4	26.0	17.7	18.2	32.8	30.5	30.0	41.0

The regional analysis of first-time patients offers important starting points for reflection.
Despite the relatively low number of patients in some regions, the heterogeneity of the characteristics of patients at first visit is clear.
The mean age of the entire sample was about 65 years, range 61 (Basilicata) to 68 (Liguria). In all regions there was a predominance of males, with the highest values observed in Basilicata (65%) and Sicilia (51.9%).

CHARACTERISTICS OF PATIENTS WITH T2DM AT FIRST VISIT, ACCORDING TO REGION

LOMBARDIA	MARCHE	PIEMONTE	SARDEGNA	SICILIA	TOSCANA	TRENTINO ALTO ADIGE	UMBRIA	VENETO
19,149	12,460	5642	5269	4165	6424	597	2955	17,144
64.8±11.4	63.8±11.9	65.7±11.3	64.8±12.3	62.4±11.3	66.0±11.5	65.8±11.4	66.5±11.2	64.5±11.8
57.2	58.6	55.3	56.2	51.9	55.6	55.9	53.6	58.5
29.3±5.3	30.1±5.2	29.7±5.2	28.9±5.1	29.9±5.3	29.3±5.3	29.3±4.8	29.8±5.0	29.8±5.2
7.6±8.3	6.0±7.4	7.6±8.2	6.5±7.2	8.1±8.4	8.3±9.1	6.7±7.6	8.3±9.2	6.2±7.8
7.4±1.6	7.0±1.5	7.5±1.6	7.0±1.8	7.5±1.6	7.6±1.8	7.5±1.6	7.2±1.7	7.5±1.6
12.3	22.4	15.7	28.8	12.4	11.1	13.5	14.4	21.3
69.7	61.7	64.7	46.1	68.4	70.9	65.6	58.1	61.6
10.6	9.4	11.9	17.6	10.5	12.3	9.4	20.6	9.7
7.4	6.4	7.7	7.5	8.7	5.7	11.6	6.9	7.4
80.6±9.7	80.3±9.7	80.6±8.7	78.7±10.4	77.7±9.6	82.4±9.1	81.7±11.5	79.7±8.6	83.3±10.2
139.6±19.7	136.6±17.7	138.7±18.4	136.9±18.9	134.2±16.2	140.7±18.0	144.0±22.2	139.8±17.0	143.9±20.2
55.5	54.5	58.0	41.7	48.1	57.1	62.3	45.1	58.7
193.4±41.3	198.1±42.6	196.7±42.1	191.6±43.0	192.7±41.3	197.1±43.0	197.3±41.9	199.9±41.5	200.8±42.8
51.7±13.7	48.4±13.1	51.9±14.0	49.3±13.3	48.5±11.9	48.9±13.6	49.7±12.4	51.6±13.3	49.7±12.7
113.2±34.9	119.8±36.2	114.7±35.7	117.5±36.1	114.8±35.8	116.8±36.1	114.2±32.0	116.2±35.9	121.7±35.5
152.7±115.7	168.7±131.3	154.2±101.6	123.8±99.2	152.0±96.7	163.7±147.2	165.1±119.3	176.5±195.9	155.5±110.7
28.0	24.2	28.8	29.3	27.7	24.9	31.3	15.3	28.3

Duration of diabetes is particularly interesting: while in some regions patients were referred to specialist services after about 6 years, in others referral might occur much later (10 years in Lazio).
Equally variable were the mean HbA1c levels (6.6-8.0%) and diabetes therapy (1-28.8% diet alone).
The cardiovascular risk profile differed widely across regions.

Commentary

Past AMD Annals examined the problems of first visits to a diabetes service, noting the huge influx of new patients (>15%) that overwhelmed the already stretched resources of diabetes centers. An analysis of patients at their first visit holds particular interest because it can provide key clinical data and information on the type of care delivered. The importance that the start of therapy has on the course of diabetes emerged strongly in recent years, especially after the Epidemiology of Interventions and Complications (EDIC) study first showed that patients receiving less intensive initial therapy were destined to a less favorable prognosis. Terms such as metabolic memory or metabolic legacy were coined, that is, the inheritance that a patient receives if elevated HbA1c levels persist.

The initial observation one can make of the analysis of the data on patients at their first visit is that these are patients not at the onset of disease but rather with a long history of illness (7 years on average) and therefore with a well-tracked metabolic history. It is therefore hoped that some are new entries on the electronic-medical record from among those already followed by other diabetes centers and are therefore considered as first visits only for the center that entered the data in the Data File. In future Annals editions we will need to define the type of patient that counts as a "new visit".

On the whole, the data describe a situation where a patient arrives at a diabetes center after a long period of external management and with a well-defined pharmacotherapy. The degree of compensation is acceptable although not optimal (mean, HbA1c 7.4%). We could say that the patients arrive at the right time for intensifying therapy to bring the level to below 7%. But what is certain is that a diabetes service cannot intervene on the early determinant phases of the illness, in which metabolic memory is fixed. Several hypotheses can be made: in the majority of regions, patients with a recent diagnosis of diabetes probably remains in the care of the general practitioner, whereas only those with a more complex management that presumably requires specialist care will be referred to a diabetes center.

This contrasts with the vision that emerged in 2008, a memorable year in the history of diabetes knowledge, specifically with surprising data from the 25-year observations of the United Kingdom Prospective Diabetes Study (UKPDS) that confirmed that also in T2DM there exists a metabolic memory. In other words, a memory of damage: the damage caused by hyperglycemia is partially reversible, but late attempts to bring up metabolic compensation to better levels are of negligible value. Also after the end of the trial, when both treatment arms (intensive and conventional) received the same type of therapy and glycated hemoglobin levels were the same in the two groups, the subjects who had received intensive therapy from the start continued to present with minor complications. The portent of this clinical message is enormous, that is the prognosis is played at the start, the better the HbA1c at the initiation of treatment, the better the prognosis over time.

In contrast, in 2008 another fundamentally complementary message came from the Action to Control Cardiovascular Risk in Diabetes (ACCORD), Action in Diabetes and Vascular Disease: Preterax and Diamicron Modified Release Controlled Evaluation (ADVANCE), and Veterans Affairs Diabetes Feasibility Trial (VADT) studies, i.e., intensive treatment may be useless or harmful when a patient in poor compensation presents with a long history of diabetes and previous cardiovascular events.

The right approach to prevention is not to lower HbA1c when it has reached unacceptable levels, but rather to keep it from rising, attempting to intervene intensively and promptly.

Within this view, the 2009 Annals data underscore the conviction that also in an integrated management program it is essential that the patient at disease onset is examined in a diabetes center and receives the best treatment plan possible to control the disease in the early years of the illness.

As concerns cardiovascular risk factors, patients with a less negative situation with respect to glycemic control are followed by the services. Here one can see year by year improvement. The mean LDL cholesterol level at first visit dropped from 122 to 115 mg/dl over four years, whereas the percentage of patients on statin treatment steadily increased. Similarly, trig-

lyceride levels in patients at first visit declined considerably, whereas HDL cholesterol levels unexplainably did not rise. This is a sure sign that lipid-lowering treatment has made more progress in recent years than hyperglycemia treatment, thanks to the introduction of potent drugs and doctors education. Blood pressure control showed a less pronounced trend yet similar to that of LDL cholesterol (mean value reduced and number of patients treated increased). BMI merits special comment. Patients at first visit presented with a higher BMI on average (0.3 kg/m^2) than those already followed by a diabetes services. This is proof of the burden that increasing obesity in the population has on diabetes services. For an effective prevention campaign we would need to activate initiatives that can reduce this phenomenon.

Carlo B. Giorda

IMPACT OF THE AMD ANNALS ON THE QUALITY OF CARE

OBJECTIVES AND METHODS

The aim of this subanalysis was to determine whether participation by diabetes centers in the AMD Annals initiative improved the quality of care delivered over the last four years.

For this purpose, two groups of centers were compared:

- **Group A** composed of centers collaborating for the first time in 2008
- **Group B** composed of centers collaborating since the start of the initiative

Centers were included in the analysis if in all four years they had furnished analyzable data for calculating the process and outcome indicators.

Selected indicators were:

- **Process indicators**: percentage of patients who had their HbA1c, blood pressure, and lipid profile measured at least once
- **Favorable outcome measures**: percentage of patients who had reached therapeutic target values for HbA1c ≤7%, blood pressure ≤130/85 mmHg, LDL cholesterol <100 mg/dl
- **Unfavorable outcome measures**: percentage of patients with HbA1c ≥9%, blood pressure ≥140/90 mmHg, LDL cholesterol ≥130 mg/dl
- **Prescribed medications**: percentage of patients treated with insulin, with ≥2 antihypertensive agents and statins.

For each indicator a multilevel analysis was performed on patients with T2DM, adjusted for age, sex, duration of diabetes, and clustering effect. Results are expressed as frequency and 95% confidence intervals. The results are given as graphs in which the dashed line represents the adjusted percentages of patients who underwent yearly monitoring, reached a given outcome or were treated with specific drugs. The vertical bars represent the 95% confidence interval. For each parameter, the bar graph reports the absolute percent changes between 2004 and 2007.

RESULTS

The tables illustrate the sample size used in the analysis.

Selection of centers

	Group A	Group B
Total no. of centers	34	82
No. of analyzable centers for all four years	18	67

No. of persons with T2DM, according to year and comparison group

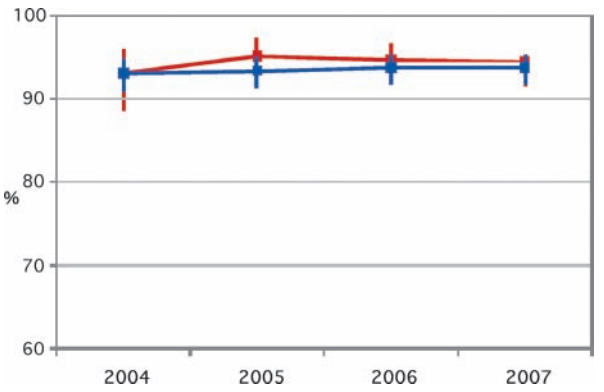
	2004	2005	2006	2007
Group A	14,050	16,677	18,256	23,527
Group B	92,269	102,614	117,921	136,572

PROCESS INDICATORS

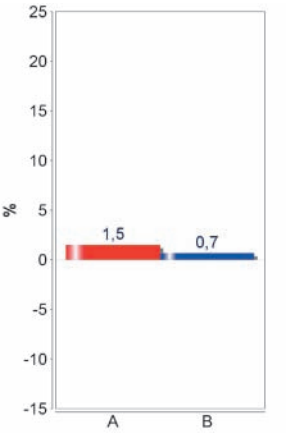
Group A Group B

VARIATIONS 2004-2007

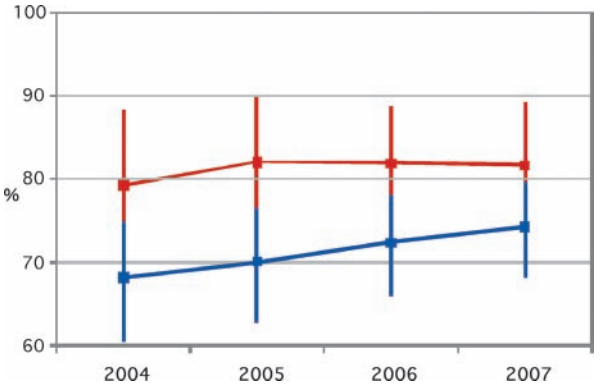
HbA1c



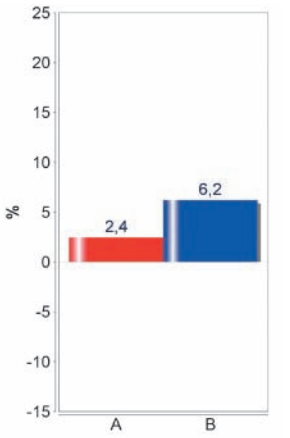
The trend for HbA1c monitoring remained basically unchanged over the four years and between the two groups, indicating elevated performance levels.



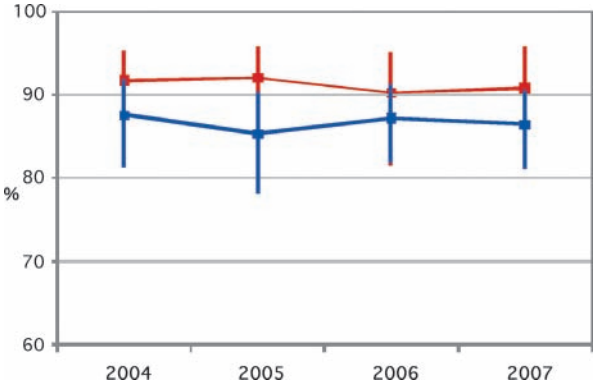
Lipid profile



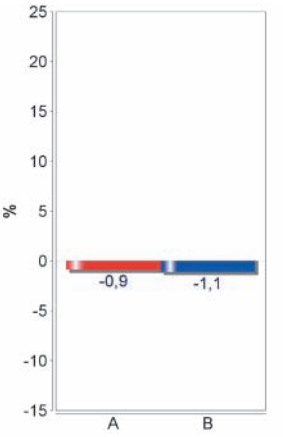
Compared with newly joining centers, those that had collaborated since the start of the initiative had lower performance levels; however, this was associated with marked performance growth trends. In absolute terms, the growth rate was 6.2% in group B (old centers) and 2.4% in group A (new centers).



Blood pressure



The newly joining centers performed slightly better on blood pressure monitoring; this trend was consistent over the four-year period, without a time trend of improvement in either group.

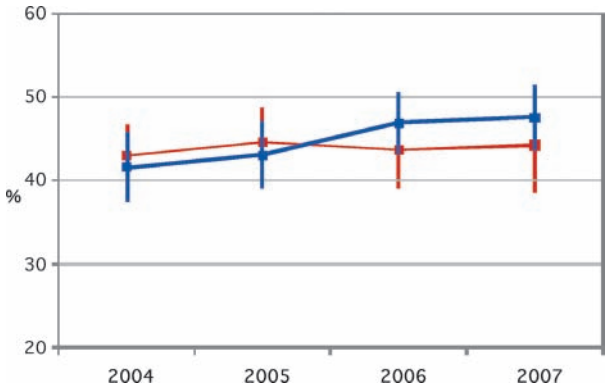


FAVORABLE OUTCOME INDICATORS

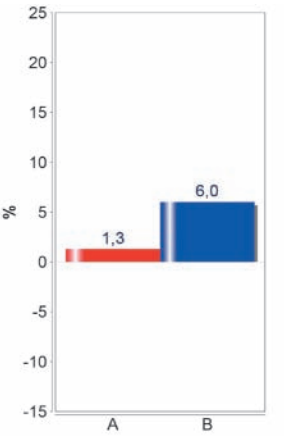
Group A Group B

VARIATIONS 2004-2007

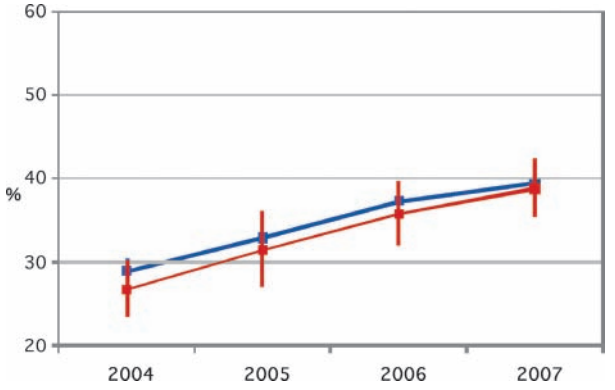
HbA1c ≤7%



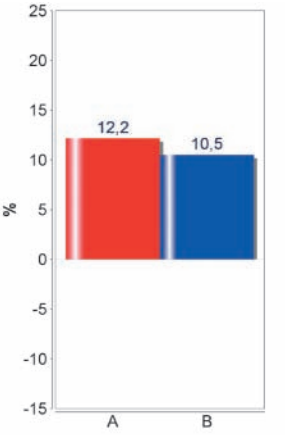
The proportion of patients with good metabolic control remained basically unchanged over the four-year period for the new centers, while the old centers showed a trend for improvement (6%).



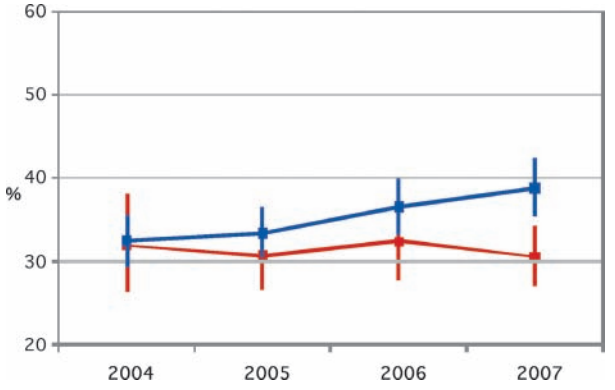
LDL cholesterol <100 mg/dl



There was a substantial improvement over time in patients with target LDL cholesterol level in both groups, with an absolute increase of over 10%.



Blood pressure ≤130/85 mmHg



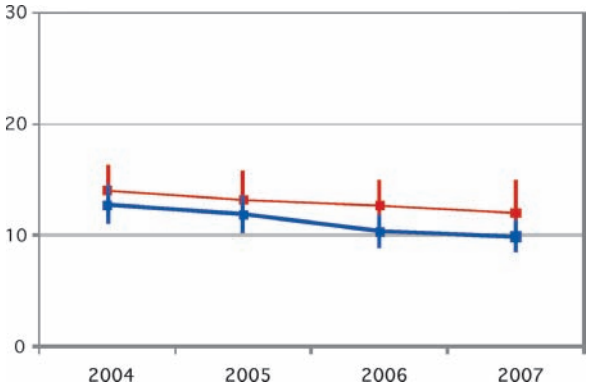
Adequate blood pressure control in a growing percentage of patients over the four-year period was noted for the old centers; this time trend was absent in the new centers where the proportion of patients with target blood pressure levels was markedly lower.

UNFAVORABLE OUTCOME MEASURES

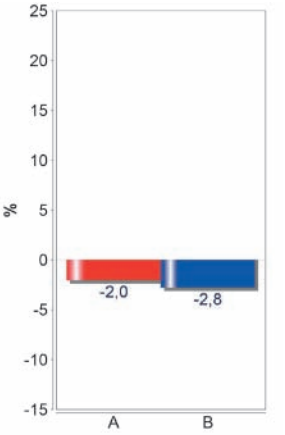
Group A — Group B

VARIATIONS 2004-2007

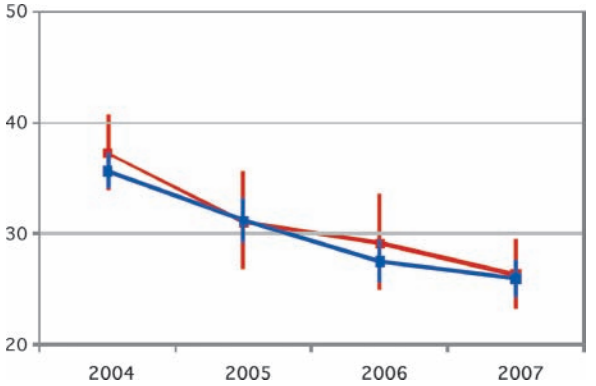
HbA1c ≥9%



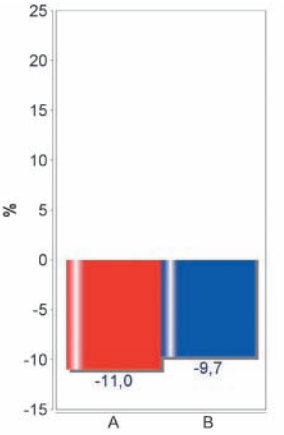
General improvement in the quality of care was confirmed by the reduction in both groups in the proportion of patients with particularly poor metabolic control.



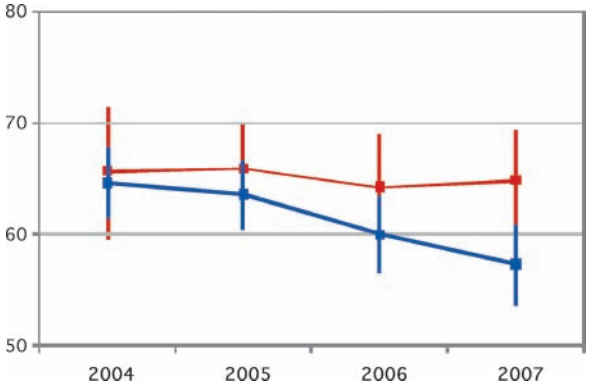
LDL cholesterol ≥130 mg/dl



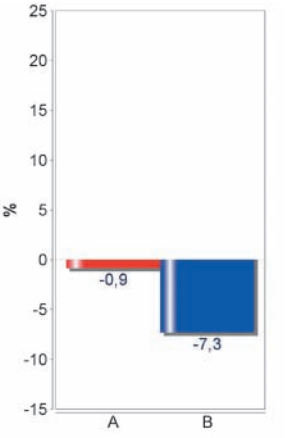
Even more marked was the improvement in lipid control in both groups, as shown by the sharp reduction in the percentage of patients with highly elevated LDL cholesterol levels.



Blood pressure ≥140/90 mmHg



The major difference between old and new centers is evident for this parameter. Old centers showed a marked reduction in the percentage of patients with elevated blood pressure values, whereas no time trend for improvement emerged for the new centers.

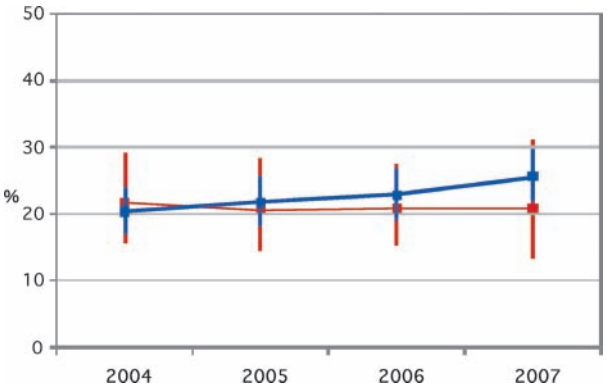


PRESCRIBED MEDICATIONS

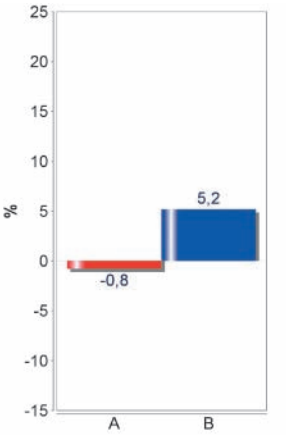
Group A Group B

VARIATIONS 2004-2007

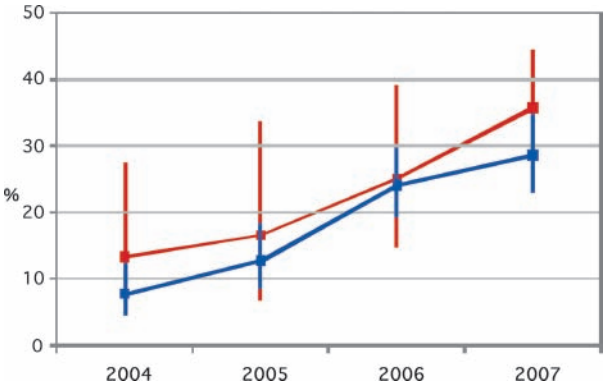
Insulin



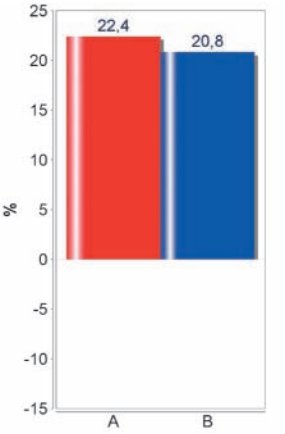
The percentage of patients treated with insulin rose over the four-year period in the old centers and remained unchanged in the new centers.



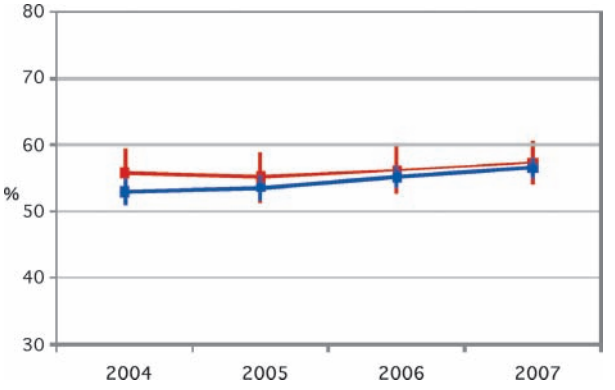
Statins



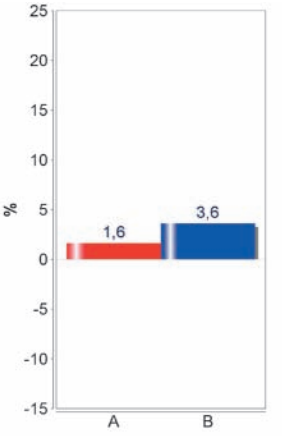
In both groups there was a marked increase over time in the use of statins, which was slightly higher in the new centers.



Two or more antihypertensive agents



A slight growth trend in the use of two or more antihypertensive agents was noted in group B; the increase was less pronounced in group A.



Commentary

The aim of sequential and comparative data analysis (2004-2007) was to obtain reference information on the quality of care and on response to good practice or organizational changes that occurred in this period.

In the 2008 AMD Annals, the regional analysis revealed reference organizational models, possible lacks, and areas for improvement. That said, from the analysis of regional data, because of the difficulty in making direct correlations between quality indicators and intermediate outcome indicators, rather than responses we identified a more complete list of possible causes for the heterogeneous behavior found in Italy

The *research* question in this analysis was: "Does participation in the Annals initiative represent per se a motive for activating a virtuous circle for improvement?".

The answer was given thanks to the success of the AMD Annals, which increasingly involved many new centers.

The global analysis was subdivided into two parts: one related to diabetes centers that had collaborated in the initiative since 2004 (82 centers), the other composed of centers that, although new entries in 2008, provided data from previous years (34 centers). The comparison between the two groups analyzed several process and positive/negative intermediate outcome indicators and prescribed medication use.

What emerged from the analysis was that the positive intermediate outcome indicators (HbA1c and blood pressure values within target range), although increasing in both groups due to a general improvement in care, improved much more in the old centers, as did the negative intermediate outcome indicators (HbA1c ≥9% or blood pressure >140/90 mmHg). Improvement in care, as measured by medications (statins, aspirin, antihypertensives), was also noted in the old centers.

Hence, the *answer* to our first question is: "The Annals, by providing a simple picture of the quality of care in Italy, also by analysis at the regional level, led to a qualitative improvement in intermediate outcome indicators and in the use of medications, with positive implications for life expectancy of patients with diabetes".

This finding, promising in itself, could become even more encouraging if, on the basis of well-defined indications, the Association of Diabetologsts, the regional authorities and the diabetes centers launched specific initiatives for improving, accelerating and strengthening the virtuous circle that the Annals and the AMD have already set in motion. We could obtain targeted improvement in the more urgent problems with little effort, showing that with the use of indicators of quality of care, the cost-benefit ratio is high. In other words, important results on target objectives are within reach. As the effort to create the Annals for each center did not require extra resources or effort, the identification of annual objectives (to be measured with the Annals after the intervention) will surely give the same result.

Giacomo Vespasiani

Conclusions

This fourth edition of the AMD Annals presents diabetes care in Italy in an entirely new perspective: not just a photograph of a single year of specialist care, the Annals give a view of its evolution over a four-year period. This makes them an essential tool for reflecting on what was done in diabetes care in Italy in the recent past and what can be planned based on facts.

Obtaining hard data has always driven AMD policy. If we do not adequately measure what we do, further improvement will be difficult if not impossible to achieve. Comparison represents another instrument for improvement. This is not intended as a race to see who is the best but rather as a stimulus for attaining a common objective: improvement of the quality of care of persons with diabetes.

Careful reading of the data reported in the Annals, reflections, punctual and not emphatic, of the authors of the sections should constitute a common patrimony for Italian diabetology and the merited pride of a scientific society, such as the AMD, which represents a reference point for specialist care for persons with diabetes.

If we put together the results of the Annals with those of other AMD studies, specifically the Quality Assessment Score and Cardiovascular Outcomes in Italian Diabetic Patients (QUASAR) Study, we realize how correct and foresighted were past choices brought forward with tenacity. The increase in the number of centers collaborating in the project, the improvement in data quality, the enthusiasm with which the regional analyses were received, testify to professionalism of diabetologists, their continuous search for adequate solutions to problems that this chronic condition poses every day.

The Annals have become an essential instrument for clinical management in diabetes care, as defined at the Cernobbio Conference: *"efficacious accompaniment of persons with diabetes through the diabetes service and the social and health care systems"*.

The AMD is ready to plan its future activities in a systematic vision that takes account of the principal criticalities of specialist care of persons with diabetes in a health care pathway that involves various players equality engaged in pursuing a common objective. Now is the time to act even more incisively to ensure all persons with diabetes earlier and longer lasting maintenance of good total metabolic compensation to dramatically reduce complications and curb health care and social costs.

In conclusion I would like to thank everyone who assisted in the data collection, giving value to the often enormous daily workload. Particular thanks are due the writers of the texts and commentaries, those who collected and analyzed the data, those who contributed with their ideas and efforts. My personal thanks go to all of them, the AMD and Italian diabetology.

Adolfo Arcangeli
AMD, President