

Trends over 8 years in quality of diabetes care: results of the AMD Annals continuous quality improvement initiative

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Abstract

Objective Quality of care monitoring is a key strategy for health policy. In Italy, the AMD Annals continuous monitoring and quality improvement initiative has been in place since 2006. Results after 8 years are now available.

Research design and methods Quality of diabetes care indicators during the years 2004–2011 were extracted from electronic medical records of 300 diabetes clinics. From 200,000 to 500,000 patients with type 2 diabetes were

analyzed per year. Six process indicators, eight intermediate outcome indicators, seven indicators of treatment intensity/appropriateness, and a quality of care summary score (*Q* score) were evaluated. Previous studies documented that the risk of developing a new cardiovascular event was 80 % higher in patients with a *Q* score <15 and 20 % higher in those with a score between 15 and 25, as compared to those with a score >25.

Results The proportion of patients with HbA1c ≤7 %, LDL cholesterol <100 mg/dl, and blood pressure ≥140/90 mmHg increased by 4.8, 21.9, and 10.0 %, respectively. Process and treatment intensity/appropriateness indicators consistently improved. The proportion of patients with a *Q* score <15 decreased from 13.5 to 6.5 %, while those with a *Q* score >25 increased from 22.9 to 38.5 %.

Conclusions AMD Annals document the progress in quality of diabetes care. Longitudinal improvements in *Q* score can translate into less cardiovascular events, with

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The full list of authors is in the “Appendix” at the end of the paper.

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evident clinical and economic implications. AMD Annals represent a physician-led effort not requiring allocation of extra-economic resources, which is easy to implement and deeply rooted in routine clinical practice. They are a potential case model for other healthcare systems.

Keywords Diabetes mellitus · Quality of care · Electronic medical records · Process measures · Outcome measures · Treatment intensity/appropriateness

Introduction

Many different projections of diabetes prevalence worldwide have been published in the last two decades [1–6], all univocally identifying type 2 diabetes as an epidemic and a major public health problem. It is estimated that diabetes prevalence ranges between 4 and 10 % in different continents and that 371 million people live with diabetes; by 2030, the number will have risen to 552 million [7]. If not adequately controlled from an early stage, diabetes increases the risk of micro- and macrovascular complications and death from other causes [8]. Life with diabetes is also commonly associated with psychosocial problems and poor quality of life [9]. Due to the problematic ratio between people with the disease and availability of resources, the sustainability and equity of access to care are at risk [10]. In fact, the estimated total economic cost of diagnosed diabetes in USA in 2012 was \$245 billion and that has increased by 41 % from 2007 [11]. In Europe, current estimates for 2010 healthcare expenditure for diabetes are US\$105 billion (10 % of total healthcare expenditure, US\$2,046 per person) [12]. Hospitalizations for diabetes complications account for 50 % of the total yearly cost of the disease per patient [13]. All these data underline the burden that diabetes imposes on society and why it is important to optimize its management.

A number of treatments and practices have been proven to be effective in reducing the burden of diabetes care, and guidelines are disseminated to aid the clinicians in diagnosis and management of diabetes and its complications [14]. However, clinical practice often differs from guideline prescriptions and several studies have shown that the desired treatment goals for diabetes and cardiovascular risk factors are not achieved in a large proportion of individuals [15–17].

To improve the current care, monitoring of health and quality of care is recognized as a key strategy in adequate public health planning [18]. American and European organizations developed and applied measures to monitor quality of diabetes care and promote continuous quality improvement initiatives [18, 19]. Indicators of quality of care have been used in different countries to get a picture

of the proportion of patients monitored or having reached the targets in specific healthcare settings in order to compare provider performance or to quantify performance incentives [15–22]. Less frequently, quality of care indicators was used to assess trends over time [23] or to evaluate the results of benchmarking activities [24].

In Italy, a continuous improvement effort implemented by a network of diabetes clinics has been in place since 2006 [25, 26]. The initiative, involving a wide network of diabetes outpatient clinics operating within the national healthcare system, allows the routine monitoring of a larger set of indicators compared to the aforementioned initiatives. The yearly evaluation of patterns of care, the dissemination of results, and their discussion with the participants was intended to improve diabetes care, both at the individual clinic level and overall. A first evaluation of the impact of the initiative was performed after 4 years [26], which documented that centers participating in the project since its first edition had improved more over time than centers joining the initiative in the following years. The aim of this paper was to report the results of the initiative after 8 years and discuss its clinical and broader implications.

Research design and methods

The Italian healthcare system

It is estimated that over 3.0 million citizens have known diabetes in Italy. Care for people with diabetes is mainly provided by a public network of about 600 diabetes clinics, delivering diagnostic confirmation, therapy, prevention, early diagnosis, and medical management of complications through regular patient follow-up by a dedicated specialist team. Most patients are referred to these care units by their GP, and care is free of charge.

The AMD Annals initiative

The Associazione Medici Diabetologi—AMD is an Italian scientific association of clinical diabetologists with the mission of exploring and improving the current diabetes care [27, 28]. The methodology of the AMD Annals initiative has been previously described [25, 26] (Table 1). Briefly, AMD identified a set of quality of care indicators to be used for benchmarking activities. Quality indicators include process measures evaluating diagnostic, preventive and therapeutic procedures performed by the participating centers, and outcome indicators measuring favorable and unfavorable modifications in the patient health status. Furthermore, the use of glucose-lowering, antihypertensive, and lipid-lowering drugs is evaluated.

Table 1 Main implementation steps of the AMD Annals initiative

Time	Activity
2002–2013	Definition of the “AMD quality indicators” and subsequent updates
2002–2008	Identification of the minimum data set including all the standardized and codified information needed for the calculation of the indicators (AMD Data File)
2004	Development and distribution of the software, compatible with different electronic medical record systems, enabling the automatic download of the AMD Data File from the data recorded during the routine clinical practice
2005	Creation of the network of diabetes centers adopting electronic medical record systems and with specialists willing to join in the initiative without allocation of extra-resources.
2006	Distribution of the software allowing participating centers to calculate their own indicators to be compared with those published in AMD Annals (benchmarking)
2006–2013	Annual publication of AMD Annals and sub-analyses. Results available on the Web site: http://www.infodibetes.it/pages/annali_amd/

Participating centers share the same AMD software enabling the data extraction from different electronic medical records. Data are annually collected in a standardized format (AMD Data File) and centrally analyzed anonymously.

All the process and intermediate outcomes indicators are compared to reference values, or “gold standard,” established by identifying the best performers. The gold standard for every indicator was represented for process and favorable outcome indicators by the 75° percentile of the ordered distribution of the results obtained in the centers and by the 25° percentile for the unfavorable outcomes. Results are publicized through the publication of the analyses (AMD Annals volumes) and in a dedicated page of the AMD Web site [16]. Using specific software, each center can calculate its own indicators and compare its performance with that of the best performers.

The initiative, started in 2006, is replicated on an annual basis, in order to provide a longitudinal picture of the quality of diabetes care provided.

Quality of care indicators

The number of quality indicators routinely measured in AMD Annals has been enlarged progressively across the years. Currently, six process, three favorable outcomes, five unfavorable outcomes, seven treatment intensity/appropriateness, and two overall quality of care indicators are considered in the yearly evaluations.

Process measures are expressed as percentages of patients monitored at least once during the previous 12 months for the following parameters: HbA1c, blood pressure (BP), lipid profile (LDL cholesterol or total and HDL cholesterol, and triglycerides), renal function, foot examination, and eye examination.

Intermediate outcome measures include the proportion of patients with satisfactory values as well as the percentage of those with unacceptably high values. Outcomes are considered satisfactory if HbA1c levels are $\leq 7.0\%$ (≤ 53 mmol/mol), BP values are $\leq 130/80$ mmHg, and LDL cholesterol (LDL-c) levels are < 100 mg/dl. Unsatisfactory outcomes include HbA1c levels $> 8.0\%$, BP values $\geq 140/90$ mmHg, LDL levels ≥ 130 mg/dl, presence of micro-/macro-albuminuria, and glomerular filtration rate (GFR) ≤ 60 ml/min. Although selected outcome indicators may not reflect the targets recommended for all patients, they have been chosen to provide a synthetic picture of the care provided to large numbers of patients over the years. In this respect, the initiative tends to put major emphasis on unsatisfactory outcomes as a lever for improvement.

Indicators of treatment intensity/appropriateness take into consideration the use of pharmacologic treatments in relation to the level of the clinical parameters: no insulin therapy despite HbA1c $> 9.0\%$, (> 75 mmol/mol), no lipid-lowering agents despite LDL-c ≥ 130 mg/dl, no antihypertensive treatment despite BP $\geq 140/90$ mmHg, no ACE inhibitors (ACE-I) and/or angiotensin receptor blockers (ARBs) despite micro-/macroalbuminuria, HbA1c $> 9.0\%$ (> 75 mmol/mol) in spite of insulin treatment, LDL-c ≥ 130 mg/dl in spite of lipid-lowering treatment, and BP $\geq 140/90$ mmHg in spite of antihypertensive treatment.

Finally, a quality of care summary score (Q score) is calculated. The Q score has been developed and validated in two previous studies (14–15) and integrated in the AMD Annals initiative since the 2009 edition [29]. The score is based on a combination of process and outcome indicators relative to HbA1c, blood pressure, LDL cholesterol, and microalbuminuria. The score ranges between 0 and 40; the higher the score, the better the quality of care (supplementary Table 1).

Sample selection and data analyses

Clinical data collected during the years 2004–2011 were extracted from electronic medical records of participating diabetes clinics. Patients with diagnosis of type 2 diabetes were selected, and quality of care indicators was evaluated yearly.

In case of multiple records collected during the same year for the same patient, the last available value was included in the quality of care profiling. Denominators for the different quality indicators vary according to the

availability of the information in the index year. No missing imputation was performed.

Microalbuminuria was defined as albumin excretion rate ≥ 20 mcg/min, albumin/creatinine ratio >2.5 (men) or >3.5 (women) mg/mmol, or microalbuminuria >30 mg/l. GFR was calculated with the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula [30].

Classes of drugs were identified according to their Anatomical Therapeutic Chemical Classification System (ATC) codes.

Statistical analyses

Patients' characteristics were described as mean and standard deviation or frequencies. Quality indicators during 8 years are expressed as crude percentages. Absolute (% in 2011–% in 2004) and relative variations (% in 2011–% in 2004)/(% in 2004) in each patient characteristic and quality of care indicator over 8 years have also been estimated. We performed a statistical analysis to evaluate whether temporal trend for each indicator was statistically significant. Generalized hierarchical models for repeated measures were applied to take into consideration the multilevel nature of data (clusterized by center and by patient, repeated by year).

Results

Overall, 300 diabetes clinics extracted their clinical database with information collected in the years 2004–2011. The number of centers using an electronic medical record system increased over the years from 180 in 2004 to 300 in 2011, providing clinical information on 200,000 to 500,000 individuals with type 2 diabetes every year. Table 2 shows patient characteristics across the years. A slightly larger proportion of men were recorded every year. Mean age of the population and diabetes duration slightly increased over 8 years.

Table 3 shows the quality of care indicators by year and their 2004–2011 absolute and relative variations. All process indicators showed trends of improvements; the most relevant results refer to lipid profile monitoring, which increased by 16.6 % from 2004 to 2011, corresponding to a relative increase of 29.0 %. For retinopathy and foot monitoring, we documented absolute changes of 8.8 and 6.1 %, respectively, corresponding to 37.5 and 72.5 % relative increases. Relevant improvements were observed for all favorable and unfavorable outcomes, with the exception of the percentages of patients with renal function impairment. In fact, we found a small increase in the proportion of patients with reduced GFR and stable percentages of patients with micro/macroalbuminuria. Table 3

also shows substantial improvements for all intensity/appropriateness indicators. The significant improvement of quality indicators across the years is reflected by a marked variation in the Q score, with a progressive reduction of patients with a score <15 and an even more pronounced increase in the proportion of those with a score over 25. All p values were of <0.001 .

A sub-analysis only including the 180 centers with data available for the whole period (from 2004 to 2011) confirmed this picture, showing completely overlapping results.

Another sub-analysis performed after the exclusion of people with a recent diagnosis of diabetes also confirmed the results (data not shown).

Conclusions

The 8-year follow-up of the AMD Annals shows a relevant improvement in quality of care for diabetes in Italy from 2004 to 2011. As the organizational network of diabetes clinics was not substantially modified during this period, the observed improvement cannot be attributed to an increased allocation of resources. It is possible that systematic control of quality of care through regular collection of data from clinical data has contributed to a greater adherence to standards of care. After the positive results of a pilot small-scale experience [24], this analysis confirms, on a much larger scale, the potential long-term benefits of a continuous quality improvement initiative, based on the monitoring of process, intermediate outcome, and treatment intensity/appropriateness measures.

After 8 years from the launch of the initiative, half of the diabetes clinics in Italy participate in AMD Annals initiative, caring for over one-sixth of all diagnosed patients, enabling a systematic and representative annual monitoring of quality of care provided by specialists.

In the USA, the process and outcomes measures established in the Diabetes Quality Improvement Program (DQIP) have been widely adopted for performance assessment in Medicare and Medicaid health plans by some government agencies, such as the Veterans Health Administration (VHA) and the Center for Medicare and Medicaid Services (CMS), and in payment programs such as the Physician Quality Reporting System (PQRS) [31]. The widest initiative of monitoring of quality of care in USA is represented by the National Health and Nutrition Examination Survey (NHANES) and the Behavioural Risk Factors Surveillance System (BRFSS), which described trends of five process indicators, seven preventive practices, and three scores of risk complications across 20 years (1999–2010) on a range of 11,000 to 60,000 individuals analyzed every year. Nevertheless, data were self-reported

Table 2 Patients characteristics by year

	2004 (%)	2005 (%)	2006 (%)	2007 (%)	2008 (%)	2009 (%)	2010 (%)	2011 (%)	2004–2011 Absolute variation (%)	2004–2011 Relative variation (%)
Number of participating diabetes clinics	180	198	214	235	251	266	286	300		
Number of patients with T2DM seen by diabetes clinics during the year	239,638	270,589	316,768	369,503	411,777	452,224	494,166	532,651		
Percentage of first visits (%)	13.0	13.0	14.2	13.4	12.2	11.5	12.6	12.0	-1.0	-7.7
Patient characteristics										
Males (%)	53.3	53.7	53.9	54.1	54.3	54.6	54.7	54.9	+1.6	+3.0
Age (years)	65.2 ± 11.5	65.4 ± 11.5	65.8 ± 11.5	66.1 ± 11.4	66.4 ± 11.4	66.8 ± 11.4	67.1 ± 11.4	67.4 ± 11.5	+2.2	+3.4
Age classes										
<65.0	46.1	44.5	43.3	42.6	41.7	40.3	39.9	39.3	-6.8	-14.8
65.0–74.9	34.0	34.6	34.6	34.5	34.8	34.8	34.1	33.4	-0.6	-1.8
≥75.0	19.9	20.9	22.1	22.9	23.6	24.9	26.0	27.3	+7.4	+37.2
Smokers (%)	16.8	16.9	17.1	17.3	17.2	17.0	16.9	17.0	+0.2	+1.2
Diabetes duration (years)	10.1 ± 9.1	10.2 ± 9.2	10.3 ± 9.3	10.4 ± 9.3	10.4 ± 9.4	10.4 ± 9.4	10.5 ± 9.4	10.7 ± 9.4	+0.6	+5.9
Diabetes duration classes (%)										
≤2	22.6	16.2	16.2	21.9	21.8	15.8	15.6	20.5	-2.1	-9.3
2–5	17.7	17.9	22.7	16.4	16.3	17.2	22.3	15.8	-1.9	-10.7
5–10	21.0	23.5	18.6	22.6	22.9	24.0	17.3	21.8	+0.8	+3.8
>10	38.7	42.4	42.6	39.0	39.0	43.1	44.8	41.8	+3.1	+8.0
HbA1c (%)	7.7 ± 1.6	7.7 ± 1.6	7.6 ± 1.6	7.5 ± 1.6	7.5 ± 1.5	7.5 ± 1.5	7.5 ± 1.5	7.5 ± 1.5	-0.2	-2.6
BMI (kg/m ²)	29.3 ± 5.0	29.3 ± 5.1	29.4 ± 5.1	29.5 ± 5.2	29.5 ± 5.2	29.6 ± 5.2	29.6 ± 5.3	29.6 ± 5.3	+0.3	+1.0
Total cholesterol (mg/dl)	203.7 ± 41.6	199.3 ± 41.3	194.8 ± 41.0	191.6 ± 40.8	188.9 ± 41.0	188.3 ± 41.3	184.5 ± 41.1	181.8 ± 40.8	-21.9	-10.8
HDL cholesterol (mg/dl)	51.7 ± 13.7	51.7 ± 13.9	52.1 ± 13.9	50.4 ± 13.6	49.9 ± 13.7	49.5 ± 13.7	49.9 ± 13.8	49.8 ± 13.9	-1.9	-3.7
LDL cholesterol (mg/dl)	122.0 ± 34.5	118.4 ± 34.6	114.4 ± 34.6	112.6 ± 34.3	110.3 ± 34.3	109.6 ± 34.5	106.5 ± 34.3	104.3 ± 34.2	-17.7	-14.5
Triglycerides (mg/dl)	155.8 ± 125.0	153.3 ± 123.0	150.8 ± 119.8	149.2 ± 116.0	149.1 ± 113.4	148.7 ± 109.8	142.9 ± 103.3	141.5 ± 102.3	-14.3	-9.2
Systolic blood pressure (mmHg)	142.1 ± 19.6	142.1 ± 19.6	141.3 ± 19.5	140.0 ± 19.3	139.7 ± 19.3	139.0 ± 19.0	138.2 ± 19.0	137.5 ± 18.7	-4.6	-3.2
Diastolic blood pressure (mmHg)	81.2 ± 9.7	81.1 ± 10.0	80.8 ± 9.9	80.0 ± 9.8	79.6 ± 9.8	79.1 ± 9.8	78.5 ± 9.7	78.2 ± 9.7	-3.0	-3.7

Table 2 continued

	2004 (%)	2005 (%)	2006 (%)	2007 (%)	2008 (%)	2009 (%)	2010 (%)	2011 (%)	2004–2011 Absolute variation (%)	2004–2011 Relative variation (%)
Diabetes treatment (%)										
Diet and lifestyle	10.1	9.8	9.3	8.9	8.0	7.1	6.6	6.2	-3.9	-38.6
Oral agents	64.3	63.7	63.7	62.6	62.4	62.3	62.3	62.3	-2.0	-3.1
Oral agents + insulin	11.5	12.0	12.2	13.0	13.8	14.7	15.3	15.9	+4.4	+38.3
Insulin	14.0	14.5	14.8	15.6	15.8	15.9	15.8	15.6	+1.6	+11.4
Lipid-lowering agents (%)	15.9	20.5	26.1	31.8	36.1	40.0	43.4	45.0	+29.1	+183.0
Antihypertensive treatment (%)	32.2	37.4	43.7	49.9	54.2	56.6	59.5	60.4	+28.2	+87.6
≥2 Antihypertensive agents (%)	17.4	20.6	24.5	28.4	31.3	33.1	35.1	35.7	+18.3	+105.2
Aspirin (%)	12.6	16.2	19.6	22.6	25.2	26.9	28.4	29.0	+16.4	+130.2

by the patients, being based on an annual household interview and on data collection in mobile examination centers.

In Europe, cross-sectional evaluations of quality of care were performed starting from the Swedish national patient register, from electronic clinical records of primary care units in Spain or in the context of pay-for-performance initiatives in UK [20–22]. Furthermore, in 2009, the European Core Indicators in Diabetes (EUCID) project aimed to create a reporting platform for the indicators using the existing data from European countries. National surveys, administrative data, and a clinical database of primary and secondary care were put together for a comprehensive description of patterns of diabetes care in Europe. Nevertheless, the information collected for the EUCID project was not homogeneous among the different countries in terms of data availability and representativeness [32].

The AMD Annals initiative allows the annual evaluation of 23 indicators by extracting a standard set of data from electronic clinical records of the participating centers. The initiative is promoted by healthcare professionals and perceived as a normal component of everyday practice, without extra-financial incentives, but only through a physician-led effort, made possible by the commitment of the specialists involved.

Over 8 years, improvements in most of the indicators have been documented, process and intermediate outcome measures consistently improved, in parallel with a more intense and appropriate use of pharmacologic treatments. Nevertheless, room for improvement still exists. The analysis of process indicators shows that the level of performance is consistently higher for some parameters, such as HbA1c, blood pressure, and lipid monitoring, while others such as foot and eye examination still require greater attention. Furthermore, one-quarter of patients still have HbA1c levels >8 %, one-fifth have LDL cholesterol levels ≥130 mg/dl, and one in two has blood pressure levels ≥140/80 mmHg. Therefore, further efforts are needed to reduce the gap between clinical practice and clinical recommendations. As underlined in previous papers, the best performers approach is a key element of the initiative, since clinicians are not faced with theoretical standards, which are often perceived as unrealistic in their structural and organizational setting, but rather with the performance of centers operating in the same healthcare system, under similar conditions.

While the importance and scientific soundness of final outcomes (i.e., diabetes complications) go uncontested, their definition was not sufficiently standardized to allow their monitoring; in fact, open text was generally used to describe the presence and the severity of the complications, hampering the ability to extract the necessary information

Table 3 Quality indicators of diabetes care by year

	2004 (%)	2005 (%)	2006 (%)	2007 (%)	2008 (%)	2009 (%)	2010 (%)	2011 (%)	2004–2011 Absolute variation (%)	2004–2011 Relative variation (%)
Process indicators										
HbA1c	89.5	89.8	90.4	90.8	91.2	91.9	92.2	92.3	+2.8	+3.1
Lipid profile	57.2	60.9	64.2	68.4	70.3	72.4	73.1	73.8	+16.6	+29.0
Blood pressure	75.2	75.1	77.1	77.1	78.2	77.5	77.1	77.8	+2.6	+3.5
Renal function	39.9	40.5	39.5	38.2	38.9	40.9	42.0	44.1	+4.2	+10.5
Foot examination	8.7	10.8	12.1	13.7	15.0	14.7	14.9	14.9	+6.2	+71.3
Eye examination	23.5	25.4	29.5	32.7	33.2	32.7	33.2	32.3	+8.8	+37.4
Favorable outcome indicators										
HbA1c ≤ 7.0 % (≤ 53 mmol/mol)	39.0	39.9	40.9	44.6	44.2	43.6	43.6	43.8	+4.8	+12.3
LDL-c < 100 mg/dl	26.2	30.2	34.9	37.3	40.1	41.4	45.4	48.1	+21.9	+83.6
BP $< 130/80$ mmHg	31.6	31.5	33.2	36.1	36.8	38.0	40.3	41.6	+10	+31.6
Unfavorable outcome indicators										
HbA1c > 8.0 % (> 64 mmol/mol)	34.9	33.3	32.2	28.9	28.7	28.2	27.6	27.2	-7.7	-22.1
LDL-c ≥ 130 mg/dl	39.6	35.6	31.2	29.2	26.9	26.4	23.5	21.7	-17.9	-45.2
BP $\geq 140/90$ mmHg	64.0	63.7	61.9	58.9	58.2	56.6	54.4	52.9	-11.1	-17.3
GFR ≤ 60 ml/min	21.5	22.2	22.8	23.8	23.3	24.1	23.8	23.8	+2.3	+10.7
Microalbuminuria	39.1	38.8	38.4	36.0	35.5	35.8	37.4	38.8	-0.3	-0.8
Indicators of treatment intensity/appropriateness										
No insulin despite HbA1c > 9.0 % (> 75 mmol/mol)	54.6	51.6	50.2	46.0	44.8	42.9	41.0	40.5	-14.1	-25.8
No lipid-lowering agents despite LDL-c ≥ 130 mg/dl	79.5	73.8	69.2	65.3	62.2	59.6	57.8	57.5	-22.0	-27.7
No antihypertensive treatments despite BP $\geq 140/90$ mmHg	60.4	55.4	48.2	40.7	36.6	32.9	30.3	30.2	-30.2	-50.0
No ACE-I and/or ARBs despite micro-/macroalbuminuria	15.2	13.4	10.6	7.9	7.0	6.9	6.7	7.0	-8.2	-53.9
HbA1c > 9.0 % (> 75 mmol/mol) in spite of insulin treatment	34.7	32.7	31.4	28.2	27.4	26.3	25.7	25.7	-9.0	-25.9
LDL-c ≥ 130 mg/dl in spite of lipid-lowering treatment	39.7	36.2	30.2	27.3	24.4	23.3	20.1	18.1	-21.6	-54.4
BP $\geq 140/90$ mmHg in spite of antihypertensive treatment	70.4	68.2	66.3	63.7	62.6	61.3	58.5	56.8	-13.6	-19.3
Overall quality of care										
<i>Q</i> score < 15	13.5	12.3	11.0	9.3	8.5	8.1	7.6	7.5	-6.0	-44.4
<i>Q</i> score > 25	22.9	24.9	27.6	31.3	33.6	35.5	37.9	38.5	+15.6	+68.1

p for temporal trend < 0.001 for all indicators

from electronic medical records. However, in previous studies [33, 34], our score of overall quality of care (*Q* score) documented a close relationship between quality of diabetes care and long-term outcomes. In fact, the risk of developing a new cardiovascular event was 80 % higher in patients with a score < 15 and 20 % higher in those with a score between 15 and 25, as compared to those with a score > 25 . Therefore, it is plausible that longitudinal improvements in *Q* score can be translated into less cardiovascular events, with evident clinical and economic implications. In

addition, a specific cost-effectiveness analysis was performed [35]: The AMD Annals initiative was associated with improvements in mean discounted life expectancy and quality-adjusted life expectancy compared to conventional management. While treatment costs were higher in the AMD initiative, this was offset by savings as a result of reduced incidence, and therefore treatment, of diabetes-related complications. The AMD Annals initiative was found to be cost saving over patient lifetimes compared to conventional management.

The AMD Annals initiative has strengths and limitations. The main strength is the sample size and the data source, largely representative of the quality of diabetes care provided by specialists in Italy. The computerized management of data extraction from electronic clinical records allows an easy evaluation of many indicators, which can be periodically revised and updated in accordance with new evidence and scientific debate [31]. However, limitations include as follows: 1. the design is not randomized; therefore, it is not possible to establish whether other factors may have played a role in the registered improvements. These factors are not mutually exclusive and could be interactive, such as better team care, increased patient awareness, better decision support and clinical practice guidelines, more general attention to risk factor control, and changes in eating and smoking habits in the population; 2. the initiative describes the care provided by specialists, and no information is available for people followed exclusively by their GPs. In addition, no information is available for diabetes clinics which do not participate in the initiative. 3. It should be considered that, for some indicators (e.g., microalbuminuria, funduscopy), the analysis is based on recorded data, generally available in the follow-up visit following the prescription; this means that if a patient is correctly prescribed a diagnostic procedure for screening of a complication, but fails to comply with the prescription, or to share with the diabetes care team the results, the prescription of the procedure is not detected. Therefore, the analysis could underestimate the actual adherence of diabetes specialists to standards of care. 4. Due to the very large sample size, even trivial differences are statistically significant, so that data need to be evaluated for their clinical relevance, in addition to their statistical significance.

In conclusion, AMD Annals are a well-established, physician-led monitoring, and continuous improvement initiative in Italy, which is easy to implement and deeply rooted in routine clinical practice. It can be used as a tool for clinical governance and for the implementation of specific improvement strategies. The initiative has been proven to be effective and cost saving, thus representing a case model to be used as an inspiration for other healthcare systems.

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Conflict of interest Maria Chiara Rossi, Riccardo Candido, Antonio Ceriello, Antonino Cimino, Paolo Di Bartolo, Carlo Giorda, Katherine Esposito, Giuseppe Lucisano, Marina Maggini, Edoardo Mannucci, Illidio Meloncelli, Antonio Nicolucci, Fabio Pellegrini, Marco Scardapane, Giacomo Vespasiani declare that they have no conflict of interest.

Ethical standard Due to the nature of the data, no approval of Ethics Committees was required.

Human and animal rights disclosure This article does not contain any studies with human or animal subjects performed by any of the authors.

Informed consent disclosure Due to the nature of the data, no informed consent signature was required from patients included in the analysis.

Appendix: AMD Annals 2012 Study Group

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