

## Original Article: Treatment

# Four-year impact of a continuous quality improvement effort implemented by a network of diabetes outpatient clinics: the AMD-Annals initiative

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### Abstract

**Aims** We evaluated the impact of a continuous quality improvement effort implemented by a network of Italian diabetes clinics operating in the national healthcare system.

**Methods** This was a controlled before-and-after study involving 95 centres, of which 67 joined the initiative since 2004 (group A) and 18 were first involved in 2007 (group B, control). All centres used electronic medical record systems. Information on quality indicators was extracted for the period 2004–2007. Data were centrally analysed anonymously and results were published annually. Each centre's performance was ranked against the 'best performers'. We compared quality indicators between the two groups of centres over 4 years.

**Results** Over 100 000 Type 2 diabetes mellitus patients were evaluated annually. The proportion of patients with glycated haemoglobin levels < 7% increased by 6% in group A (2007–2004 difference) and by 1.3% in group B. The proportion of patients with low-density lipoprotein-cholesterol < 100 mg/dl improved by over 10% in both groups. The rate of patients with blood pressure values ≤ 130/85 mmHg increased in group A (+6.4%), but not in group B (–1.4%). The use of insulin increased in group A only (+5.2%), while the use of statins increased by over 20% in both groups.

**Conclusions** A physician-led quality improvement effort, based on the systematic evaluation of routine data, is effective in improving the performance of a large number of diabetes clinics. The small percentage increase in the number of patients at target, if applied to large numbers of patients, would translate into a significant impact on public health.

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**Keywords** electronic medical record, outcome measure, process measure, quality of care, use of drugs

**Abbreviations** AMD, Associazione Medici Diabetologi; HbA<sub>1c</sub>, glycated haemoglobin; HDL, high-density lipoprotein; LDL, low-density lipoprotein

### Introduction

The burden of Type 2 diabetes and its cardiovascular complications are expected to grow in forthcoming years because of the increasing incidence of the disease worldwide [1,2].

A large body of evidence has clearly shown that a number of effective treatments and practices may substantially reduce this burden [3]. However, clinical practice often differs from guideline prescriptions, owing to suboptimal available care resources and to the increasing number of patients in charge. As a consequence, a marked variability has been documented in the application of preventive and therapeutic strategies, suggesting that the level of diabetes care currently delivered may not produce the possible health-related gains. In this respect, several studies have shown that the desired treatment goals for diabetes

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and cardiovascular risk factors are not reached in a large proportion of patients [4–8]. Furthermore, a close relationship between the quality of diabetes care and risk of cardiovascular events has been documented [9].

Given these premises, several American and European organizations have been working on the development, specification and field-testing of measures for quality of diabetes care, to provide high-quality care while controlling costs [10–15]. Quality measures identified include process and intermediate outcome indicators, selected under the assumption that they are linked to downstream health outcomes. These measures have been widely used to monitor quality of care and promote continuous quality improvement initiatives [4,16,17]. These initiatives have themselves led to mixed results, and effective changes in clinical practice have been more frequently documented in small-scale, local experiences [18]. In Italy, a continuous improvement effort implemented by a network of diabetes clinics in Sicily documented that a tangible improvement in the quality of diabetes care over 5 years could be obtained by sharing the same electronic health record system, and by adopting standardized process and outcomes measures [17]. In the same years, a larger initiative adopting the same methodology has been launched, involving over 120 clinics throughout Italy. These centres, accounting for approximately one-fifth of all the clinics operating within the national healthcare system, all share the same software for data extraction from electronic medical records. Data from participating centres are annually collected and centrally analysed anonymously. Results are publicized through a specific publication (*AMD Annals*) and on a dedicated web page of the *Associazione Medici Diabetologi* [19]. Furthermore, by using a specific software package developed by *Associazione Medici Diabetologi* and distributed free of charge to all the participants, individual centres can compare their own process and intermediate outcome indicators with the published results and estimate the gap existing between their own performance and the national ‘gold standard’.

In the context of this continuous quality improvement effort, we conducted a controlled before-and-after study, by comparing the performance of clinics participating in the initiative from the beginning with that of clinics involved only in the last year. In particular, the aim of this analysis was to evaluate whether the benchmarking initiative undertaken improved quality indicators of diabetes care over a period of 4 years (2004–2007).

## Patients and methods

### The Italian healthcare system

All Italian citizens, irrespective of social class or income, are cared for by a general practitioner as part of the National Health System. It is estimated that over 2.5 million citizens have known diabetes in Italy. Care for people with diabetes is mainly provided by a public network of about 700 diabetes clinics, delivering diagnostic confirmation, therapy, prevention and early diagnosis of complications through close patient follow-up by a team of

specialists, and the scheduling of regular check-ups. Most patients are referred to these care units by their general practitioner, and care is free of charge.

Diabetes clinics can be classified, according to their level of complexity of organization, into three categories. The highest level is represented by clinics with complete financial autonomy and a dedicated staff (physicians, nurses, dieticians, etc.) led by a director. Structures with an intermediate level of organizational complexity depending on other wards or departments may have financial autonomy and have a dedicated staff led by a responsible physician identified by the director of the department. Finally, the structures with the lowest level of complexity are represented by ambulatory facilities without financial autonomy, with a dedicated staff of physicians but without dedicated nurses.

### *Associazione Medici Diabetologi* quality indicators

This Italian Association of Clinical Diabetologists identified a set of indicators to be used in the context of quality improvement initiatives. Quality indicators include process measures evaluating diagnostic, preventive and therapeutic procedures performed by the centres, and outcomes indicators measuring favourable and unfavourable modifications in the patient health status. Process measures included frequency of measurement of glycated haemoglobin (HbA<sub>1c</sub>), blood pressure, lipid profile [low-density lipoprotein (LDL)-cholesterol or total and high-density lipoprotein (HDL)-cholesterol, and triglycerides]. Process measures were expressed as percentages of patients monitored at least once during the previous 12 months. Intermediate outcome measures included the proportion of patients with satisfactory values, as well as the percentage of those with unacceptably high values. Outcomes were considered satisfactory if HbA<sub>1c</sub> levels were  $\leq 7.0\%$ , blood pressure values were  $\leq 130/85$  mmHg and LDL cholesterol levels were  $< 100$  mg/dl. Unsatisfactory outcomes included HbA<sub>1c</sub> levels  $\geq 9\%$ , blood pressure values  $\geq 140/90$  mmHg and LDL levels  $\geq 130$  mg/dl. The rate of use of specific classes of drugs (insulin, statins, and two or more anti-hypertensive agents) was also evaluated.

In the case of multiple records during the year, the last value was considered for the analyses. Low-density lipoprotein-cholesterol was estimated by the Friedwald equation. Since normal ranges for glycated haemoglobin varied among the different centres, to allow the comparison among centres, the percentage change with respect to the upper normal value (measured value/upper normal limit) was estimated and multiplied by 6.0.

As for final outcomes (diabetes complications), while their importance and scientific soundness as outcome measures go uncontested, their definition was not sufficiently standardized to allow between-centres comparisons; in fact, open text was generally used to describe the monitoring, the presence and the severity of the complications, hampering the ability to extract the necessary information from electronic medical records.

## Data collection

Participating centres adopted different electronic medical record systems for the everyday management of outpatients. A software package specifically developed for the project enabled the extraction from all these clinical databases of the information (AMD Data File) needed for the evaluation of process and outcomes indicators. Each individual centre had the possibility of obtaining the information on its performance directly from the electronic record system, using an *ad hoc* software package. Moreover, data from all participating centres were collected and centrally analysed anonymously.

Information on all patients with Type 2 diabetes seen every year was obtained.

All the process and intermediate outcomes indicators were compared to reference values, or 'gold standards', established by identifying the best performers. The gold standard for every indicator was represented by the 75th percentile of the ordered distribution of the results obtained in the centres.

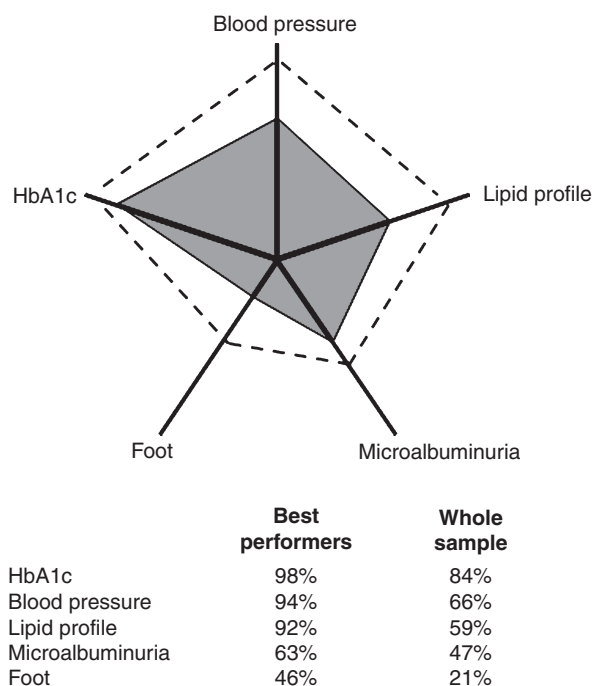
Results were publicized on a dedicated page of the Associazione Medici Diabetologi website and through a book (AMD Annals) [19] distributed to each diabetes clinic; overall, 5000 copies have been disseminated every year. Besides tables, several graphical approaches were used to facilitate the interpretation of the results. In addition to pie-charts and histograms, used to represent the distribution of frequencies of every indicator, maps, box-plots, star-plots and variability graphs were produced to facilitate the interpretation of results and the comparisons with the gold standard. An example star-plot for process measures is presented in Fig. 1. Using these graphs, each centre was able to locate its own performance with respect to the overall picture. Results of all the analyses done were also discussed with participating centres on the occasion of an annual meeting and presented in several regional conferences.

The entire project is conducted without allocation of extra resources or financial incentives, but simply through a physician-led effort, made possible by the commitment of the specialists involved.

In this context, we report here the results of the analysis evaluating whether and to what extent this continuous quality improvement effort had an impact on the care delivered by the participating diabetes clinics. The analysis refers to individuals with Type 2 diabetes, representing the vast majority of the sample. In particular, we compared quality indicators between centres joining the initiative since the first edition (2004) and centres first involved in the last one (2007). All the participating centres extracted data relative to the 4 years analysed from their electronic databases. In addition to the analyses performed on the whole sample of patients seen every year, we also evaluated patterns of care in the cohort of patients seen for 4 years.

## Statistical analysis

To account for the hierarchical nature of the data (patients clustered within centres) and to control simultaneously for the



**FIGURE 1** Example of star-plot graph used in the AMD Annals to summarize centres' performance. The star-plot graph allows visualization of multiple indicators at the same time. Each axis contains the percentage of patients having the specific measurement (e.g. process indicators) performed, with 0% located in the middle and 100% on the extreme. The full polygon obtained by joining the different points identified on each axis represents the performance of the whole sample. The dashed line polygon represents the performance of the 'gold standard' centres. The distance on every axis between full polygon and 'gold standard' represents the existing gap between delivered care and attainable quality levels.

possible confounding effects of the different variables, we used multilevel regression models [20,21]. For each indicator, estimates are thus adjusted for sex, age, diabetes duration and clustering effect. Results are expressed as frequencies with their 95% confidence intervals. Analyses were performed using SAS® Language (release 9.1. Cary, NC, USA; 2002–2003).

## Results

Overall, 122 clinics participated, of whom 87 joined the initiative since 2004 (group A) while the remaining 35 were first involved in 2007 and served as the control group (group B). Diabetes clinics participating in the project were more likely to have a high level of organizational complexity compared with the total sample of diabetes clinics in Italy (30 vs. 20%), while the proportion of centres with a low level of complexity was similar (14 vs. 17%). Centres able to provide full data for 4 years (from 2004 to 2007) were selected from both groups, leaving 67 centres in group A and 18 centres in group B included in the analysis (Centres of group B used electronic clinical records to manage their patients in the years 2004–2007 although they were not participating in the AMD Annals initiative.). Numbers of

patients evaluated in the 4 years were 92 269 in 2004, 102 614 in 2005, 117 971 in 2006 and 136 572 in 2007 for group A, and 14 050 in 2004, 16 677 in 2005, 18 256 in 2006 and 23 527 in 2007 for group B. The cohort of individuals followed for 4 years included 83 426 patients, of whom 72 426 were from group A and 11 000 from group B.

Group A and group B did not differ in terms of organizational characteristics (group A, 11.9, 52.2 and 35.8% of centres with high, intermediate and low level of complexity, respectively; group B, 11.1, 55.6 and 33.3% of centres with high, intermediate and low level of complexity, respectively). Numbers of patients evaluated in the 4 years and their characteristics according to study group are reported in Table 1.

Table 2 shows for the two groups of centres the annual proportion of patients with at least one value registered during the year (process measures) and the percentage of patients reaching specific favourable or unfavourable targets (intermediate outcome measures) and rates of use of drugs.

Regarding process measures, HbA<sub>1c</sub> monitoring was stable across the years, reaching satisfactory levels in both groups of centres. Lipid monitoring was performed in a higher proportion of patients in group B than in group A for the entire period of observation; nevertheless, the rate of increase in lipid monitoring was higher in group A (+6.2% from 2004 to 2007) than in group B (+2.4%). No major changes in blood pressure monitoring were detected in both groups during the years.

Regarding outcomes, an increasing trend in the proportion of patients with HbA<sub>1c</sub> levels below 7% was documented in group A (+6%), whereas it was smaller in group B (+1.3%). The reduction in the percentage of patients with HbA<sub>1c</sub> over 9% was similar in the two groups. The proportion of patients with LDL-cholesterol at target increased by over 10% in both groups, together with a parallel reduction in the proportion of individuals with particularly high levels. Adequate blood pressure control was attained in an increasing percentage of individuals in group A (+6.4%), but not in group B (-1.4%). In parallel, a reduction in the proportion of patients with blood pressure values  $\geq 140/90$  mmHg was documented in group A (-7.3%), but not in group B (-0.9%).

Finally, an increasing use of insulin was documented in group A only, while the use of statins increased by over 20% in both groups. The proportion of patients treated with two or more anti-hypertensive agents increased by 3.6% in group A and by 1.6% in group B.

The last two columns of Table 2 show that variations documented in the cohort of patients seen during 4 years were very similar to those registered in the whole sample.

## Discussion

Our study documents the feasibility and efficacy of conducting practice-based quality-of-care studies across large numbers of outpatient practices, after having reached a consensus in how to measure the quality of care in priority areas. This nationwide initiative is based on the methodology adopted in a previous, smaller scale efforts, that documented over 5 years a constant improvement in process and intermediate outcome measures, associated with increasing rates of drug prescriptions and substantial reductions in between-centres variability [17].

A key feature of the continuous quality improvement effort implemented is represented by the decision to use the 'best performers' approach [22]. In other words, clinicians are not faced with theoretical standards, often perceived as unrealistic in their structural and organizational setting, but rather with the performance of centres operating in the same healthcare system, in similar conditions. By comparing their own performance with that of centres reaching better overall results, specialists could easily realize the real margin of improvement made possible by simply increasing the level of attention to disease monitoring and treatment.

Our data show that, when promoted by healthcare professionals and perceived as a normal component of everyday practice, diabetes care profiling and benchmarking activities are able to improve clinical outcomes.

Improvements in lipid profile monitoring, use of statins, and proportion of patients reaching the LDL target were similar in both groups, thus suggesting a natural trend, largely independent from the activities undertaken. In contrast, results relative to

**Table 1** Patient characteristics by study group and year of observation

Study group	2004		2005		2006		2007	
	A	B	A	B	A	B	A	B
<i>n</i>	92 269	14 050	104 033	19 920	124 940	26 173	151 698	40 269
Males (%)	54.05	54.38	54.26	54.70	54.68	55.36	54.65	55.50
Age (years)	66.75 (11.45)	66.67 (11.11)	66.93 (11.41)	66.56 (11.40)	67.20 (11.35)	66.80 (11.22)	67.56 (11.26)	67.23 (11.23)
Body mass index (kg/m <sup>2</sup> )	29.27 (5.02)	29.24 (5.01)	29.31 (5.05)	29.33 (5.09)	29.39 (5.07)	29.27 (5.10)	29.47 (5.11)	29.34 (5.15)
Diabetes duration (years)	10.61 (9.25)	9.75 (8.73)	10.74 (9.29)	10.10 (8.81)	10.96 (9.25)	10.63 (8.83)	11.49 (9.24)	10.90 (8.93)

Data are means (standard deviation) or percentages.

**Table 2** Between-group comparison for process and intermediate outcome indicators and rates of use of drugs

Indicator	Whole sample					Cohort		
	2004 (%)	2005 (%)	2006 (%)	2007 (%)	2004–2007 difference (%)	95% Confidence interval of 2004–2007 difference	2004–2007 difference (%)	95% Confidence interval of 2004–2007 difference
<b>Process</b>								
<b>HbA<sub>1c</sub></b>								
A	93.05	93.41	93.72	93.71	0.66	0.54; 0.78	-0.05	-0.31; 0.22
B	93.08	95.12	94.68	94.57	1.49	0.34; 2.64	0.17	-0.54; 0.86
<b>Blood pressure</b>								
A	87.52	85.29	87.22	86.41	-1.11	-2.50; 0.28	-3.39	-3.76; -3.00
B	91.66	92.04	90.18	90.79	-0.87	-1.30; -0.44	-3.04	-4.00; -2.08
<b>Lipid profile</b>								
A	68.12	70.07	72.39	74.31	6.19	5.63; 6.75	1.03	0.45; 1.60
B	79.3	82.04	81.94	81.75	2.45	0.31; 4.59	-4.32	-5.60; -3.02
<b>Outcome</b>								
<b>HbA<sub>1c</sub> ≤ 7%</b>								
A	41.57	43.03	46.85	47.58	6.01	5.52; 6.50	2.89	2.29; 3.50
B	43.01	44.61	43.72	44.29	1.28	0.70; 1.86	-0.24	-1.92; 1.44
<b>HbA<sub>1c</sub> ≥ 9%</b>								
A	12.67	11.79	10.27	9.88	-2.79	-3.11; -2.47	-2.95	-3.34; -2.56
B	14.04	13.16	12.66	11.99	-2.05	-3.56; -0.54	-0.12	-1.24; 1.00
<b>Blood pressure ≤ 130/85 mmHg</b>								
A	32.42	33.35	36.57	38.84	6.42	5.95; 6.89	5.94	5.25; 6.65
B	31.92	30.67	32.43	30.55	-1.37	-1.77; -0.97	-6.38	-8.00; -4.76
<b>Blood pressure ≥ 140/90 mmHg</b>								
A	64.66	63.61	59.94	57.32	-7.34	-7.82; -6.82	-6.85	-7.56; -6.14
B	65.66	65.88	64.23	64.80	-0.86	-3.62; 1.90	2.42	0.77; 4.07
<b>LDL-Cholesterol &lt; 100 mg/dl</b>								
A	28.97	32.94	37.33	39.47	10.05	9.92; 11.08	13.58	12.88; 14.28
B	26.7	31.46	35.79	38.86	12.16	10.84; 13.48	16.73	14.97; 18.48
<b>LDL-Cholesterol ≥ 130 mg/dl</b>								
A	35.69	31.18	27.51	25.99	-9.70	-10.29; -9.11	-12.42	-13.09; -11.75
B	37.26	31.03	29.15	26.28	-10.92	-12.21; -9.75	-15.19	-16.98; -13.60
<b>Treatment</b>								
<b>Insulin ± oral agents</b>								
A	20.41	21.74	22.84	25.59	5.18	4.76; 5.60	10.16	9.80; 10.52
B	21.68	20.55	20.79	20.9	-0.78	-0.91; -0.65	9.93	8.81; 11.05
<b>≥ 2 anti-hypertensive agents</b>								
A	52.89	53.59	55.21	56.49	3.60	3.09; 4.11	9.69	9.19; 10.19
B	55.71	55.17	56.19	57.33	1.62	0.79; 2.45	8.91	7.57; 10.25
<b>Statins</b>								
A	7.75	12.74	24.02	28.58	20.83	20.33; 21.33	14.66	14.29; 15.03
B	13.27	16.47	25.03	35.67	22.40	21.08; 23.72	19.24	18.07; 20.41

\*Estimates are based on multilevel analyses adjusted for sex, age, diabetes duration and clustering effect. For each year, frequencies represent the proportion of patients with at least one value registered during the year (process measures), the percentage of patients reaching specific favourable or unfavourable targets (intermediate outcome measures), and rates of use of drugs. The last four columns represent the absolute variation from 2004 to 2007 and their 95% confidence intervals for the whole sample and for the cohort of individuals seen for 4 years.

metabolic control and blood pressure control do suggest a specific effect of the benchmarking activities, being present only in group A. It should be emphasized that the percentage increase in the number of patients at target, though numerically small, applies to large numbers of individuals, thus translating into a significant impact in terms of public health. Furthermore, the positive results were obtained during a limited period of observation, and the trends documented suggest that even

greater benefits could be achieved in the long run. Overall, temporal changes documented in group A seem more pronounced than those documented in the USA over 10 years [16], particularly for metabolic control, in terms of proportion of patients with HbA<sub>1c</sub> levels below 7.0%. Furthermore, while no changes in blood pressure levels were documented across the years in the USA, the proportion of individuals at target (i.e. ≤ 130/85 mmHg) constantly increased in our study. Although



based on different indicators, similar trends of improvement were documented in the United Kingdom after the introduction of performance-based payment incentives as part of the general practitioner contract [23]. Overall, when compared with data derived from different European countries and relative to secondary care, the proportion of patients with HbA<sub>1c</sub> levels above 7.0% in Italian patients followed by diabetes clinics (i.e. 57% in 2005) is similar to that reported in Germany (55%) and lower than that reported in Denmark (64%) and Belgium (69%) [8]. Similar figures were also found in other countries where estimates were derived from both primary and secondary care databases. Regarding the proportion of patients with LDL-cholesterol levels below 100 mg/dl, the performance of Italian centres closely resembles that of other countries. Similarly, the percentage of patients with poor blood pressure control (i.e. > 140/90 mmHg) in Italy (37% in 2005) falls in the range documented in other European countries (from 22% in Belgium to 46% in Sweden) [8].

Despite the improvements documented, the quality of diabetes care is still suboptimal. In agreement with previous findings, our study confirms the difficulties in reaching the desired therapeutic goals [4–8,24]. Less than half of the patients attain a satisfactory HbA<sub>1c</sub> level, and only one in three has LDL-cholesterol or blood pressure levels on target. These findings are mirrored by the relevant proportion of patients with particularly high levels of HbA<sub>1c</sub> (about 15%), LDL-cholesterol (about one in three), and blood pressure (over 60%). Getting more patients on target thus represents an important priority of the initiative in the years to come. The inclusion of additional indicators representing broader aspects of diabetes care (i.e. eye and foot examination, education and influenza vaccine) as well as the addition of distal outcomes (i.e. cardiovascular events and severity of retinopathy) also constitute a necessary step to implement. Nevertheless, the results obtained so far, if maintained, would translate into a substantial reduction in the risk of major complications.

Our study has limitations. First, this is not a randomized trial, and centres participating in the initiative from the beginning could differ systematically from those that joined the programme later. We examined structural and organizational characteristics of the two groups of clinics, but we were unable to find any meaningful difference.

Second, the considerable success documented was obtained without allocation of extra resources or financial incentives, but simply through a physician-led effort, made possible by the commitment of the specialists involved. While this is a qualifying aspect of the initiative, it can at the same time represent a factor that might limit its generalizability to other areas where clinicians do not display a similar willingness to share their experiences with colleagues.

Finally, centres could have used the quality improvement system by using only the annual data of their own clinic, without comparing the results with the 'gold standard'. In other words, the positive results described could at least in part derive from the self-evaluation of performance, rather than from benchmarking activities. Nevertheless, it should be underlined that all the

centres used electronic medical record systems enabling the evaluation of their own performance. What presumably made the difference between the groups of centres was the possibility of comparing their own practice with that of the best performers and with the average performance of the overall sample of centres.

In conclusion, our study shows that a physician-led quality improvement effort, based on the systematic evaluation of routinely collected clinical data, is effective in improving the performance of diabetes clinics. These results confirm those previously obtained in a smaller, more homogeneous area, highlighting the applicability of this approach to a much larger number of clinics throughout Italy. This experience opens important perspectives. First, the number of participating clinics is increasing year on year, and it is expected that at least one-quarter of Italian diabetes centres will join the programme in the near future. Second, new initiatives will be launched in the individual regions to promote a more intensive debate on the data collected at the local level, to drive changes through the recognition of problem areas and barriers and the identification of possible solutions. Finally, the list of quality indicators will be expanded to include humanistic outcomes (i.e. quality of life, patient satisfaction) [25] as well as distal clinical outcomes. If these initiatives prove to be effective, substantial benefits can be foreseen for individuals with diabetes in Italy in the years to come. This could also represent a public health model, deeply rooted in routine care and not requiring additional effort by busy clinicians, to be extended to other chronic conditions.

## Competing interests

Nothing to declare.

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