

**The impact of a programme to improve quality of care for people with type 2 diabetes on hard
to reach groups: The GEDAPS study**

Abstract

Aims. We investigated whether a continuous quality improvement programme in primary care for people with type 2 diabetes led to better care and outcomes in hard to reach groups.

Methods. GEDAPS was implemented in Catalonia, Spain between 1993 (n=2239) and 2002 (n=5819). Process (e.g. education), intermediate (e.g. HbA1c) and final (e.g. retinopathy) outcomes were compared between urban and rural areas, and between younger (≤ 74 years) and older (≥ 75 years) individuals as examples of harder to reach groups.

Results. In 1993, people in urban areas had significantly better or similar outcomes to rural areas; by 2002, most outcomes improved in urban and rural areas. For all outcomes, the improvement in rural areas was similar to or better than urban areas. Similarly, for most outcomes, the younger and older group improved, with the older group experiencing similar or better improvements than the younger group for all indicators, except coronary artery disease.

Conclusions. A quality improvement programme was associated with equivalent or better outcomes in hard to reach groups, regardless of whether they were specifically targeted. The ability to apply one programme to all populations could save time and money.

Keywords. Diabetes Mellitus, Type 2; Quality Improvement; Quality of Health Care; Rural Population.

Abbreviations: GEDAPS, Group of Study of Diabetes in Primary Care; GP, General Practitioner; T2DM, Type 2 Diabetes Mellitus.

Background

Type 2 diabetes mellitus (T2DM) complications are often avoidable through adequate care, thus there has been an increase in programmes to improve the quality of routine care received by people with T2DM [1]. Generally, such programmes have been shown to impact positively on patients' care and health [2-4], including the GEDAPS programme (Group of Study of Diabetes in Primary Care) which was implemented in primary care in Catalonia, Spain between 1993 and 2002 [5,6]. GEDAPS resulted in improvements in process, intermediate and final outcomes when the patient population was considered as a whole [5,6]. It is however unclear whether quality improvement programmes, including GEDAPS, impact positively on all populations or whether a different approach is required for some hard to reach groups.

We examined whether GEDAPS was associated with improvements in process, intermediate and final outcomes for two hard to reach populations. GEDAPS was a continuous quality improvement programme with a multifactorial approach, and its main aim was to implement the St Vincent recommendations [7]. The programme was shown to improve intermediate and long term outcomes for patients with T2DM [5,6], and has been partly adopted by the national health service in Spain [8].

We consider here two groups that are hard to reach in Spain: those living in rural areas and those aged 75 years or older. We chose these groups as ensuring that rural areas were reached was a focus of GEDAPS, since these areas are often remote, sparsely populated and have a lower socio-economic status compared with urban areas. Conversely, there was no focus on older age groups, and with the aging population of Catalonia and other countries it is important to understand the best way to care for older adults with diabetes. Research into this area is very limited, particularly regarding older adults, and while quality improvement programmes in rural areas have resulted in improved patient outcomes, these tended to be solely conducted in rural areas, rather than as part of a wider programme [9-11]; these novel analyses aim to address these gaps in knowledge.

Methods

GEDAPS programme

GEDAPS is described in detail elsewhere [5,6]. Briefly, GEDAPS was implemented in Catalonia, where there is a public health system, 70% of the population live in urban areas, and the prevalence of diabetes was approximately 4.7% when the programme began [5]. GEDAPS was based on continuous quality improvement methodology and primarily consisted of regular publication of guidelines, the provision of workshops and seminars, and of data audit and feedback for process outcomes. Workshops to disseminate the GEDAPS guidelines and recommendations and to propose local corrective interventions were held in Primary Health Care centres approximately every year, and were delivered by region. Typically one general practitioner (GP) and one nurse attended from each centre, and they were provided with teaching slides to pass on their gained knowledge to other members of their centre. Guidelines and proposals were available to health care professionals regardless of whether they attended the workshops. Anonymous data feedback consisted of providing workshop attendees with average values of key indicators for their centre, the local area and for Catalonia, and then discussing these to provide information to improve services, rather than being punitive. Ad hoc activities occurred between sessions, such as the transfer of articles on request. Centres volunteered to participate in the programme. The number of participating centres increased over time as more centres enrolled and as changes to the health care system meant that new centres were created. There was a focus on ensuring that centres from rural, as well as urban, localities took part.

Data collection

These analyses used data collected at the beginning (1993) and end (2002) of the study. At each time-point, data were collected from paper medical records. Centres were asked to only provide data pertaining to the year prior to data collection. Summary information about the centre was collected, as well as individual level data for approximately 5% (n=30-50) of randomly selected patients with T2DM registered at that centre. Patients were excluded if they had type 1 diabetes, had been diagnosed or registered at the practice for less than 6 months, were cared for solely by other professionals or in

secondary care, were terminally ill or had an extremely limited quality of life, or had not had any contact with the centre in the preceding year. If a patient was excluded then the next patient of the same gender was included instead. A different random selection was conducted at each time-point, thus a series of cross-sectional studies were conducted. Patients were not required to give written informed consent because the study was based on retrospective, anonymous clinical records. The study was approved by the Consell Assessor de la Diabetis (Advisory Board on Diabetes) of the Health Department of the Autonomous Government in Catalunya that behaved as the Institutional Review Board.

Variables

Process, intermediate and final outcomes were used as outcome variables. These were decided upon in advance in agreement with the health care professionals in GEDAPS. Process indicators pertain to the organisation. This included the occurrence of 2-4 GP/nurse visits, which was perceived to indicate sufficient care without overburdening patients with appointments. At least three educational interventions were desirable, where education was delivered by nurses and/or GPs, and the number of interventions was defined as the number of different educational topics covered, regardless of the number of visits required to cover these topics. Other process indicators were the occurrence of at least one measurement of blood pressure, HbA1c, total cholesterol, and weight, of screening for funduscopy and microalbuminuria, and of a foot examination. The intermediate patient outcomes included were reaching American Diabetes Association 2002 [12] target levels for HbA1c ($\leq 8\%$; 64mmol/mol), HDL cholesterol ($>1\text{mmol/l}$), total cholesterol ($\leq 5.2\text{mmol/l}$), body mass index ($<30\text{kg/m}^2$), blood pressure ($\leq 140/90\text{mmHg}$), and smoking status (non-smoker). Final patient outcomes were the presence of foot ulcers (registered in the clinical record of the foot examination), nephropathy (microalbuminuria diagnosed as $>30\text{mg}/24\text{-hour}$ in 1993 and albumin/creatinine ratio $>30\text{mg/dl}$ in 2002), retinopathy (presence of any lesion diagnosed by an ophthalmologist), coronary artery disease (acute myocardial infarction or angor pectoris recorded in primary care or hospital records), stroke or transient ischaemic attack (recorded in primary care or hospital records) and hospital admission for amputation, hypoglycaemia or glycaemia $>500\text{mg/dl}$. All outcome variables

were binary. Individual demographic characteristics were gender, age and duration of diabetes. Urban/rural status of the centre was reported by an individual working at the centre.

Statistical analysis

Centre and participant characteristics are presented by year. Count and continuous variables are presented as n (%) and mean (standard deviation), and were compared between years using chi-squared tests and t-tests, respectively. In preliminary analyses, age and sex were significantly different in 1993 and 2002, therefore results were directly standardised to the age and sex distribution, as appropriate, of the 1993 population. For each outcome, the age and sex standardised percentage (standard error) of people attaining it was summarised by urban/rural status separately by year, and the age and sex standardised change (95% confidence interval) from 1993 to 2002 was estimated separately by urban/rural status; these values were compared using a linear hypothesis test. The same analysis was performed for age group (≤ 74 years, ≥ 75 years), except that results were only sex standardised. Analyses were performed in Stata v13, p-values were two-sided, and $p < 0.05$ was treated as statistically significant.

Results

Table 1 shows characteristics of the centres and participants. There was not a significant change in the percentage of urban centres between 1993 and 2002 ($P=0.41$). There were more male ($P<0.001$) and older ($P<0.001$) participants in 2002 than 1993. The average diabetes duration was also longer in 2002 ($P<0.01$), but this was due to the older age of the 2002 cohort (data not shown).

Table 2 compares urban and rural areas. In 1993, those living in urban areas had significantly better outcomes than those in rural areas for GP/nurse visits ($P=0.02$), educational interventions ($P<0.001$), and having an HbA1c measurement ($P<0.05$), with no significant differences in the other outcomes. In 2002, those living in urban, compared with rural, areas had significantly better outcomes for GP/nurse visits ($P=0.02$) and funduscopy ($P=0.04$). Conversely, those living in rural areas were now more likely to have better outcomes for educational interventions ($P=0.02$) and having an HbA1c measurement

($P < 0.01$), as well as blood pressure measurement ($P = 0.04$), foot examination ($P < 0.001$), microalbuminuria screening ($P = 0.01$), total cholesterol target ($P = 0.02$), smoking ($P = 0.02$), coronary artery disease ($P < 0.001$), stroke ($P < 0.001$), and hospital admission ($P < 0.001$). For most but not all outcomes, both the urban and rural areas improved over time. The change from 1993 to 2002 in the rural areas was either similar to or better than that observed in the urban areas for all outcomes.

Table 3 shows the results by age group. In 1992, younger adults had better outcomes for HbA1c measurement ($P = 0.01$), cholesterol measurement ($P < 0.01$), funduscopy ($P < 0.01$), foot ulcers ($P = 0.04$), nephropathy ($P = 0.02$), and stroke ($P = 0.02$) than older adults, but worse outcomes for blood pressure measurement ($P = 0.03$), body mass index target ($P = 0.03$) and smoking ($P = 0.04$). In 2002, other than the number of GP/nurse visits, all of the indicators displayed the same direction of difference. HbA1c measurement, cholesterol measurement and foot ulcers were now similar between the two age groups. Foot examination ($P < 0.01$), microalbuminuria screening ($P < 0.001$), total cholesterol target ($P < 0.001$), body mass index target ($P < 0.001$) and smoking ($P < 0.001$) were significantly better in older than younger adults, whereas coronary artery disease ($P < 0.001$) and hospital admission ($P < 0.01$) were significantly worse. Again, most but not all outcomes improved over time in both groups. The change from 1993 to 2002 in the older age group was either similar to or better than that observed in the younger age group for all indicators except coronary artery disease.

Discussion

Our results suggest that a continuous quality improvement programme aimed at improving the care of patients with T2DM in primary care was associated with equivalent or better outcomes in hard to reach groups, specifically those living in rural areas and adults aged 75 years or older.

At the start of the study, there were few differences between urban and rural areas with urban areas having better outcomes only in terms of three process indicators. By the end of the study, this picture had changed somewhat with rural areas having better outcomes for many of the process, intermediate and final indicators. Furthermore, the improvements over time tended to be greater in rural areas. Since the absolute values in the rural areas were then higher than the urban ones, this suggests that there was not a ceiling effect in urban areas and so they had the capacity for further

improvement. A possible explanation for the equivalent or greater improvement in rural areas is that GEDAPS specifically targeted them for centre recruitment to ensure that they were well represented. This targeted recruitment was successful with approximately 40% of the included centres from rural areas. Moreover, some aspects of the programme may have made it particularly amenable to rural areas. For example, workshops were delivered in all participating regions, and attendees were encouraged to disseminate their gained knowledge to other members of their centre. This could have resulted in greater knowledge transference to practitioners in rural areas than would have been achieved if workshops had only been delivered in urban areas, which would have limited attendance. This approach could be easily generalised to other rural areas outside of Catalonia. Another possible explanation is that when the programme started the professionals in rural areas could not easily access recommendations for diabetes care, so GEDAPS tried to correct this by ensuring that recommendations were widely disseminated within rural areas. There was higher attendance at workshops held in rural locations supporting this idea. This situation may now be less relevant due to widespread internet use in most areas. Other studies have shown previously that quality improvement programmes in rural areas can result in improved patient outcomes [9-11]. However, these programmes were generally conducted only in rural areas, and the strength of GEDAPS is that it was conducted in both rural and urban areas. This is an important distinction because using only one programme for both types of area will result in savings in terms of cost and time through economies of scale.

At the start of the study, younger adults had better outcomes for several process and final indicators than older adults, whereas older adults had better outcomes for some of the intermediate outcomes. By the end of the study, younger adults only had better outcomes than older adults for coronary artery disease and hospital admission. Improvements over time in the older age group were similar to or better than those in the younger age group for all but one of the indicators. The continued worse outcomes for older adults in terms of coronary artery disease and hospital admissions compared with younger adults is unsurprising given the high association between these conditions and older age [13,14]. More than half of older adults met each of the intermediate targets that are risk factors for these conditions suggesting that preventative measures are being put into place. GEDAPS did not specifically target care quality in older adults. For many of the indicators, similar improvements were seen for both the younger and older adults suggesting that care improvements were made for all

patients. This is encouraging as it suggests that the importance of improving care for all patients, and not only those who may be easier to treat, was understood and implemented. Research in this area is very limited and, to our knowledge, this is the first study to investigate whether a quality improvement programme is successful in older adults. This issue is becoming ever more important with the aging population of most countries and the increased propensity towards long term conditions of older adults [15], and suggests that it may be appropriate to approach the care of older adults with T2DM in a similar way to that for younger adults.

Overall, some process indicators were very high in 2002, but further improvements could be achieved. The percentage of people with more than three educational interventions and weight measurements was approximately 35%. While these could be improved upon, it may be that these process indicators were set too high to reflect clinical practice, even though they were defined with health care professionals. Patients may need less than three educational interventions depending on which topics are relevant to them. Moreover, they may not attend their health centre three or more times per year, and most guidelines recommend measuring weight as part of a routine health visit and in line with clinical judgement so it would usually be inappropriate to call people in solely to measure their weight. The percentage of people who had funduscopy was also below 50% and actually decreased over time. Funduscopy is performed by an ophthalmologist and there are many barriers to it taking place, such as lack of referral by the GP, and patient's ability to attend an appointment with the ophthalmologist either due to time limitations or inability to travel. It is notable that funduscopy rates were higher in urban than rural areas, which is probably because ophthalmologists tend to be based in urban areas.

The intermediate target with the lowest adherence was total cholesterol. There was a large increase in the percentage of patients reaching cholesterol targets from approximately 25% in 1993 to 45% in 2002, which may be largely due to the increased use of statins during this period [16]. However, our findings suggest that further improvements are still required, which can be achieved through a combination of improved dietary intake, more exercise and statin use [17]. Retinopathy and coronary artery disease were the most common final outcomes and were experienced by approximately 12% of the study population in 2002. This may be a consequence of the noted low rates of funduscopy

attendance and attaining cholesterol targets, further suggesting that these are areas on which future interventions should focus.

The primary limitation of this study is that there was no control group. This was because the programme was not initially designed to be part of a study, but was instead a clinical endeavour. This limits the extent to which it is possible to draw conclusions that observed changes were a consequence of the programme, rather than external influences. Indeed, while the programme is likely to have contributed towards these changes, they probably also reflect general trends towards better care to some extent, since similar improvements over this time period were noted in other countries [3,18,19]. Only a selection of patients was included from each centre, because data were collected by paper record, but this should have a minimal effect because patients were selected randomly, and the analysis adjusted for demographic factors. Participation in the study was voluntary, and so included centres may have been more motivated. However, only one health care professional per centre was responsible for the study, thus it does not necessarily follow that the whole centre was motivated and the impact of this limitation is likely to be small. Finally, the study data are now relatively old (1993-2002), however these results remain relevant because the aspects of diabetes care considered, such as regular screening and measurement, are still advocated. The study has many strengths, including the multifactorial, pragmatic approach of the programme, the adoption of the programme into practice ensuring that findings are clinically relevant, the availability of long term outcomes, and the large sample.

In conclusion, we have demonstrated that a programme aimed at improving the quality of care of patients with T2DM in primary care was associated with improved outcomes in hard to reach populations, namely those living in rural areas and adults aged 75 years or older, regardless of whether these hard to reach populations were specifically targeted. Further research is required to determine whether this is the case for other quality improvement programmes as the ability to apply one programme to all populations has implications in terms of time and cost savings.

Conflict of interest: The authors declare that they have no conflict of interest.

Acknowledgements: We thank all of the doctors and nurses that have contributed patient data to the study: ARBUCCIES-ST.HILARI: Pelegri M.; AGRAMUNT: Vendrell JM.; BONAVIDA: Policarpo M., Grive M.; BADIA DEL VALLES: Mayordomo L.; BORDETA-MAGORIA: Madrid M., Galindo G.; CALDES DE MONTBUI: Talavera ML.; CAMPS BLANCS: Hernandez AR.; CAN VIDALET: Porta I.; CAN SERRA: Calleja G.; CANTERAS: Adzet ME.; CARDONA: Hernandez A.; CARLES RIBAS: Oller M.; CERVERA-SEGARRA: Baillo P., Berga M.; CIRERA MOLINS: Baylach J.; CONSTANTÍ: Aragones E.; CHAFARINAS: Estruch M.; EL CARMEL: Lopez R.; FLORIDA NORD: Berengué M.; FLORIDA SUD: Carillo R.; FONERIA-SDA. FAMILIA: Ribas E.; GAVA 2: Galera C., Almirall C.; GIRONA3: Gonzalez C.; GORNAL: Mercader J.; IGUALADA: Florensa E.; LA JONQUERA: Lecumberri X.; LA GARRIGA: Marti J.; LA LLAGOSTA: Riba F.; LA MINA: Bobé I.; LA PAU; Rovira A., Babi P., Peñas F.; LES BORGES BLANQUES: Garcia J M.; LLEFIA: Martin J A., Muñoz M.; LLORET-TOSSA: Ruiz J.; MANLLEU Esquerra T.; MANRESA-2 CATALUNYA: Tobias J.; MARTORELL: Fuentes M.; MATARO-1 (LA RIERA): Fau E., Fernandez M., Ramon J.; MOLI NOU (S.BOI): Domenech C.; MOLINS DE REI: Plaza I.; MOLLERUSA Martinez V.; POBLE NOU: Pascual R.; RONDA PRIM: Bundo M., Massons J.; PONTS. Ciria C.; EL PRAT-2: Espuga M.; SILS: Garrido J M.; S.HIPOLIT VOLTREGA: Plana A., Comas F.; Costa X.; SARRIA TER: Creus R.;SANT JOAN DE VILATORRADA: Vives R.; STA EUGENIA DE BERGA: Espinàs J.; STA.MGDA.MONTBUI: Caballero I., Sanchez C.; SÚRIA: Farras P.; TERRASSA NORD: Sender Ma J., Vernet M., Carabi A.; TARREGA: Carrera JP. Domingo J M.; TERRASSA (ANTONI CREUS) Camps R., Ramos A.; TORDERA: Prat J., Garcia C.; TORELLO (VALL DEL GES): Casals Ma A., Esquerra M., Catala D., Serrabasa I.; TORROELLA DE MONTGRÍ: Gonzalez A., Tarradas S., Garcia V.; TORTOSA EST: Monclús JF.; TREMP: Pujol R., Ribes T., Nogués C., Riart M.; VILADECANS 2: Padilla A.; VILANOVA CAMI: Oliva M.

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Table 1. Characteristics of participating centres and their patients.

	1993	2002	P-value
Centre characteristics			
Number of participating centres	55 (100.0)	92 (100.0)	
Urban centres	36 (65.5)	54 (58.7)	0.410
Participant characteristics			
Number of participants	2239 (100.0)	5819 (100.0)	
Female	1268 (56.6)	3017 (51.8)	<0.001
Age, years	65.2 [10.2]	67.3 [10.9]	<0.001
Diabetes duration, years	7.5 [7.1]	8.0 [7.0]	0.004

Data are n (%) or mean [standard deviation].

Table 2. Age and sex standardised percentages for key patient-level indicators by year and urban/rural status.

	Percentage (SE) in 1993			Percentage (SE) in 2002			Change (95% CI) from 1993 to 2002		
	Urban	Rural	P-value	Urban	Rural	P-value	Urban	Rural	P-value
	(n=1498)	(n=741)		(n=3451)	(n=2368)				
Process outcomes									
2-4 GP/nurse visits	16.51 (0.95)	12.94 (1.23)	0.022	28.59 (0.79)	25.74 (0.94)	0.020	12.08 (9.65, 14.51)	12.80 (9.77, 15.83)	0.716
≥3 educational interventions	28.14 (1.15)	19.94 (1.47)	<0.001	34.46 (0.83)	37.62 (1.05)	0.018	6.32 (3.53, 9.11)	17.68 (14.15, 21.22)	<0.001
≥1 BP measurement	94.29 (0.59)	94.75 (0.82)	0.651	91.43 (0.49)	92.92 (0.56)	0.040	-2.87 (-4.37, -1.37)	-1.80 (-3.74, 0.14)	0.393
≥1 HbA1c measurement	69.59 (1.19)	65.37 (1.75)	0.045	85.61 (0.61)	88.58 (0.69)	0.001	16.02 (13.41, 18.63)	23.22 (19.54, 26.89)	0.002
≥1 cholesterol measurement	74.70 (1.12)	78.16 (1.51)	0.066	85.94 (0.61)	87.50 (0.72)	0.097	11.24 (8.75, 13.73)	9.35 (6.06, 12.63)	0.368
≥3 weight measurements	40.36 (1.26)	41.86 (1.80)	0.496	35.51 (0.84)	33.39 (1.02)	0.110	-4.86 (-7.83, -1.89)	-8.47 (-12.53, -4.41)	0.160
Funduscopy	53.17 (1.31)	50.07 (1.86)	0.173	48.32 (0.88)	45.47 (1.09)	0.041	-4.85 (-7.94, -1.76)	-4.61 (-8.84, -0.38)	0.927
Foot examination	49.58 (1.29)	47.62 (1.83)	0.382	52.52 (0.87)	61.98 (1.05)	<0.001	2.94 (-0.10, 5.99)	14.35 (10.22, 18.49)	<0.001
Microalbuminuria screening	34.98 (1.23)	31.68 (1.71)	0.116	70.96 (0.79)	74.08 (0.95)	0.012	35.98 (33.11, 38.86)	42.41 (38.58, 46.24)	0.009
Intermediate targets									
HbA1c ≤8 % (64 mmol/mol)	61.99 (1.63)	64.49 (2.88)	0.451	78.48 (0.78)	77.42 (0.98)	0.399	16.49 (12.94, 20.04)	12.93 (6.97, 18.90)	0.315
HDL cholesterol >1 mmol/l	73.75 (1.88)	77.29 (2.68)	0.279	80.15 (0.77)	81.53 (0.93)	0.252	6.40 (2.42, 10.37)	4.24 (-1.31, 9.80)	0.537
Total cholesterol ≤5.2 mmol/l	25.67 (1.27)	25.79 (1.81)	0.955	43.71 (0.92)	47.23 (1.14)	0.017	18.04 (14.96, 21.12)	21.44 (17.24, 25.63)	0.201
Body mass index <30 kg/m ²	63.07 (1.39)	64.42 (1.94)	0.573	53.76 (0.97)	56.26 (1.17)	0.099	-9.31 (-12.64, -5.98)	-8.15 (-12.60, -3.71)	0.683
BP ≤140/90 mmHg	49.02 (1.30)	46.63 (1.82)	0.285	64.87 (0.86)	63.29 (1.08)	0.251	15.85 (12.79, 18.91)	16.66 (12.51, 20.80)	0.759

Non-smoker	85.74 (0.86)	87.77 (1.19)	0.166	83.94 (0.62)	86.08 (0.69)	0.021	-1.80 (-3.88, 0.28)	-1.69 (-4.38, 1.00)	0.951
Final outcomes									
Ulcers	7.59 (0.68)	7.62 (0.96)	0.984	1.99 (0.24)	2.18 (0.29)	0.620	-5.60 (-7.01, -4.18)	-5.44 (-7.40, -3.48)	0.896
Nephropathy	7.66 (0.69)	6.56 (0.91)	0.330	10.35 (0.53)	11.50 (0.68)	0.180	2.68 (0.99, 4.38)	4.94 (2.72, 7.16)	0.113
Retinopathy	19.32 (1.02)	17.64 (1.38)	0.329	10.03 (0.52)	9.28 (0.63)	0.358	-9.29 (-11.53, -7.05)	-8.36 (-11.34, -5.39)	0.627
Coronary artery disease	13.78 (0.93)	10.88 (1.17)	0.052	12.74 (0.59)	9.29 (0.60)	<0.001	-1.03 (-3.18, 1.12)	-1.59 (-4.16, 0.98)	0.745
Stroke	7.63 (0.73)	5.62 (0.87)	0.077	6.10 (0.43)	4.00 (0.40)	<0.001	-1.53 (-3.19, 0.13)	-1.62 (-3.50, 0.26)	0.944
Hospital admission ^a	3.60 (0.50)	4.12 (0.73)	0.557	7.28 (0.47)	5.03 (0.47)	<0.001	3.68 (2.34, 5.03)	0.91 (-0.79, 2.61)	0.012

Abbreviations: BP, Blood Pressure; CI, Confidence Interval; SE, Standard Error.

^a For amputation, hypoglycaemia or glycaemia > 500 mg/dl

Table 3. Sex standardised percentages for key patient-level indicators by year and age group.

	Percentage (SE) in 1993			Percentage (SE) in 2002			Difference (95% CI) from 1993 to 2002		
	≤74 years	≥75 years	P-value	≤74 years	≥75 years	P-value	≤74 years	≥75 years	P-value
Process outcomes									
2-4 GP/nurse visits	14.79 (0.82)	16.63 (1.99)	0.392	27.75 (0.70)	27.03 (1.11)	0.585	12.96 (10.85, 15.07)	10.40 (5.94, 14.87)	0.310
≥3 educational visits	26.23 (1.02)	22.76 (2.26)	0.161	35.92 (0.75)	34.28 (1.19)	0.243	9.69 (7.21, 12.17)	11.52 (6.52, 16.52)	0.520
≥1 BP measurement	94.14 (0.54)	96.54 (0.97)	0.030	91.66 (0.42)	94.73 (0.56)	<0.001	-2.48 (-3.82, -1.14)	-1.81 (-4.00, 0.39)	0.609
≥1 HbA1c measurement	69.32 (1.07)	62.23 (2.59)	0.012	86.94 (0.52)	86.06 (0.87)	0.383	17.63 (15.30, 19.96)	23.83 (18.47, 29.18)	0.038
≥1 cholesterol measurement	77.21 (0.97)	69.94 (2.43)	0.006	86.69 (0.53)	86.28 (0.86)	0.684	9.48 (7.31, 11.65)	16.34 (11.29, 21.39)	0.015
≥3 weight measurements	40.15 (1.13)	44.14 (2.65)	0.167	34.27 (0.74)	36.26 (1.21)	0.160	-5.88 (-8.53, -3.23)	-7.88 (-13.58, -2.17)	0.534
Funduscopy	53.82 (1.17)	44.49 (2.75)	0.002	47.97 (0.78)	43.86 (1.26)	0.006	-5.85 (-8.61, -3.08)	-0.63 (-6.55, 5.30)	0.118
Foot examination	48.62 (1.16)	50.66 (2.66)	0.482	55.49 (0.77)	60.17 (1.23)	0.001	6.87 (4.14, 9.60)	9.50 (3.76, 15.25)	0.416
Microalbuminuria screening	34.37 (1.10)	30.87 (2.45)	0.192	71.18 (0.70)	77.11 (1.05)	<0.001	36.81 (34.24, 39.37)	46.24 (41.01, 51.46)	0.002
Intermediate targets									
HbA1c ≤8 % (64 mmol/mol)	62.05 (1.55)	61.75 (3.80)	0.943	77.85 (0.70)	80.14 (1.09)	0.076	15.81 (12.48, 19.14)	18.39 (10.64, 26.15)	0.549
HDL cholesterol >1 mmol/l	74.09 (1.67)	77.36 (4.50)	0.496	80.58 (0.68)	82.26 (1.08)	0.188	6.48 (2.94, 10.02)	4.89 (-4.18, 13.97)	0.749
Total cholesterol ≤5.2 mmol/l	25.72 (1.13)	24.49 (2.75)	0.680	44.06 (0.82)	50.39 (1.33)	<0.001	18.34 (15.59, 21.08)	25.90 (19.90, 31.89)	0.025
Body mass index <30 kg/m ²	61.78 (1.23)	68.95 (3.07)	0.030	52.50 (0.86)	65.99 (1.30)	<0.001	-9.29 (-12.23, -6.34)	-2.96 (-9.49, 3.57)	0.084
BP ≤140/90 mmHg	49.23 (1.18)	43.60 (2.66)	0.053	64.86 (0.78)	60.58 (1.25)	0.004	15.63 (12.86, 18.41)	16.98 (11.22, 22.74)	0.680
Non-smoker	86.15 (0.76)	90.06 (1.78)	0.043	83.29 (0.55)	93.17 (0.65)	<0.001	-2.86 (-4.70, -1.02)	3.12 (-0.59, 6.83)	0.005

Final outcomes

Foot ulcers	6.94 (0.59)	10.60 (1.63)	0.035	2.04 (0.22)	2.83 (0.42)	0.092	-4.90 (-6.12, -3.67)	-7.77 (-11.07, -4.47)	0.110
Nephropathy	6.47 (0.57)	10.42 (1.58)	0.019	10.87 (0.47)	10.39 (0.76)	0.597	4.39 (2.95, 5.84)	-0.02 (-3.46, 3.41)	0.020
Retinopathy	19.32 (0.92)	16.63 (1.99)	0.219	9.51 (0.46)	10.67 (0.77)	0.199	-9.81 (-11.81, -7.80)	-5.96 (-10.14, -1.78)	0.104
Coronary artery disease	12.58 (0.79)	14.36 (1.99)	0.406	10.44 (0.49)	16.99 (0.97)	<0.001	-2.15 (-3.97, -0.32)	2.62 (-1.71, 6.96)	0.047
Stroke	6.12 (0.58)	10.42 (1.75)	0.020	4.43 (0.33)	9.17 (0.75)	<0.001	-1.70 (-3.01, -0.38)	-1.25 (-4.99, 2.49)	0.825
Hospital admission ^a	3.76 (0.45)	4.00 (1.08)	0.835	6.07 (0.39)	8.58 (0.74)	0.003	2.31 (1.14, 3.48)	4.58 (2.02, 7.13)	0.114

Abbreviations: BP, Blood Pressure; CI, Confidence Interval; SE, Standard Error.

^a For amputation, hypoglycaemia or glycaemia > 500 mg/dl