JA-CHRODIS

Work Package 7

Diabetes: a case study on strengthening health care for people with chronic diseases

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Recommendations to improve early detection, preventive interventions, and the quality of care for people with diabetes. Definition and agreement on a common minimum set of indicators

CHRODIS
ADDRESSING CHRONIC DISEASES & HEALTHY AGEING ACROSS THE LIFE CYCLE

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Acknowledgements

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Executive Summary

This report presents the results of an extensive process carried out to identify quality criteria and to formulate recommendations to improve prevention and quality of care for people with diabetes. The process followed a structured methodology involving the WP7 community, and experts from a wide number of organizations across Europe and from a variety of professional backgrounds. The consultation with the expert panel followed the RAND modified Delphi methodology.

The objective was to define a core set of quality criteria that may be applied to various domains (prevention, care, health promotion, education, and training), are general enough to be applied in countries with different political, administrative, social and health care organization, and could potentially be used in other chronic diseases.

The process led to the agreement on 9 quality criteria, made up of 39 categories ranked and weighted, to assess whether an intervention, policy, strategy, program, as well as processes and practices, can be regarded as a "good practice" in the field of diabetes prevention and care.

These criteria have also been the basis to formulate recommendations to implement practices on prevention, health promotion, care management, education, and training, and ultimately to improve prevention and quality of care for people with diabetes.

The quality criteria and the recommendations presented in this report constitute a tool for decision makers, health care providers, patients and their associations, and health care personnel to support implementation of good practices, and to improve, monitor, and evaluate the quality of diabetes prevention and care. The adoption of an agreed core set of quality criteria should help to decrease inequalities in health and to improve diabetes prevention and care within and across European countries.

Quality criteria

Practice design
Target population empowerment
Evaluation
Comprehensiveness of the practice
Education and training
Ethical considerations
Governance
Interaction with regular and relevant systems
Sustainability and scalability

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Recommendations

Design the practice

The design should clearly specify aims, objectives and methods, and rely upon, relevant data, theory, context, evidence, and previous practices including pilot studies. The structure, organization and content of the practice is defined, and established together with the target population, that is clearly described (i.e. exclusion and inclusion criteria and the estimated number of participants).

Human and material resources should be adequately estimated in relation with committed tasks. Relevant dimensions of equity have to be adequately taken into consideration, and targeted.

Promote the empowerment of the target population

The practice should actively promote the empowerment of the target population by using appropriate mechanisms, such as self-management support, shared decision making, education-information or value clarification, active participation in the planning process and in professional training, and considering all stakeholders needs in terms of enhancing/acquiring the right skills, knowledge and behaviour.

Define an evaluation and monitoring plan

The evaluation outcomes should be linked to action to foster continuous learning and/or improvement and/or to reshape the practice. Evaluation and monitoring outcomes should be shared among relevant stakeholders, and linked to the stated goals and objectives, taking into account social and economic aspects from both the target population, and formal and informal caregiver perspectives.

Comprehensiveness of the practice

The practice should consider relevant evidence on effectiveness, cost-effectiveness, quality, safety, the main contextual indicators, as well as the underlying risks of the target population using validated tools to individual risk assessment.

Include education and training

The practice should include educational elements to promote the empowerment of the target population (e.g. strengthen their health literacy, self-management, stress management…). Relevant professionals and experts are trained to support target population empowerment, and trainers/educators are qualified in terms of knowledge, techniques and approaches.

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Ethical considerations

The practice should be implemented equitably (i.e. proportional to needs). The objectives and strategy are transparent to the target population and stakeholders involved. Potential burdens (i.e. psychosocial, affordability, accessibility, etc.) should be addressed to achieve a balance between benefit and burden.
The rights of the target population to be informed, to decide about their care, participation and issues regarding confidentiality should be respected and enhanced.

Governance approach

The practice should include organizational elements, identifying the necessary actions to remove legal, managerial, financial, or skill barriers, with the contribution of the target population, carers and professionals that is appropriately planned, supported and resourced. There is a defined strategy to align staff incentives and motivation with the practice objectives.

The practice should offer a model of efficient leadership, and should create ownership among the target population and several stakeholders considering multidisciplinarity, multi-/inter-sectoral, partnerships and alliances, if appropriate.

The best evidence and documentation supporting the practice (guidelines, protocols, etc.) should be easily available for relevant stakeholders (e.g. professionals and target populations), which should support the multidisciplinary approach for practices.

The practice should be supported by different information and communication technologies (e.g. medical record system, dedicated software supporting the implementation of screening, social media etc.), defining a policy to ensure acceptability of information technologies among users (professionals and target population) to enable their involvement in the process of change.

Interaction with regular and relevant systems

The practice should be integrated or fully interacting with the regular health, care and/or further relevant systems, enabling effective linkages between all relevant decision makers and stakeholders, and enhancing and supporting the target populations ability to effectively interact with the regular, relevant systems.

Sustainability and scalability

The continuation of the practice should be ensured through institutional anchoring and/or ownership by the relevant stakeholders or communities, and supported by those who implemented it.
The sustainability strategy should consider a range of contextual factors (e.g. health and social policies, sex and gender issues, innovation, cultural trends and general economy, and epidemiological trends), assessing the potential impact on the population targeted.

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Introduction

Diabetes is a common and serious disease: in 2015 there were 415 million adults (aged 20-79 years) with diabetes (type 1 and 2) worldwide, according to the most recent estimates of the International Diabetes Federation[1]. This represents about 9% of the population of this age group. If current trend continue, some 642 million people are expected to have diabetes by 2040. In the European Union, the frequency of diabetes varies from around 4.0 to 4.5% in Lithuania, Estonia and Ireland to just under 10% in Cyprus, Malta and Portugal.

Diabetes increases the risk for many serious health problems such as cardiovascular diseases, blindness, nephropathy, neuropathy, and foot complications. However, lifestyle intervention provided for people at high risk may prevent many cases of type 2 diabetes, the most common type, or delay significantly its onset. Moreover, many people with diabetes are able to prevent or delay the onset of complications with treatment (pharmaceutical and non- pharmaceutical), lifestyle changes and efficient self-management.

How to re-design health care systems to better meet the complex needs of persons with chronic diseases like diabetes is a challenge decision-makers and leaders in health care all over Europe are facing. In 2011, the General Assembly of the United Nations [2], with EU support, adopted a political declaration on the Prevention and control of non-communicable diseases (NCDs). World leaders committed themselves to strengthen international cooperation, including collaborative partnerships in support of national, regional, and global plans for the prevention and control of non-communicable diseases, through the exchange of best practices in the areas of research, health promotion, legislation, regulation and health systems strengthening, training of health personnel, and development of appropriate health-care infrastructure.

The European Summit on chronic diseases (Brussels, 2014) stressed the need for joint efforts, at European level, to optimize resources and sustained commitment to address major chronic diseases acknowledging the need for a coalition across society to prevent chronic diseases, preserving the best state of health and sustainability of a modern health system, with the aim of maximizing the years of healthy life of European citizens[3].

The launch, in 2014, of the European Joint Action on Chronic Diseases and Promoting Healthy Ageing across the Life Cycle (JA-CHRODIS) is a response to the European Commission's encouragement to join forces towards prevention and care of major chronic diseases, including diabetes.

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[1] International Diabetes Federation. IDF Diabetes Atlas, seventh edition. 2015. Brussels, Belgium: International Diabetes Federation. Available at:http://www.diabetesatlas.org

[2] United Nations. Political declaration of the high-level meeting of the General Assembly on the Prevention and control of non-communicable diseases - Draft resolution 16 September 2011. A/66/L.1. Available from: www.un.org/ga/search/view_doc.asp?symbol=A%2F66%2FL.1&Lang=E%20

[3] http://ec.europa.eu/health/major_chronic_diseases/events/ev_20140403_en.htm

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In the frame of the JA-CHRODIS, diabetes is considered a case study on strengthening health care for people with chronic diseases. The work package on diabetes (WP7) focuses on all the major aspects of a serious disease like diabetes: prevention focused on people at high risk, health promotion, comprehensive multi-factoral and interdisciplinary care, educational strategies for people with diabetes and training for health professionals and research. Its main objective is to use existing knowledge, to improve coordination and cooperation between countries to act on diabetes, including the exchange of good practices, and to create ground for innovative approaches to reduce the burden of chronic diseases. Special emphasis has also been given to support the development and implementation of National diabetes policies[4] whether in specific plan or within a NCD strategic framework.

This report presents a set of quality criteria to assess whether an intervention, policy, strategy, program, as well as processes and practices, can be regarded as a "good practice" in the field of diabetes prevention and care. These criteria are the result of a comprehensive cooperation among CHRODIS partners and experts from a wide number of organizations across Europe and from a variety of professional backgrounds.

The objective was to define a core set of quality criteria/indicators that may be applied to various domains (prevention, care, health promotion, education, and training), are general enough to be applied in countries with different political, administrative, social and health care organization, and could potentially be used in other chronic diseases. These criteria have also been the basis to formulate recommendations to implement practices to improve prevention and quality of care for people with diabetes.

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[4] http://www.chrodis.eu/our-work/07-type-2-diabetes/wp07-activities/national-plans

Prevention and management of diabetes across Europe

Overview

To provide an overview of practices for prevention and management of type 2 diabetes, the WP7 team conducted a survey to provide a structured overview about current programs (interventions, initiatives, approaches or equivalents) that focus on the various aspects of diabetes. The full results of the survey are presented in the Report "Survey on practices for prevention and management of diabetes" [5].

A total of 19 countries, with 63 experts, contributed to the collection of data.

In general, the importance of the prevention of diabetes is acknowledged and addressed at policy level: 75% of countries report that diabetes prevention is supported by national policies and legislation. However, early identification of people at risk is supported only by 63.2%. This might indicate that prevention of diabetes is recognized at population level (e.g. advocating physical activity and healthy body weight as means to prevent diabetes) but specific actions targeted at people at risk are not addressed in diabetes policies in all countries.

Almost all the countries, 18 out of the 19 respondents, have a management program for diabetes, but only 50% of the programs take into consideration vulnerable groups, e.g. ethnic minorities and low socio-economic groups. Defined care pathways exist to deal with persons with diabetes, either with or at risk for micro- and macro vascular complications, in 77.8% of the countries. Most of the programs (72.2%) are monitored through intermediate outcome indicators, 44.4% use long-term outcome indicators, but 16.7% of the countries did not use any kind of indicator.

On the whole, 15 out of the 19 participating countries reported educational programs for persons with diabetes. The core criteria of the quality of education programs are defined, e.g. the goal, the rationale, the target group, the setting, the scheduling of the education sessions. More than half reported to have an evidence-based curriculum and defined specific education methods and didactics. However, only 60% of the participants reported that the curriculum is evaluated, and 20% reported that long-term effect indicators were used.

Training programs for professionals exist in two thirds of the participating countries, and the core criteria of the quality of training programs appear to be defined, e.g., the goal, the rationale, the target group, the setting, the scheduling of the training sessions. More than half reported to have an evidence-based curriculum, and defined specific training methods and didactics. As for the education program, a low number (38.5%) reported that a monitoring of effectiveness and quality of the training program is defined, and 30.8% reported that intermediate outcome indicators are applied.

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[5] www.chrodis.eu/wp-content/uploads/2016/01/Report-prevention-and-management-diabetes-Final.pdf

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SWOT analyses

To complement this quantitative analysis, a SWOT analysis was conducted by Country. The SWOT analysis is a strategic tool used to evaluate the Strengths, Weaknesses, Opportunities, and Threats of a policy, program, project or intervention. The aim is to offer insights and partners' point of view, on what makes a policy/program applicable, sustainable, and effective from a public health and from the stakeholders' perspectives, what are the necessary preconditions for its implementation and what are the lessons learnt from the experience. It also provides a background perspective of the setting where good practices are developed. A total of 53 stakeholders in 12 Countries contributed to the SWOT reporting and analyzing 39 policies, programs, projects, and interventions.

According to the responders, to be a "success", a policy or a program needs to be dynamic, bottom up, flexible, integrated, multi-inter-sectoral, and equity oriented. External communication and dissemination is a key point for success, and the partnership among stakeholders should be kept engaged throughout the process, a strong scientific background is considered a key point. Strategies should be comprehensive and address the most common risk factors of the main NCDs. A clear description of the care pathways is needed, supported by an information system at national, sub national and local level. Planning and definition of sound objectives on Integrated Care, is a leading starting point. Good educational models and care strategies are essential and need to be shared with the persons with diabetes. Regular monitoring and evaluation, with a defined and shared set of outcomes and indicators, are identified as important drivers for program implementation. A strong and efficient leadership is needed.

Some threats may stand in the way of program implementation. Despite improving, the culture of disease prevention and health promotion is still weak; on the other hand, from the science perspective, we still have gaps in our knowledge of diabetes and NCDs in general. The prevalence of NCDs is growing, as well as obesity in children, with the persistence of social inequalities in health. Specific legislation promoting healthy lifestyles are scarce across Europe, and industry and economic lobbies in general may adversely affect political decisions and do not always support healthy lifestyle.

Different care paradigms coexist and sometimes conflict with one another. Prevention and care are still seen as "competitors" for resources, workforce, and facilities, as programs and projects may compete over the same funding and same personnel. Despite some successful experiences, not one of the countries that participated reported a systematic integration of national policies or programs embracing different sectors. Moreover, university curricula and health professionals' pre-service education are still not dealing with the changing needs of the ageing population.

An opportunity that may facilitate implementation of policies/programs is the increasing awareness across European institutions and health care systems that action must be taken to address chronic conditions prevention and health promotion. Sharing and exchange of best practices of chronic care management and integrated care at European level is also acting as a motivator; some programs have been used as a model outside the original Country of implementation.

The SWOT analysis was undertaken on policies/programs from across Europe, in countries that vary in political, administrative, social and health care organization. These differences, as well as the different levels of cultural and organizational preparedness to face the NCDs burden, lead some to identify as a weakness or threat what for others is a strength or opportunity. The totality of these considerations, thoughts, experiences and insights draws an overall picture of the complexity of designing and implementing good policies and programs. These results may apply in any context and may be used by decision makers, managers, professionals and other stakeholders to focus on key issues, recognizing areas for attention [6].

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[6] https://drive.google.com/file/d/0B8Xu4R_n0-nzc0c5cGxKOFRlMlU/view?pref=2&pli=1

The process to define quality criteria

The approach taken to define the quality criteria presented in this report involved several steps and a long process to select a core list of criteria:

- literature reviews to identify quality criteria/indicators for practices/interventions on diabetes prevention targeted at people at high risk, health promotion, management of care, patients' education and health professionals' training[7] (see Appendix);
- cooperation among the work package task leaders, and all the associated and collaborating partners toward the revision of criteria and the definition of a preliminary lists of quality criteria. This activity was carried out through the WP7 platform, a web environment aimed at enhancing the development of a Community of Practice within WP7, and to promote exchanges, discussion, and sharing of resources and experiences;
- joint collaboration among WP7 leaders, representative of the European Patient Forum and the WP4 team from Aragon Health Science Institute (Spain) to define a list of universal quality criteria based on the indicators defined in WP7 and categories from Delphi 1-3 (Health promotion and primary prevention of chronic disease; Organizational interventions focused on dealing with people with multiple chronic conditions; Patient's empowerment interventions with chronic conditions);
- all the criteria were mapped out and redundancies were collapsed or rephrased, the resulting criteria were organized into 10 thematic drivers including a total of 71 items clustered, and included in the first online questionnaire to be submitted to an expert panel;
- selection of the expert panel, inviting WP7 partners and external experts, to decide on the suitability and priority of a series of criteria to assess whether an intervention -policy, strategy, programme/service, processes and practices- can be regarded as 'good practice' in the field of prevention and care of type 2 diabetes. A total of 28 European experts (diabetologists, general practitioners, nurses, representative of patients and governmental bodies, public health professionals, researchers) were invited to join the panel, they came from different countries (Austria, Belgium, Finland, France, Germany, Greece, Ireland, Italy, Norway, Portugal, Romania, Slovenia, Spain, and United Kingdom) covering a variety of health system models;
- consultation with the expert panel following the RAND modified Delphi methodology.

A thorough description of the Delphi method, for defining the core quality criteria for prevention and care of type 2 diabetes, can be obtained from the WP4 Delphi report available on the JA-CHRODIS website [8].

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[7] http://www.iss.it/publ/index.php?lang=1&id=2887&tipo=3

[8] https://drive.google.com/file/d/0B8Xu4R_n0-nzT3R4RVRDSnZ1UGc/view?pref=2&pli=1

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In synthesis, the RAND modified Delphi methodology entails two on-line rounds using a web-based questionnaire, followed by a face-to-face meeting. The consultation was launched in April 2016. All the panel experts completed the questionnaire in the first round, and 26 completed the second round. In both first and second round, experts were invited to add any driver they thought relevant or missing, but no additional items were suggested during the process. The expert meeting to refine and prioritise criteria was held on May 12th-13th, 2016, in Brussels. 16 experts were able to attend the face-to-face meeting. After the definition of the final set of criteria, experts weighted criteria by distributing 100 points among them (criteria weight), and weighted categories for each criteria (category weight). A trained facilitator (EB) following a structured consensus methodology conducted the face-to-face meeting.

Quality criteria

The extensive process carried out for the definition of criteria to improve prevention and quality of care for people with diabetes has led to the agreement on 9 criteria made up of 39 categories ranked and weighted. The list is reported in Table 1.

During the discussion the experts agreed to use the word “practice”, instead of “intervention” because it is more appropriate and inclusive; also they agreed on using the term “target population” rather than “patients”, for widening the potential scope of the practices.

The highest weight (14 % of the total valuation of a practice) was attached to criterion ‘Practice design’, followed by 'Target population empowerment' (13%) and ‘Evaluation’ (13%). ‘Sustainability and scalability’ rated the lowest (8 % of total), these criteria were addressed as very important for strategic clinical policy making, but considered not a necessary requirement to be a good practice, e.g. sustainability is linked to resources rather to the quality of practice itself. Information and communication systems and technologies were considered an important topic to facilitate access to information, and the exchange of information among different levels of social and health care. However, it was emphasized that practices must enhance and support the patient involvement and their interaction with the health and care system.

The criteria have been designed to apply to all types of practices; although, when used to implement practices, inevitably some criteria are more applicable to one setting or another, or will need adaptation to specific settings. The consensus list represents a 'gold standard' that would apply to an “ideal practice”. Therefore, not every criterion will be strictly relevant to every practice by every specialty. In the circumstance that a criterion or indicator cannot be applied, the reason should be discussed and justified.

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Table 1. Final list of weighted criteria and categories to evaluate the quality of practices in prevention and care of type 2 diabetes. Criteria and categories are ranked by weight.

Criteria	Criteria Weight	Categories	Category Weight
Practice design	14	The practice aims, objectives and methods were clearly specified	19
		The design builds upon relevant data, theory, context, evidence, previous practice including pilot studies	18
		The structure, organization and content of the practice were defined, and established together with the target population	14
		There was a clear description of the target population (i.e. exclusion and inclusion criteria and the estimated number of participants)	13
		The practice includes an adequate estimation of the human resources, material and budget requirements in clear relation with committed tasks	13
		There was a clear description of the target population, carers and professionals specific role	12
		In design, relevant dimensions of equity are adequately taken into consideration, and are targeted (i.e. gender, socioeconomic status, ethnicity, rural-urban area, vulnerable groups)	11
			100
Target population empowerment	13	The practice actively promotes target population empowerment by using appropriate mechanisms (e.g. self-management support, shared decision making, education-information or value clarification, active participation in the planning process and in professional training).	50
		The practice considered all stakeholders needs in terms of enhancing/acquiring the right skills, knowledge and behavior to promote target population empowerment (target population, carers, health and care professionals, policy makers, etc.)	50
			100
Evaluation	13	The evaluation outcomes were linked to action to foster continuous learning and/or improvement and/or to reshape the practice	31
		Evaluation outcomes and monitoring were shared among relevant stakeholders	26
		Evaluation outcomes were linked to the stated goals and objectives	25
		Evaluation took into account social and economic aspects from both target population, and formal and informal caregiver perspectives	18
			100
Comprehensiveness of the practice	11	The practice has considered relevant evidence on effectiveness, cost-effectiveness, quality, safety, etc.	38
		The practice has considered the main contextual indicators	33
		The practice has considered the underlying risks of the target population (i.e. validated tools to individual risk assessment)	29
			100
Education and training	11	Educational elements are included in the practice to promote the empowerment of the target population (e.g. strengthen their health literacy, self-management, stress management….etc.)	40
		Relevant professionals and experts are trained to support target population empowerment	30
		Trainers/educators are qualified in terms of knowledge, techniques and approaches	30
			100

Ethical considerations	11	The practice is implemented equitably (i.e. proportional to needs)	25
		The practice objectives and strategy are transparent to the target population and stakeholders involved	25
		Potential burdens of the practice (i.e. psychosocial, affordability, accessibility, etc.) are addressed, and there is a balance between benefit and burden	25
		Target population rights to be informed, to decide about their care, participation and issues regarding confidentiality, were respected and enhanced	25
			100
Governance	10	The practice included organizational elements, identifying the necessary actions to remove legal, managerial, and financial or skill barriers	15
		The contribution of the target population, carers and professionals was appropriately planned, supported and resourced	13
		The practice offers a model of efficient leadership	13
		The practice creates ownership among the target population and several stakeholders considering multidisciplinary, multi-/inter-sectorial, partnerships and alliances, if appropriate.	11
		There was a defined strategy to align staff incentives and motivation with the practice objectives	10
		The best evidence and documentation supporting the practice (guidelines, protocols, etc.) was easily available for relevant stakeholders (e.g professionals and target populations)	10
		Multidisciplinary approach for practices is supported by the appropriate stakeholders (e.g professionals associations, institutions etc)	10
		The practice is supported by different information and communication technologies (e.g. medical record system, dedicated software supporting the implementation of screening, social media etc)	10
		There was a defined policy to ensure acceptability of information technologies among users (professionals and target population) i.e., enable their involvement in the process of change	8
			100
Interaction with regular and relevant systems	10	The practice was integrated or fully interacting with the regular health, care and/or further relevant systems	42
		The practice enables effective linkages across all relevant decision makers and stakeholders	30
		The practice enhances and supports the target populations ability to effectively interact with the regular, relevant systems	28
			100
Sustainability and scalability	8	The continuation of the practice has been ensured through institutional anchoring and/or ownership by the relevant stakeholders or communities	32
		The sustainability strategy considered a range of contextual factors (e.g.health and social policies, innovation, cultural trends and general economy, epidemiological trends).	28
		There is broad support for the practice amongst those who implemented it	20
		Potential impact on the population targeted (if scaled up) is assessed.	20
Total	**100**		100

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Recommendations

Based on the extensive process carried out for the definition of quality criteria to assess practices, the following recommendations will be of use in implementing practices or interventions on prevention, health promotion, care management, education, and training, and ultimately to improve prevention and quality of care for people with diabetes.

Design the practice

The design should clearly specify aims, objectives and methods, and rely upon relevant data, theory, context, evidence, and previous practices including pilot studies. The structure, organization and content of the practice is defined, and established together with the target population, that is clearly described (i.e. exclusion and inclusion criteria and the estimated number of participants).
Human and material resources should be adequately estimated in relation with committed tasks. Relevant dimensions of equity have to be adequately taken into consideration, and targeted.

Promote the empowerment of the target population

The practice should actively promote the empowerment of the target population by using appropriate mechanisms, such as self-management support, shared decision making, education-information or value clarification, active participation in the planning process and in professional training, and considering all stakeholders needs in terms of enhancing/acquiring the right skills, knowledge and behaviour.

Define an evaluation and monitoring plan

The evaluation outcomes should be linked to action to foster continuous learning and/or improvement and/or to reshape the practice. Evaluation and monitoring outcomes should be shared among relevant stakeholders, and linked to the stated goals and objectives, taking into account social and economic aspects from both the target population, and formal and informal caregiver perspectives.

Comprehensiveness of the practice

The practice should consider relevant evidence on effectiveness, cost-effectiveness, quality, safety, the main contextual indicators, as well as the underlying risks of the target population using validated tools to individual risk assessment.

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The practice should include educational elements to promote the empowerment of the target population (e.g. strengthen their health literacy, self-management, stress management…). Relevant professionals and experts are trained to support target population empowerment, and trainers/educators are qualified in terms of knowledge, techniques and approaches.

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The rights of the target population to be informed, to decide about their care, participation and issues regarding confidentiality should be respected and enhanced.

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The practice should include organizational elements, identifying the necessary actions to remove legal, managerial, financial, or skill barriers, with the contribution of the target population, carers and professionals that is appropriately planned, supported and resourced. There is a defined strategy to align staff incentives and motivation with the practice objectives.

The practice should offer a model of efficient leadership, and should create ownership among the target population and several stakeholders considering multidisciplinarity, multi-/inter-sectoral, partnerships and alliances, if appropriate.

The best evidence and documentation supporting the practice (guidelines, protocols, etc.) should be easily available for relevant stakeholders (e.g. professionals and target populations), which should support the multidisciplinary approach for practices.

The practice should be supported by different information and communication technologies (e.g. medical record system, dedicated software supporting the implementation of screening, social media etc), defining a policy to ensure acceptability of information technologies among users (professionals and target population) to enable their involvement in the process of change.

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Sustainability and scalability

The continuation of the practice should be ensured through institutional anchoring and/or ownership by the relevant stakeholders or communities, and supported by those who implemented it. The sustainability strategy should consider a range of contextual factors (e.g. health and social policies, sex and gender issues, innovation, cultural trends and general economy, and epidemiological trends), assessing the potential impact on the population targeted.

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Key messages

The quality criteria/indicators and the recommendations presented in this report constitute a tool for decision makers, health care providers, patients and their associations, and health care personnel to support implementation of good practices, and to improve, monitor, and evaluate the quality of diabetes prevention and care. The adoption of an agreed core set of quality criteria/indicators should help to decrease inequalities in health and to improve diabetes prevention and care within and across European countries.

The criteria presented here will be used in the context of The CHRODIS Platform developed by WP4[9]. The platform will use the criteria agreed by experts across the EU via an online tool to allow users to evaluate practices, interventions and policies. The platform will become the virtual space where decision-makers, caregivers, patients, and researchers across the Europe can find and share the best knowledge and practice on chronic diseases.

The process of identifying quality criteria presented here followed a structured methodology involving the WP7 community and other experts in the field of prevention and care of diabetes across Europe. The separate lists of qualitative and quantitative quality indicators (for prevention focused on people at high risk, health promotion, care, educational strategies for people with diabetes and training for health professionals, see the Appendix) can be used side-by-side with the universal quality criteria. They can serve as practical “check lists” of how the quality criteria can be operationalized in activities targeted at improving type 2 diabetes prevention and care.

All the WP7 activities have aimed to provide opportunities to share expertise and experiences among a wide range of European countries. Implicit in all the activities is the assumption that the sharing and discussion of experiences is an effective means to create a knowledge capital that can be shared and used in the future.

To improve the quality of care for people with diabetes, and for most people with chronic diseases, we need to reshape our health and social care systems to facilitate the transition from fragmentation to integration of care, including prevention efforts, and incorporating community resources, in order to ensure a seamless care coordinated with and around the needs of people with chronic diseases. Use and implementation of the quality criteria presented in this report will contribute to the cultural shift needed to redesign the care systems.

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[9] http://www.chrodis.eu/our-work/04-knowledge-platform/

Appendix

Summary of evidence

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Quality indicators for diabetes prevention programs in health-care targeted at people at high risk

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The development of diabetes via various stages of insulin resistance and hyperglycaemia into overt diabetes can take 10 years or longer. This "lag period" is an important window of opportunity for preventive actions. It offers the time to prevent or delay the development of diabetes.

A review of the scientific literature and grey literature was performed to identify existing quality criteria and indicators for type 2 diabetes prevention [1]. The following electronic databases were searched: Academic Search Elite, CINAHL, Web of Science Core Collection, MEDLINE (Ovid), The Joanna Briggs Institute EBP Database, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, Cochrane Central Register of Controlled Trials, Health Technology Assessment, Applied Social Sciences Index and Abstracts (ASSIA), ProQuest Health Management, Social Services Abstracts, Worldwide Political Science Abstracts, Google, Google Scholar, NICE Evidence Search.
The literature search strategy included the terms "quality assurance", "quality indicator", "good practice", "best practice", "quality standard", "quality management" combined with "diabetes" and "prevention" and covered the time from 2000 to February 2015. Only publications in English were included. We also hand searched reference lists of relevant articles and previous systematic reviews. Publications that presented specified quality indicators for type 2 diabetes programs completed in health care setting were considered eligible. In addition, some generally acknowledged diabetes management guidelines, e.g. the NICE guidance [2], were consulted for reference.

Publications specifically presenting quality indicators for diabetes prevention proved to be scarce. The only publication identified was Pajunen et al. [3]. Indicators of IMAGE (Development and Implementation of a European Guideline and Training Standards for Diabetes Prevention) were developed along with the European evidence-based guideline for the prevention of type 2 diabetes [4] and the Toolkit for diabetes prevention [5]. These products of the multidisciplinary consortium IMAGE were used as the starting point for the definition of the preliminary list of indicators.

The suggested quality indicators for diabetes prevention are presented in Table 1. As in the original IMAGE publication, the indicators are arranged according to operational level and categorized as structure/process and outcome indicators, as suggested by Donabedian [6]. The structure indicators relate to material and human resources, as well as organizational structure. The process indicators describe how activities are undertaken to implement prevention. The outcome indicators are related to the actual clinical results of the preventive interventions. These classifications help the user to perceive that good quality is a multifaceted phenomenon and that there are different level operators that have differing responsibilities, and good practices in all levels are needed for good overall outcome.

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Table 1: Quality indicators for diabetes prevention programs and activities

Type	Description
Macro level	
Structure/Process	In activities of diabetes prevention, ethnic minorities and low socio-economic groups are considered.
Outcome	Prevalence of diabetes in the population.
Outcome	Percentage of the population physically inactive.
Outcome	Prevalence of overweight, obesity and abdominal obesity in population.
Outcome	Percentage of population following national recommendations on nutrition.
Meso level	
Structure/Process	Screening protocols to identify high-risk persons have been evaluated at national level.
Structure/Process	Validated diabetes risk assessment tools are available to health care providers.
Structure/Process	Information technology systems supporting the implementation of screening are available at health care provider level
Outcome	Proportion of the population screened (by health care provider) per year.
Outcome	The percentage of identified high-risk individuals remitted to diagnostic procedures.
Outcome	The percentage of identified high-risk individuals remitted to lifestyle interventions.
Structure/Process	High-risk prevention strategies are included in the education of the health care professionals.
Structure/Process	Defined clinical pathways exist for the health care provider to deal with individuals at risk for diabetes.
Structure/Process	Multidisciplinary approach for interventions is supported by the health care provider.
Structure/Process	Health care providers are collaborating with other players in health promotion.
Structure/Process	Medical record system supports interventions for chronic disease prevention.
Outcome	The percentage of remitted high-risk individuals participating in lifestyle interventions.
Outcome	Proportion of individuals dropping out of interventions.
Outcome	Proportion of high-risk individuals in interventions achieving clinically significant changes in risk factors at 1-year follow-up.
Outcome	Diabetes incidence rate among high-risk individuals in interventions at health care provider.
Micro level	
Structure/Process	Individual's risk factor profile is assessed.
Structure/Process	Individual's motivation for behavioural changes is discussed.
Structure/Process	Structure and content of the interventions have been defined at individual level.
Structure/Process	Individualized targets for interventions have been established.
Structure/Process	Plan for follow-up is defined.
Outcome	Proportion of planned intervention visits completed over 1 year.
Outcome	Weight change over 1 year.
Outcome	Change in waist circumference over 1 year.
Outcome	Change in glucose over 1 year.
Outcome	Change in the quality of nutrition over 1 year.
Outcome	Change in physical activity over 1 year.

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Quality indicators for health promotion interventions targeting people with type 2 diabetes

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Health Promotion, as defined by the Ottawa Charter for Health Promotion in 1986 [1], refers to the process of “enabling people to increase control over, and to improve, their health”. In the 4th International Conference on Health Promotion in 1997, The Jakarta Declaration was set out [2], and gave the following five key prerequisites of success for Health Promotion strategies:

- Build healthy public policy
- Create supportive environments
- Strengthen community action
- Develop personal skills
- Reorient health services

Health promotion strategies in T2DM may consist of one or a combination of programs targeting health- and dietary education, self-management, psychological support, or constitute initiatives targeting health care professionals or community stakeholders, and in addition have an intention to increase partnership across sectors. Also, patient empowerment is an upmost important and central topic in health promotion interventions [3].

A systematic literature search was conducted to bring attention to the most commonly used health promotion interventions in T2DM, and to provide a deeper understanding of the scope of such interventions and how they are evaluated in order to define quality indicators of good practices interventions [4].

A search strategy was developed and conducted to identify studies that assessed health promotion interventions in patients with T2DM. The electronic databases searched were: MEDLINE (Ovid), EMBASE, PubMed, Cochrane Database of Systematic Reviews (CDSR), DARE and NHS Economic Evaluation Database (EED). All articles published in English, Norwegian, Swedish and Danish from January 2010 through March 2015. Qualitative, quantitative or mixed method systematic reviews, meta-analyses, guidelines, review articles, narrative syntheses, HTAs and policy statements that evaluated non-pharmacological health promotion interventions in patients with T2DM, age ≥18 years, were considered eligible.

Of the 313 articles screened, seven were identified as being relevant for revision [5-11].

The draft list of indicators defined by WP5 was considered too.

A crucial part of health promotion interventions is targeting patient self-management skills, either by education of health care providers or direct targeting the patients individually or in a group. In this, it's desired that the intervention be designed in consultation with the target group, so that potential burdens of the intervention are addressed.

The list of indicators proposed for the Delphi consultation is reported in Table 1.

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Table 1 - Quality indicators for health promotion interventions

CONCEPTS AND DESIGN

The concept includes an adequate estimation of:
  - human resources
  - material and non-material requirements
  - budget requirements

A theoretical basis of the program exists and includes:
  - description of the method
  - description of activities in a chain of causation and time frame
  - description of interactions between key stakeholders and processes

Transparency:
  - the concept includes a specification of the project aims and objectives (e.g. SMART goals: Specific, Measurable, Acceptable for the target group, Realistic, Time-framed)

The following elements of the program are described and theoretically justified:
  - frequency
  - intensity
  - duration
  - selection and recruitment method
  - location

RELEVANCY

The target population is defined on the basis of needs assessment

The following dimensions are taken into consideration:
  - socioeconomic status
  - ethnicity and cultural factors
  - gender differences
  - rural-urban area
  - vulnerable groups

The intervention aims to promote the target group(s) self-management skills

The intervention has designed in consultation with the target group

Potential burdens of the intervention are addressed and the benefit-burden balance are fairly balanced

The intervention creates ownership among the target group and several stakeholders considering:
  - multidisciplinary
  - multi-/inter-sectoral
  - partnerships and alliances

EVALUATION

There is a defined evaluation framework, assessing structure, process and outcome

The evaluation methods and/or tools are validated

There is a monitoring system in place to deliver data aligned with evaluation and reporting needs

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Indicators on the quality of care for people with type 2 diabetes

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Diabetes mellitus is an important risk factor for micro and macro vascular diseases. Risk factors and outcomes vary across countries, reflecting a mixture of genetic background, societal and cultural factors, as well as public health policies, in combination with local health care practices [1]. Effective as well as efficient diabetes management is essential to prevent or delay complications and comorbidities in diabetes. Evaluation criteria are needed to identify key components of high quality of care [2,3].

A literature search on quality indicators of diabetes care was performed on 20 October 2014 searching the Cochrane library and Medline. Publications with information about structure, process and outcome indicators in according to diabetes were included. Studies that did not report quality criteria of management of diabetes, unpublished articles and conference abstracts were excluded. Following search strategy was used: ((structure OR process OR outcome) AND (quality indicators OR key components)) AND (type 2 diabetes). We applied the following limit in order to increase the specificity of our search: ("humans"[MeSH Terms] AND (English[lang] OR German[lang])). Additionally, we scanned reference lists of relevant articles.

The literature search generated a total of 190 hits. Thirty-three publications were relevant for analysis. Quality indicators on structure [4-8], process [9-19], intermediate outcomes [9, 15, 16, 19-32] comprising quality of life [33, 36], as well as on long term outcomes [9, 17, 26, 33-35]) were identified.

The criteria were reviewed, discussed and commented by WP7 leader, co-leader and task leaders, until a preliminary set of quality criteria were selected. The list of indicators proposed for the Delphi consultation is reported in Table 1.

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Table 1 - Indicators on the quality of care for people with diabetes

STRUCTURE INDICATORS

The program/experience was initiated by:

- governmental body, insurer
- primary care organizations / diabetes specialized care associations / hospitals / patient organizations…

Key components are:

- self-management support
- delivery system design
- decision support tools (e.g. guidelines for type 2 diabetes, complex guidelines for persons with type 2 diabetes and multiple chronic conditions)
- integrated care delivery system
- interdisciplinary working practice team (e.g. involving general practitioners, diabetologists/endocrinologists, diabetes specialized nurses, specialists for diabetic complications)
- clinical information system supporting interdisciplinary working practice and monitoring
- patient centered approach
    (e.g. risk assessment for complications, defined clinical pathways to deal with individuals at different risk for complications, risk adjusted targets for interventions, shared decision making, plan for follow-up defined)

The program/experience takes into account:

- ethnic minorities
- low socio-economic groups
- gender differences

The main objectives are defined and reached

(e.g. preventing or reducing inappropriate health care, improving integration of different organizations / care providers, increasing multi-disciplinary / multi-professional collaboration, improving patient involvement/centeredness, improving quality of care for persons with diabetes, improving early detection of co-morbidities, decreasing/delaying complications, ...reducing inequalities in access to care, reducing costs)

Incentive payment (e.g pay for performance/pay for outcome)

PROCESS INDICATORS

Process indicators are calculated

- proportion of persons with diabetes
    - enrolled in the program
    - dropping out of program
    - who regularly self-check (blood glucose)

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    - with regular education
- proportion of persons with diabetes who were regularly checked
    - HbA1c
    - body weight
    - blood pressure
    - lipid parameters
    - uric acid
    - creatinine
    - Albumin i. U
    - foot pulses and vibration sensation test (or filament test)
    - foot inspection
    - ocular fundus
    - ECG+ 24 RR profile
- proportion of planned visits completed

INTERMEDIATE OUTCOME INDICATORS

Intermediate outcome indicators are calculated

- proportion of persons with diabetes with parameters under/above a defined target
    - HbA1c
    - BMI
    - waist circumference
    - blood pressure
    - HDL-C
    - LDL-C
    - triglycerides
    - quality of life (ideally measured through QALY)
    - smoking people

LONGTERM OUTCOME INDICATORS

Longterm outcome indicators are calculated

- incidence rates
    - major limb amputation
    - myocardial infarction
    - stroke
    - microangiopathy
        - nephropathy or dialysis
        - retinopathy or blindness
        - neuropathy or diabetic foot syndrome
- mortality rate as a result of
    - cardiovascular events
    - uremia

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Quality indicators for education and health professionals training programs for people with diabetes type 2

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Diabetes education is an essential component of diabetes treatment. It is intended to prevent or delay the complications of diabetes [1]. In the context of patient education, an education program is an international accepted and vital intervention with a targeted structure of education for people with diabetes with an evident effect on the therapy and prognosis of diabetes. Usually, in education programs the core contents, goals, methods and didactics are described in a curriculum and materials or tools for the educators and participants are provided. Patient education is described as a complex intervention with special requirements on evidence and transparency regarding its rationale, methodology, performance and outcome representation [2, 3].

A literature review on evaluation criteria of education and training programs was conducted searching the Cochrane library, Medline and Google scholar. Literature from 2000 to May 2014 was selected to identify the latest state of art [4].

Publications that provide criteria overviews as systematic reviews, curricula, standards and guidelines were included. Literature recommendations of the experts, if meeting the inclusion criteria, were considered. The publications had to provide descripted quality criteria for patient education and health professionals' training programs and they had to be described in German or English language. Grey literature was not searched. The quality criteria from different publications were compared with each other separately for patient education programs and health professionals training programs. Common aspects were summarized. It was aimed to provide a short list of criteria on high abstract level that were applicable for both types of programs (education and training).

In total, 10 publications [1, 2, 5, 6-12] that met the inclusion criteria were identified out of 46 full-texts. Six dealt with education programs and four with professionals training (Table 1).

After the comparison and evaluation of the 55 individual criteria of the 10 publications, a set of 14 quality criteria (Table 2) was developed. Predominately, criteria were chosen that were mentioned in most of the publications. There were two exceptions, the "source of funding" and "implementation level". The source of funding was deducted from the ADA recommendations, and the implementation level from the IDF. The set contained only criteria on structure level to provide a basic set on a consistent measurement level.

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Table 1: Overview of the publications considered

Author/year	Aim	Type of publication/ country	Findings	Methods
Patient education				
Haas et al. 2012	Recognition and accreditation	National standard, USA	Quality requirements based on standards	Review the current National Standards for Diabetes Self-Management Education by a task force
American Association of Diabetes Educators 2013	Recognition and accreditation	National standard and guidance, USA	Quality requirements based on standards	Guidance based on current National Standards of the American Diabetes Association
The National Collaborating Centre for Chronic Conditions	Clinical recommendations for the management	National clinical guideline, UK	Quality requirements based on quality standards	Systematic search for evidence, critical appraisal, extraction and synthesis of data, development of recommendations and grading, consenting the recommendations
Bundesärztekammer et al. 2012	Recommendation, implementation, definition, increasing the number of educated patients	National guideline, Germany	Quality requirements based on quality standards	Systematic guideline search, full text evaluation and evaluation of the methodical quality of final guidelines using the DELBI-Instrument
Kulzer et al. 2007	To evaluate the efficacy of education programmes	RCT, Germany	Outcome measures	Prospective, randomized trial comparing three different treatment programmes
Deakin et al. 2005	To assess the effects of group-based, patient-centred training	Cochrane Review, UK	Outcome measures	Systematic Review
Professionals training				
International Diabetes Federation 2003	Provision of structure and framework	Standard, International	Quality indicators based in structure, process and outcome standards	Standard setting in 1997, consensus process, when possible on evidence based standards
International Diabetes Federation 2008	Framework and a common standard	Curriculum, International	Quality requirements based on quality standards	Based on standards and developments from the IDF in 1998, 2003, 2008
American Diabetes Association 2014	General standards for care	Standard, position statement, USA	Quality requirements based on quality standards	Literature Review
Department of Health 2015	Reference point, framework for developing and evaluating local programmes	Report, framework, UK	Quality requirements based on education programmes	Agreement of criteria by the Patient Education Working Group

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Table 2: Selected quality criteria for patient education and health professionals training programs

Defined criteria on structure level	Description
1. Goals	Education and is a systematic and targeted process to empower people with diabetes and to strengthen their health literacy, self-management, health promotion, prevention of diabetes complications, stress management
2. Rationale	A clear identification of the need to train health professionals A justification with regard to the evidence level
3. Target group	Inclusion and exclusion criteria regarding the programme participation
4. Setting	Location of the programme (e.g. inpatient, outpatient) or social environment (e.g. group sessions)
5. Scheduling of the education/training sessions	Description of the number of the education/training units (45 minutes)
6. Environmental requirements	Definition of an appropriate and accessible facility
7. Qualification of the trainers/educators	Certified trainees regarding content and methodology
8. Core components of the educator/trainer's role	Definition of roles regarding clinical practice, health promotion, counselling and behavioural change techniques
9. Curriculum	Description if and in which way the programme is evaluated, theory driven, evidence based
10. Education methods	Approaches to education that are interactive and patient-centred have been shown to be effective
11. Education didactics	Description how the didactical principles consider the individual needs and learning styles of the participants
12. Monitoring of the effectiveness and quality of the programme	Description how the quality of the programme is measured (e.g. audit, indicators (structure, process, outcome level),, frequency of measurement)
13. Implementation level	How the programme is implemented (e.g., local, regional or national level)
14. Source of funding	Supported by local/central government or other public system

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