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| **WP7 - Croatia****Individual pilot action report** |
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**1. Title:** Croatian minimum diabetes data set implementation using JA CHRODIS recommendations and criteria

**2. Abstract**

Patients with diabetes need to be treated more efficiently in order to postpone development of chronic complications. However, not all healthcare providers included in the care of patients with diabetes are using the same internationally accepted minimum data set and are not providing good quality data. Therefore, there is an assumption that not all the patients with diabetes are being treated by the same clinical standards, and through clinical pathways providing similar outcomes. Furthermore, general practitioner teams rarely keep track of secondary prevention activities in diabetes.

The aim of this project was to improve the management of diabetes according to international standards, based on JA CHRODIS recommendations and criteria. Specific aims were the following: toimprove general practitioners’ awareness and practice in diabetes monitoring, to improve patients understanding on the importance of yearly check-ups, and to harmonize diabetes information systems and coordination mechanisms according to international standards.

Primary target population were general practitioners which provide primary healthcare services to the patients. There were 3 groups of teams in the intervention: those who have received education and feedback, those who have received only information about the project and have been told that their minimum diabetes data set (MDDS) use will be monitored, and teams that have been analyzed without any intervention.

The results have shown that MDDS usage among general practitioners increased after intervention. Average number of patients with fulfilled minimum diabetes data set per GP increased for 52.30% from 20.2 before to 30.8 after intervention. Education of general practitioners may contribute to better monitoring of patients with diabetes. Qualitative research confirmed that most general practitioners have positive attitude towards MDDS, which can serve as reminders in regular monitoring of patients with diabetes. There are many possibilities for improving MDDS and quality of care, and our recommendations for better care are based on them.

**Short summary**

Diabetes is one of the largest global health emergencies of the 21st century. In Croatia there were 303.992 cases of diabetes in 2018. Patients with diabetes need to be treated more efficiently in order to postpone development of chronic complications which are main cause of impaired quality of life, disability and death in persons with diabetes. Not all healthcare providers included in the care of patients with diabetes are using the same internationally accepted minimum data set standard and are not providing data on their patients of a good quality (coverage, reliability, accuracy, transparency, timeliness and relevance). Therefore, there is an assumption that not all the patients with diabetes are being treated equally, by the same clinical standards and led through clinical pathways providing similar outcomes. Furthermore, secondary prevention activities in diabetes in general practitioner teams are relatively rare recorded.

Diabetes registries can serve to interventional purposes and are proven to be efficient in quality improvement trough implementation of standardized minimum data set (Harris MF. et al 2002, Bu D. et al 2007, Han W. et al 2016, Shojania KG. et al 2008, Peterson A. et al 2014, Burry E. et al 2018). Well established electronic patient registries improve quality indicators of diabetes control at population level due to better insight in patients’ health status, improved healthcare delivery (more of and better quality reminders, education, recording information and reporting) and better patient compliance (therapeutic planning, setting goals and following achievements) as well as continuous organizational improvement within and between involved healthcare providers (clearer functions and responsibilities, communication, evaluation).

The aim of this project was to improve the management of diabetes according to international standards, based on JA CHRODIS Recommendations and Criteria (Zaletel J, Maggini M 2020). Minimum data set we used was defined by having in mind availability and validity of certain parameters, and in coordination with our stakeholders (relevant expert societies, referral centers, Ministry of Health, Croatian Health Insurance Fund). It was developed in accordance with CHRODIS recommendations and criteria and previous initiatives and EU projects in that field (EUBIROD and BIRO data set, St. Vincet declaration). Specific aims were the following: toimprove general practitioners’ awareness and practice in diabetes monitoring, to improve patients understanding on the importance of yearly check-ups, and to harmonize diabetes information systems and coordination mechanisms according to international standards. Finally, based on the pilot results, we aim to prepare recommendation for raising awareness of general practitioners and patients regarding MDDS for future implementation.

Primary target population were general practitioners which provide primary healthcare services to the patients with diabetes in order to influence care of greater proportion of patients with diabetes. Patients with diabetes were also included directly in interventions via diabetic patient association and trough distributed leaflets. The general aim of all interventions was to improve the management of diabetes according to international standards.

In the intervention, we had 3 groups of teams: 8 teams have received education on registry and feedback, and the analysis for their patients and data quality has been conducted; 10 teams have only received information regarding project and have been told that their MDDS will be monitored during CHRODIS PLUS; 10 additional teams have been analyzed without any intervention. In total, 1109 patients were covered by the intervention.

We have used both qualitative and quantitative approach for analyzing our data. Quantitative analyses have been used to track change in teams’ baseline performance, measured by share of persons with regularly completed MDDS among patients with diabetes in care, quality of MDDS completeness, and change of chosen diabetes quality indicators within MDDS. Qualitative analysis has been used to assess semi-structured interviews carried out before and after education. As a part of the intervention on governance and education and training level LIWG platform have been used to enable influence on the stakeholders’ processes and activities. The results have shown that MDDS usage among general practitioners increased after intervention, and that education of general practitioners may contribute to better monitoring of patients with diabetes. We have anticipated changes in chosen diabetes quality indicators as well, but we could not “catch” them because they are collected annually and the time lag between education and its effect on quality indicators is longer than project duration. Qualitative research confirmed that most of general practitioners have positive attitude towards MDDS which can serve as reminders in regular monitoring of patients with diabetes. There are many possibilities for improving MDDS and quality of care, and our recommendations for better care are based on them.

**Introduction**

**3. Problem Description**

Diabetes is one of the largest global health emergencies of the 21st century. In Croatia there were 303.992 cases of diabetes in 2018. Additionally, forty-two percent or 92.000 cases are not yet diagnosed. Undiagnosed cases must be lowered as soon as possible but at the same time patients need to be treated more efficiently in order to postpone development of chronic complications which are main cause of impaired quality of life, disability and death in persons with diabetes. Diabetes mellitus was the fourth leading cause of death in 2017 with 2.331 or 4.4% of total deaths in Croatia. The age-adjusted death rate is higher than average of EU countries and constantly increasing. Without effective prevention and control programs, diabetes will likely continue to increase as well as number of persons with diabetes with developed chronic complications of disease.

In Croatia, there are around 2300 general practitioner teams (GPs) providing primary healthcare services. Within around 100 of stationary healthcare institutions on secondary and tertiary level there are 7 clinical hospital centers seated in biggest Croatian cities that are providing diabetologist and multi-professional expertise services to the patients with longer history of diabetes and developing multiple complications i.e. comorbidities. Not all the providers are using the same internationally accepted minimum data set standard and are not providing data on their patients of a good quality (coverage, reliability, accuracy, transparency, timeliness and relevance). Therefore, there is an assumption that not all the patients with diabetes are being treated equally, by the same clinical standards and led through clinical pathways providing similar outcomes. Furthermore, secondary prevention activities in diabetes in general practitioner teams are relatively rare recorded.

**4. Available knowledge**

Diabetes registries can serve to interventional purposes and are proven to be efficient in quality improvement trough implementation of standardized minimum data set (Harris MF. et al 2002, Bu D. et al 2007, Han W. et al 2016, Shojania KG. et al 2008, Peterson A. et al 2014, Burry E. et al 2018). They lead to improvements in glycemic control, enable efficient monitoring of other intermediate indicators and complication and screening rates, lead to reductions in emergency department visits and avoidable hospitalizations, and estimated reductions in health-care expenditures, and can be used efficiently especially in comparison with other more expensive health interventions at population level.

**5.Rationale**

Well established electronic patient registries improve quality indicators of diabetes control at population level due to better insight in patients’ health status, improved healthcare delivery (more of and better quality reminders, education, recording information and reporting) and better patient compliance (therapeutic planning, setting goals and following achievements) as well as continuous organizational improvement within and between involved healthcare providers (clearer functions and responsibilities, communication, evaluation).

**6.Specific aims**

The aim of this project was to improve the management of diabetes according to international standards, based on JA CHRODIS Recommendations and Criteria (Zaletel J, Maggini M 2020). Specific aims were the following: toimprove GPs awareness and practice in diabetes monitoring, to improve patients understanding on the importance of yearly check-ups, and to harmonize diabetes information systems and coordination mechanisms according to international standards. Finally, based on the pilot results, we aim to prepare recommendation for raising awareness of GPs and patients regarding MDDS for future implementation.

**Methods**

**7. Context**

The topic of better diabetes management was discussed with stakeholders (relevant expert societies, referral centers, Ministry of Health, Croatian Health Insurance Fund), and all JA CHRODIS recommendations and criteria were taken into account. SWOT analysis was created upon the discussion with stakeholders and investigation of key aspects of JA CHRODIS recommendations and criteria, which were all incorporated in the analysis.

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|  | **STRENGHTS** | **WEAKNESSES** |
| **INTERNAL** | **Governance** - 3 years of available routine data collected from EHRs in GPs**Practice design** – Minimum diabetes data set (MDDS) module is a useful decision-making tool which meets the administrative needs of Croatian Health Insurance Fund (CHIF), all GPs have MDDS module within their EHRs**Target population empowerment** - GPs are motivated to participate in development of tool to help them in efficient monitoring of patients with diabetes**Education and training** - there is system of continuous health professional’s education in place, patients are generally highly motivated to attend regular check-ups**Sustainability and scalability** - CIPH has an important role in strategic planning and implementation of pilot good practices**Ethical considerations** - MDDS module burden is addressed and it has positive benefit to burden ratio | **Governance** - unclear institutional mandates in health information standards in Croatia**Practice design** - MDDS module doesn’t provide an insight into the health history of the patient, GPs have no control over their work in the MDDS module, MDDS is not aligned with CroDiab**Target population empowerment** - some GPs are not informed on MDDS, GPs are generally overworked**Education and training** - diabetes is only until recently in the domain of general practitioners, the importance of diabetes registry in quality of care not perceived by patients and partially neither GPs**Sustainability and scalability** - unclear institutional responsibilities and mandates regarding eHealth **Ethical considerations** - the need for regular use of MDDS module is highest in the rural area where education is less frequent |
|  | **OPPORTUNITIES** | **THREATS** |
| **EXTERNAL**  | **Governance** - decision supporting tools in GPs**Practice design** - easily modifiable data structure of MDDS module within EHR in GPs**Target population empowerment** - strong evidence of efficiency of diabetes registries associated interventions**Education and training** - potentially high interest in insight of personal health history, status, goals and achievements **Sustainability and scalability** - CIPH holds diabetes registry and has a sustainable source of funding**Ethical considerations** - through the education of patients impact on GPs might be increased  | **Governance** - relatively slow implementation of new technical solutions in GPs**Practice design** - relatively low awareness of the importance of standardized clinical practice and health information systems**Target population empowerment** - potentially low motivation due to topics that are covering basic clinical practice (such as “proper washing hands”)**Education and training** - relatively low interest of patients in “internal” organizational issues within healthcare system**Sustainability and scalability** - decrease in data quality over time (coverage, timeliness, accuracy etc.) due to lack of feedback from reporting authorities |
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**8. Intervention(s)**

Primary target population were GPs which provide primary healthcare services to the patients with diabetes in order to influence care of greater proportion of patients with diabetes. Patients with diabetes were also included directly in interventions via diabetic patient association and trough distributed leaflets. The aim of all interventions was to improve the management of diabetes according to international standards, based on JA CHRODIS Recommendations and Criteria.

The aim of the intervention on GPs was to improve their awareness of the importance of better diabetes monitoring. Field intervention group consisted of 4 urban and 4 rural-area teams with approximately 1100 patients with diabetes in care which went through an education on project and MDDS /registry and got feedback on their MDDS performance. Control groups consisted of 10 teams which got a letter with information about project and their monitoring (controlling the potential confounding and estimating the influence of education and feedback to data source, i.e. awareness) and 10 teams that didn’t receive any information (controlling the potential confounding and estimating the influence of all other potential external influences during the study period). Teams were randomly selected and allocated to the groups and initial prerequisite for all the groups were distribution of urban and rural teams, while other characteristics were monitored throughout the analysis. The performance of the selected diabetes quality indicators before the pilot were compared with the performance after provided intervention analyzing the data from the same year period. BMI, fasting glucose, HbA1C, lipids fractions, albumin/creatinine ratio, systolic and diastolic blood pressure, smoking, alcohol consumption, feet examination and fundoscopic examination were monitored.

In parallel with this intervention, there was an intervention on patient education on their rights and responsibilities as a diabetes patient. As a part of this intervention, leaflets about importance of regular diabetes monitoring were developed and distributed to the patients. Qualified professionals from LIWG (GPs, patients, National Health Insurance Fund, Ministry of Health) participated in creating the leaflet, helping to frame the information in such a manner to strengthen patients’ health literacy and self-management. The leaflet was presented at Croatian Conference of people with Diabetes and it was also published in “Dijabetes” magazine.

The last intervention focused on MDDS standardization and improvement, with a goal to coordinate stakeholders to finalize and approve aligning MDDS with internationally accepted minimum data set, so that the MDDS changes can be included in countries’ internal and national legislation.

As a part of the intervention on governance and education and training level LIWG platform was used to enable influence on the stakeholders’ processes and activities. LIWG was organized to support multidiciplinary approach, with members coming from diffetent parts of healthcare system (Croatian Institute of Public Health, Ministry of Health, National Health Insurance Fund, patient representatives). Each member of LIWG contributed to the practice by providing evidence and supporting documentation about their area of interest, which enabled easy access to wide range of information. LIWG members were motivated to participate because they realized the changes that would happen as a result of the project would improve the care for patients with diabetes, but also make their work easier.

LIWG consisted of 3 persons at Organizers level to plan, prepare, chair and run the group workshops, run the secretariat and write reports (Croatian Institute of Public Health, full participation), 3 persons on Experts level to provide knowledge and faculty on the intervention (Croatian Institute of Public Health, full participation), 4 persons on decision makers level to provide strategic vision, support and sponsor the implementation and to eliminate bottlenecks (Croatian Institute of Public Health, Ministry of Health and Croatian Health Insurance Fund, full participation), 2 front-line stakeholders representatives to give knowledge and expertise on real-life practice experience, choose the right type of subject to implement, motivate and empower implementers, equip and support implementers to deal with the implementation (Croatian Family Physicians Coordination, Association of Teachers in General Practice / Family Medicine, full participation), 2 implementers to implement the intervention following the agreed plan, continuously assess the implementation process, provide input and feedback to the local implementation group (General practitioners, full participation) and patient representatives to give the input during the pilot action development, implementation, monitoring and evaluation (Representatives of diabetes patients associations, consultation, information).

**9. Study of the Intervention(s)**

In the intervention, we had 3 groups of teams:

* 8 teams have received education on registry and feedback, and the analysis for their patients and data quality has been conducted.
* 10 teams have only received information regarding project and have been told that their MDDS will be monitored during CHRODIS PLUS.
* 10 additional teams have been analyzed without any intervention.

Differences between teams with education and feedback and those that got only info helped us to quantify impact of raising awareness effort. Difference to teams that have been only monitored indicated level of impact of all other factors that are not part of the intervention (any activity that may influence GPs diabetes care and that may occur simultaneously with project interventions).

We have used both qualitative and quantitative approach for analyzing our data. Quantitative analyses have been used to track change in teams’ baseline performance, measured by share of persons with regularly completed MDDS among patients with diabetes in care, quality of MDDS completeness, and change of chosen diabetes QI within MDDS. Qualitative analysis has been used to assess semi-structured interviews carried out before and after education.

As a part of the intervention on governance and education and training level LIWG platform have been used to enable influence on the stakeholders’ processes and activities. Changes in MDDS that enable higher (or complete) level of agreement with internationally accepted minimum data set and monitoring of health status history as well as improving awareness of GPs on and patients of potential benefits from aligning MDDS with internationally accepted minimum data set has been assessed using quantitative methods.

**10.Measures**

1. KPI – Average number of patients with fulfilled MDDS per GP before/ after intervention

Input – Educational material on importance of good registry and regular check-ups

Process – Number of trained GPs/ number of interviews conducted with GPs/

Outputs – Number of fulfilled MDDS after education/ before education

Outcomes – Average number of patients with fulfilled MDDS per GP

2. KPI – Defined feedback report template

Input – MDDS

Process – Number of semi-structured qualitative interviews conducted

Outputs – GPs usage and attitude towards MDDS

Outcomes – Comparison of each GP MDDS data with national average

3. KPI – Number of patients reached by educational material for patients

Input – Developed leaflet for patients

Process – Number of leaflets distributed/ Presentation about importance of regular diabetes monitoring held/Number of patients reached by the magazine/ Organized promotion of educational material for patients with patient representatives

Output – Knowledge about importance of regular check-ups

Outcomes - Representatives of Patients Associations participated through all phases of the implementation

4. KPI – Revised Croatian Health Insurance Fund specification and specification of additional chapter regarding diabetes in Yellow book

Input – International minimum data set

Process – Discussion with stakeholders

Outputs – MDDS aligned with international minimum data set

Outcomes – Revised Croatian Health Insurance Fund specification and specification of additional chapter regarding diabetes in Yellow book

**11. Pilot Action Plan**

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| Improvement area(s) | Objective(s) | Change package | Person(s) involved | Timeline (months) | KPIs |
| To improve the management of diabetes according to international standards | **SO1.** To improve GPs awareness and practice in diabetes monitoring  | SO1.1 – Explore GPs attitudes towards MDDSSO1.2 – Develop educational material on MDDS for diabetes for GPsSO1.3 – Train GPs on the importance MDDSSO1.4 – Develop and disseminate feedback reports to GPs about their work  | TP, DVResponsible: TP | M21 – M22M20M21 - M22M20 - M22 | KPI1 - Average number of patients with fulfilled MDDS per GP before/ afterKPI2 - Number of trained GPsKPI3 - Number of interviews conducted with GPsKPI4 – Defined feedback report template |
| * **SO2.** To improve patients understanding on the importance of yearly check-ups
 | SO2.1 – Develop leaflets on the importance of regular diabetes monitoringSO2.2 – Distribute leaflets (about importance of regular diabetes monitoring) to patients through GP’s SO2.3 – Disseminate the information and material during the Croatian Conference of People with DiabetesSO2.4 – Develop article about importance of regular diabetes monitoring in “Dijabetes” magazine (the magazine for people with diabetes) | TP, DV Responsible: TP | M18 – M19M20 – M22M21M21 | KPI5 - Number of patients reached by educational material for patientsKPI6 - Developed leaflet for patientsKPI7 - Number of leaflets distributedKPI8 - Presentation about importance of regular diabetes monitoring heldKPI9 - Number of patients reached by the magazineKPI10 - Organized promotion of educational material for patients with patient representatives |
| **SO3.** To harmonize diabetes information systems and coordination mechanisms according to international standards | SO3.1 – Align MDDS with international standard SO3.1 - Define institutional responsibilitiesSO3.1 - Strengthen coordination among stakeholders | TP, DVResponsible: TP | M1 - M36  | KPI11 - Revised Croatian Health Insurance Fund specification and specification of additional chapter regarding diabetes in Yellow book |

**12. Analysis**

We have used both qualitative and quantitative approach for analyzing our data. Quantitative analyses have been used to track change in teams’ baseline performance, measured by share of persons with regularly completed MDDS among patients with diabetes in care, quality of MDDS completeness, and change of chosen diabetes quality indicators within MDDS. In initial design, it was planned to measure the performance of the selected quality indicators six months after the education. However, during intermediate evaluation and study visit this period was shortened, because of the assumption that qualitative change in quality indicators takes longer than 6 months (presumably one year). Since the limited duration of the project period, the decision was made to measure the performance of intervention up to 3 months following the intervention, which was long enough period to avoid the leg effect. For the reasons mentioned above, the measure of intervention performance was focused on change in average number of persons with regularly completed MDDS, rather than on performance of quality indicators.

Qualitative analysis has been used to assess semi-structured interviews carried out before and after education.

As a part of the intervention on governance and education and training level LIWG platform have been used to enable influence on the stakeholders’ processes and activities. Changes in MDDS that enable higher (or complete) level of agreement with internationally accepted minimum data set and monitoring of health status history as well as improving awareness of GPs on and patients of potential benefits from internationally accepted minimum data set have been assessed using quantitative methods.

**13. Ethical considerations**

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

**14. Results**

In qualitative part of the research we have analyzed MDDS and educated GPs about importance and usage of MDDS. Besides, semi-structured qualitative interviews about different aspects of MDDS (indicators, general impression, MDDS usage in everyday work, barriers in everyday work, necessity of a feedback, motivation for fulfilling MDDS, room for improvement, general comments) were conducted with each GP. The answers were coded according to categories mentioned above. The qualitative research confirmed that most of GPs have positive attitude towards MDDS which can serve as reminders in regular monitoring of patients with diabetes. There are many possibilities for improving MDDS and quality of care, and our recommendations for better care are based on them. Recommendations are the following:

* Implementing albumin/ creatinine index in laboratories on primary level of care
* Regular MDDS feedback to GPs
* Involving nurses in MDDS work
* Reducing number of MDDS and number of indicators per p MDDS
* Copying data from other sources and archive data (previous MDDS, hospitals)
* Possibility of overview/browsing and alerts about possible absence of yearly check-ups on all patients with diabetes under one GP
* Stimulation of infirmaries which are parts of medical centers
* Additional funding

Total number of patients included in quantitative part was 1242, i.e. 566 patients with fulfilled MDDS in Jul-Oct 2018 and 862 patients with fulfilled MDDS in Jul-Oct 2019. Average number of patients with fulfilled MDDS per general practitioner were 20.2 in Jul-Oct 2018 and 30.8 Jul-Oct 2019 (total increase 52.30%). In group 1 number of patients with fulfilled MDDS per general practitioner were 13.0 in Jul-Oct 2018 and 28.8 Jul-Oct 2019 (group 1 increase 121.15%), in group 2; 27.5 vs. 33.5 (group 2 increase 21.82%) and in group 3; 18.7 vs. 29.7 (group 3 increase 58.82%). Greatest increase in group 1 can be explained with influence of provided education and interviews while lowest increase in group 2, we believe might be result of negative feedback on MDDS when participation in project were not discussed and accepted with participants (general practitioners were informed that they will be monitored).

Description and availability of chosen QI as well as differences between groups in 2018 and 2019 are presented in table 1a and 2b. It can be observed that before intervention there were no differences between groups (all p’s>0.05) while after intervention, statistically significant differences in BMI and diastolic blood pressure were revealed (p<0.001, p=0.049) with decreasing trend in groups 1 and 2 and increasing values in group 3. Analysis revealed that there is no sufficient data regarding waist and hip circumference and albumin/ creatinine ratio as well as feet and fundoscopic examination. In the detailed qualitative analysis, the causes for very low availability of that variables were addressed (waist and hip circumference are not perceived as important, albumin/ creatinine ratio is not available on the primary level and general practitioners were not aware that if they record feet and fundoscopic examination they won’t be recorded as self-performed intervention).

Changes in 1st and 2nd measure before and after the intervention are presented in the table 2a and 2b. Results showed that on the level of total investigated patients there were no statistically significant changes of the indicators except total and LDL cholesterol. However, since the window between intervention and collection of data due the project time frame was limited, we could not expect significant changes in the quality indicator values, but only better usage of MDDS that was clearly confirmed.

Table 1a. Availability of main indicators of quality of diabetes care pre and post intervention (continuous variables)



Table 1b. Availability of smoking and alcohol status pre and post intervention



 Table 2a. Mean values of indicators of quality of diabetes care pre and post intervention (continuous variables)



Table 2b. Contingency tables of smoking and alcohol status pre and post intervention



**Discussion**

**15. Implementation process**

Enablers of our research were large quantity of available data, since all GPs are using MDDS module within their electronic health records. Lots of stakeholders were involved in all processes so we got very broad picture with many different perspectives. The target of our research was both patients and GPs, and they were all educated about importance and benefits of regular diabetes monitoring.

One of the barriers of practice was that diabetologists, due to organizational issues in diabetologists associations, were not formally included. Nurses were not included either, partly because they do not have formal associations in primary healthcare that would represent them. However, the pilot research showed they have major role in communicating with patients with diabetes and data input.

Nurses and diabetologists should be included in future implementation, regardless of the organizational issues. Evaluation outcomes should be shared with nurses and diabetologists, as well as with all other relevant stakeholders. Due to nurses’ involvement in the whole process, they as well should be educated about benefits of MDDS and regular monitoring.

When it comes to JA CHRODIS recommendations and criteria, it was very helpful in the process of planning and it served as a navigator and check list which ensured that all important elements were covered by the practice. Besides, JA CHRODIS recommendations and criteriaeased the project tracking in the execution phase, because it made us aware of how the project develops and helped to identify if some indicators were not specific enough.

On the negative side, the use of the tool was a bit unclear during intermediate evaluation, since some categories of JA CHRODIS recommendations and criteria implied the evaluation of already finished project, and Croatian pilot field research did not start at that moment. Besides, the wording of the tool was sometimes abstract and not clear.

**16. Summary**

The first aim of this project was toimprove GPs awareness and practice in diabetes monitoring. This was supposed to be accomplished by educating GPs on importance of using MDDS and by exploring their attitudes towards MDDS through semi-structured qualitative interviews. MDDS analyses conducted after the education showed that the intervention increased the usage of MDDS among GPs. When it comes to quality indicators, results showed there were no statistically significant changes of the indicators, probably because the time window between intervention and data collection was limited due to project time frame.

Qualitative analyses gave us important and useful insight in GPs usage and attitude towards MDDS, which is going to be very helpful in preparing recommendations for better care. GPs use MDDS as reminders in regular monitoring of patients with diabetes and most of them have positive attitude towards MDDS. However, their usage might be improved by: implementing albumin/ creatinine index in laboratories on primary level of care, regular MDDS feedback to GPs, involving nurses in MDDS work, reducing number of MDDS and number of indicators per MDDS, copying data from other sources and archive data (previous MDDS, hospitals), possibility of overview/browsing and alerts about possible absence of yearly check-ups on all patients with diabetes under one GP, stimulation of infirmaries which are parts of medical centers, additional funding.

The second aim was to improve patients’ understanding on the importance of yearly check-ups. In order to reach this aim, we have developed leaflets about importance of regular diabetes monitoring and distributed them through GPs included in the pilot, but we have also published it in “Dijabetes” magazine, the magazine for people with diabetes which reaches 30 000 patients with diabetes. Besides, the leaflet was presented at Croatian Conference of People with Diabetes.

The third specific aim was to harmonize diabetes information systems and coordination mechanisms according to international standards. This aim was addressed by discussing internationally accepted minimum data set with all relevant stakeholders and coordinating them to finalize and approve aligning MDDS with minimum data set. As a result, revised Croatian Health Insurance Fund specification and specification of additional chapter regarding diabetes in Yellow book have been produced.

**17. Interpretation**

In the intervention, we had 3 groups of teams – those who have received education and analysis, those who have received only information about the project and have been told their MDDS are monitored, and those who have been analyzed without any intervention.

Differences between teams with education and feedback and those that got only information about monitoring helped us to quantify impact of raising awareness effort. Difference to teams that have been only monitored indicated level of impact of all other factors that are not part of the intervention (any activity that may influence GPs diabetes care and that may occur simultaneously with project interventions). The results have shown that MDDS usage among GPs increased after intervention, and that education of GPs may contribute to better monitoring of patients with diabetes. We have anticipated changes in chosen diabetes quality indicators as well, but we could not “catch” them because they are collected annually and the time lag between education and its effect on quality indicators is longer than project duration.

Qualitative analysis has been used to assess semi-structured interviews carried out before and after education. The interviews have shown that most of GPs have positive attitude towards MDDS which can serve as reminders in regular monitoring of patients with diabetes. Based on GPs usage and attitude towards MDDS, discussed during semi-structured interviews, feedback report template was defined. Such a report would enable to GPs to compare their own MDDS with national average.

For patients, the leaflet about importance of regular diabetes monitoring has been developed and distributed. It should improve their awareness on importance of yearly check-ups and consequently lead to better diabetes monitoring.

As a part of the intervention on governance and education and training level, LIWG platform has been used to enable influence on the stakeholders’ processes and activities. Changes in MDDS that enable higher (or complete) level of agreement with internationally accepted minimum data set and monitoring of health status history as well as improving awareness of GPs on and patients of potential benefits from aligning MDDS with international minimum data set have been assessed using quantitative methods.

**18. Limitations**

There are two basic limitations of this study, and both are related to limited duration of the project. First, effect of patient leaflets on better monitoring of diabetes is hard to measure in such a short period of time. Second, we cannot measure changes in most quality indicators (e.g. HbA1c), since most of them are collected annually and the time lag between education and its effect on quality indicators is longer than project duration.

**19. Conclusions**

MDDS and the Registry have from before been a part of Croatian Health Insurance Fund (CHIF) and Croatian Institute of Public Health (CIPH) regulatory systems. The Registry is regulated by law and it is obligatory for all doctors. We have used current framework as a starting point, in order to ensure sustainability. All changes have been implemented in amending bylaw acts, that is internal stakeholders’ procedures. At the moment, no funding and resources were allocated to continue the activities beyond the implementation. However, activities in that direction have been initiated and they will be continued.

We have used mechanisms (CIPH, Ministry of Health, CHIF) that cover all Croatian residents. National committee for strategy and treatment of patients with diabetes will include the results into strategy of treatment. Through LIWG and National committee for strategy and treatment of patients with diabetes, all stakeholders were included.

For future implementations, we would suggest including all important stakeholders and future implementers in the project, preferably through LIWG. Also, we would advise involvement in all regular organizational processes, and usage of current frameworks and processes whenever possible.

**20.** **Funding**

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Annexes:

Annex 1: Individual pilot action plan

Annex 2: Intermediary evaluation report

Annex 3: Study visit report

Annex 4: Final evaluation report

Annex 5: Barriers, Enablers and Suggestions for future implementations

Annex 6: Sustainability and Replicability/Transferability

Annex 7: Essential elements of pilot action report

Annex 1: Individual pilot action plan

1. Introduction *(that explains, why did you start)*

*Diabetes is one of the largest global health emergencies of the 21st century. Highest among the elderly, prevalence rates are rising among younger and productive populations in developing countries. Each year more and more people live with this condition, which can result in life-changing complications.*

*Based on the estimation of the International Diabetes Federation for 2017, approximately 425 million people worldwide, or 1 in 11 adults aged 20-79, have diabetes, and there are 352 million adults with impaired glucose tolerance (1 in 14 adults aged 20-79) which put these adults at high risk of developing diabetes in the future. Two-thirds of people with diabetes live in urban areas (279 million) and are of working age (327 million). Four million people aged between 20 and 79 years are estimated to die from diabetes every year, which is 1 death every 8 seconds. If these trends continue, by 2045 some 629 million people will have diabetes. The largest increases will take place in regions where economies are moving from low- to middle-income levels.*

*Croatia accounted approximately 304.408 cases of diabetes in 2017. According to the International Diabetes Federation, forty-two percent or 92.000 cases are yet to be diagnosed. Undiagnosed cases must be lowered as soon as possible while persons with diabetes need to be treated more efficiently in order to postpone development of chronic complications of disease which are main cause of impaired quality of life, disability and death in persons with diabetes. Diabetes mellitus was the eighth leading cause of death in 2017 with 1.674 or 3.5% of total deaths. The age-adjusted death rate is 17.33 per 100,000 of population which ranks Croatia #127 in the world. Without effective prevention and control programs, diabetes will likely continue to increase in Croatia as well as number of persons with diabetes with developed chronic complications of disease.*

1.1 Problem Description: *Nature and significance of the local problem*

*(based on the “Problem/challenge” from the Scope definition; appendix 3)*

-Describe in narrative the Problem based on the information elaborated with the appendix 3, by using available data on population (health, organizational, regulatory aspects, resources), and any other information deemed relevant to describe the problem and/or to justify your intervention.

-Make reference to relevant policies at national and subnational level (or identify their absence)

*In Croatia, there are around 2300 general practitioner teams (GPs) providing primary health care services to more than 300.000 patients with diabetes. Within around 100 of stationary healthcare institutions on secondary and tertiary level there are 7 clinical hospital centres seated in biggest Croatian cities that are providing diabetologist and multiprofessional expertise services to the patients with longer history of diabetes and developing multiple complications i.e. comorbidities.*

*All those healthcare providers are required to use internationally accepted health information standards within the field of diabetes using minimum data set (MDS) as part of their routine check-list practice for periodic examination of patients with diabetes as part of secondary health care preventive services. Nevertheless, due to non-consistent health information standards on process and semantic level, not all the providers are using the same international MDS standard and are not providing data on their patients of a good quality (coverage, reliability, accuracy, transparency, timeliness and relevance). Therefore, there is an assumption that not all the patients with diabetes are being treated equally, by the same clinical standards and led through clinical pathways providing similar outcomes.*

1.2. Available knowledge: *Summary of what is currently known about the problem, including relevant previous studies*

*(based on the “Problem/challenge” from the Scope definition; appendix 3)*

-Report relevant studies conducted at international, national or subnational level to describe the problem and/or to justify your intervention.

*There are many studies reporting that diabetes registries, most probably more than any other chronic disease registries serve interventional purposes efficiently. Especially in comparison with other more expensive health interventions at population level.*

*Interventions that use adult diabetes registry data for QI have shown improvements in glycaemic control, monitoring and complication screening rates, reductions in emergency department visits and avoidable hospitalizations, and estimated reductions in health-care expenditures (Harris MF. et al 2002, Bu D. et al 2007, Han W. et al 2016).*

*The most convincing was the meta-regression analysis study conducted by Shojania KG. et al in 2008 comparing various population level intervention’s effects. Patient education, patient reminders, patient electronic registries and clinician education were some of the most effective health interventions (figure).* 

*The case study from Sweden conducted by Peterson A. et al in 2014 suggested that by involving paediatric diabetes teams in a quality improvement collaborative together with access to a quality register, the quality of paediatric diabetes care can improve, thereby contributing to a reduced risk of late complications for children and adolescents with diabetes. Change concepts were, for example, improved guidelines, appointment planning, informing the patients, improving teamwork and active use of the registry, and health promotion activities.*

*The newest systematic review conducted by Burry E. et al in 2018 concluded that paediatric diabetes registries are underused for QI and may facilitate improved care and outcomes. Existing vast amount of paediatric registry data could be used to foster the development of learning health systems and to improve diabetes care and outcomes.*

1.3. Rationale*: Informal or formal frameworks, models, concepts, and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work*

*There is strong evidence that well established electronic patient registries improve quality indicators of diabetes control at population level.*

*Implementation team strongly believes that causal relationship is due to better insight in patients’ health status, improved health care delivery processes (more of and better quality reminders, education, recording information and reporting) and better patient compliance (therapeutic planning, setting goals and following achievements) as well as continuous organisational improvement within and between involved health care providers (clearer functions and responsibilities, communication, evaluation).*

1.4. Specific aims: *Purpose of the project and of this report*

*(based on “General purpose of the intervention” and “Quality criteria” from the Scope definition (Guideline 5.1;* Appendix 3*)*

Describe the General Purpose of an intervention based on the information elaborated in Appendix 3.

*Croatian diabetes registry (CroDiab) has been built to satisfy international standard in building diabetes registries and ensure collection of diabetes data as well as improvement in quality care of diabetic patients. The concept was confirmed while Croatia was project partner in EUBIROD project which was a working solution to fulfil the European Parliament resolution of 14 March 2012 on addressing the EU diabetes epidemic for the systematic data collection and monitoring of diabetes complications and health outcomes across Europe. The project defined and applied common rules and a minimum common dataset that is applicable to all European countries in the context of their existing datasets.*

*Healthcare providers on primary level, i.e. general practitioners within their electronic health records are using data entry module called „diabetes panel“, which is to some extent aligned with international minimum common data set, but not completely. However, fully standardised MDS should be used by all general practitioner teams. It represents the minimum data entry of each patient with diabetes and at the same time a check-list for each physician if the complete control of glycaemia and diabetes complications are being assessed and recorded regularly. MDS should be collected at least once a year and therefore can serve as a primary data source form diabetes registry.*

*Good quality of recorded and captured information enables then analyses at population level and feedback from public health level on the performance of each single healthcare provider and how to improve. Therefore, the improvement of collaborative use of MDS and diabetes registry is main aim of this pilot together with the promotion of diabetes control check-list use in a standardised manner. Quality will be assessed from the aspect of governance (minimum common data set aligned with international standards and mutually between systems as well as clearly defined institutional responsibilities and mandates regarding eHealth and health information systems in Croatia) practice design and target population empowerment (info to general practitioners on the current and expected use of diabetes control check-list as a minimum dataset within diabetes registry as well as empowerment for their regular use) education and training and sustainability and scalability.*

2. Methods (that explains, what will you do)

2.1. Context: *Contextual elements considered important at the outset of introducing the intervention(s)*

*(based on (Guideline 5.1) and the main output of the SWOT analysis (Appendix 4)*

-Summarize the identified Strengths, Weaknesses, Opportunities and Threats identified.

*STRENGTHS*

*3 years of available routine data collected from EHRs in GPs*

*“Diabetes panel” module is a useful decision-making tool which meets the administrative needs of Croatian Health Insurance Fund*

*In Croatia, all GPs are using “diabetes panel” module within their EHRs.*

*GPs are motivated to participate in development of tool to help them in efficient monitoring of diabetic patients*

*Diabetes patients are generally highly motivated to attend regular check-ups.*

*There is system of continuous education of health professionals in place that can be used for the pilot purpose.*

*General practitioners are educated through various educational platforms which regularly cover diabetes topics*

*CIPH has an important role in strategic planning and implementation of pilot good practices*

*“Diabetes panel” module burden is addressed and it has positive benefit to burden ratio*

*WEAKNESSES*

*Unclear institutional mandates in health information standards in Croatia*

*“Diabetes panel” module doesn’t provide an insight into the health history of the patient*

*GPs have no control over their work in the “diabetes panel” module*

*The MDS of diabetes panel is not aligned with CroDiab*

*Diabetes patients are generally poorly aware of their rights and responsibilities as a diabetes patient*

*Diabetes patients are not aware of their potential benefits from CroDiab*

*GPs are generally overworked*

*Diabetes is only until recently in the domain of GPs*

*Some GPs are not informed on what the panels are and how to use them*

*Guidelines for the GPs are constantly changing*

*Unclear institutional responsibilities and mandates regarding eHealth and health information systems*

*The need for regular use of Diabetes panel” module is highest in the rural area where education is less frequent*

*OPPORTUNITIES*

*Decision supporting tools in GPs*

*The data structure of diabetes panel module within EHR in GPs is easily modifiable and affordable.*

*With the increase of using “diabetes panel” module, more patients with diabetes can be diagnosed.*

*There is potentially high interest of diabetic patients to have a better insight in personal health history, status, therapeutic plans, goals and personal achievements.*

*There is strong scientific evidence of efficiency of interventions with help of diabetes registries*

*CIPH holds diabetes registry and has a sustainable source of funding.*

*Through the education of patients awareness of module benefit can be increased with influence on the better treatment*

*THREATS*

*Relatively slow implementation of new technical solutions in GPs*

*There is relatively low awareness of the importance of standardised clinical practice and health information systems*

*Relatively low awareness of the importance of standardised clinical practice and health information systems*

*There is relatively low interest of patients in “internal” organisational issues within health care system*

*Some parameters in the “diabetes panel” module are not equally available for all the GPs*

*Potentially low motivated personnel in education due to topics that are covering basic clinical practice (such as “proper washing hands”)*

*Although improved reporting practices, if not maintained with good quality feedback to data source tend to decrease in data quality over time (coverage, timeliness, accuracy etc.)*

-Describe the improvement Areas (strategic actions) selected in order to overcome identified Weaknesses and Threats (based on Guidelines 5.3.2 and Appendix 5).

*- at decision making level (MoH) try to align MDS of diabetes panel with CroDiab and mutually between systems and clearly define institutional responsibilities and mandates regarding eHealth and health information systems in Croatia*

*- try to improve awareness of patients with diabetes on their potential benefits from CroDiab, and how participate within health care system organisation in order to improve health outcomes*

*- try to improve awareness of GPs on potential benefits from MDS and CroDiab*

*- based on the results of the study prepare recommendation for raising awareness of GPs and patients regarding MDS (education, feedback to data source …)*

2.2. Intervention(s):

2.2.1 Specifics of the team involved in the work

(based on the description of the LIWG (number, profiles, roles) from LIWG definition and stakeholders identification, if deemed relevant) (Guidelines 3; Appendix 2).

*The team includes:*

* *3 persons at Organizers level to plan, prepare, chair and run the group workshops, run the secretariat (prepare agendas and minutes) and write reports - Croatian Institute of Public Health, Ivan Pristaš, Marija Švajda, Domina Vusio*
* *3 persons on Experts level to provide knowledge and faculty on the intervention - Croatian Institute of Public Health, Tamara Poljičanin, Marko Brkić, Marija Švajda*
* *4 persons on decision makers level to provide strategic vision, support and sponsor the implementation and to eliminate bottlenecks - Croatian Institute of Public Health, Tamara Poljičanin, Ministry of Health, Dunja Skoko Poljak, Sanja Kiš and Croatian Health Insurance Fund, Tatjana Bekić*
* *2 front-line stakeholders representatives to give knowledge and expertise on real-life practice experience, choose the right type of subject to implement, motivate and empower implementers, equip and support implementers to deal with the implementation - Croatian Family Physicians Coordination, Vjekoslava Amerl Šakić, Association of Teachers in General Practice / Family Medicine - Valerija Bralić Lang*
* *2 implementers to implement the intervention following the agreed plan, continuously assess the implementation process, provide input and feedback to the local implementation group - General practitioners - Vjekoslava Amerl Šakić, Valerija Bralić Lang*
* *2 patient representatives to give the input during the pilot action development, implementation, monitoring and evaluation - Representatives of diabetes patients associations, Zrinka Mach*

2.2.2 Description of the intervention(s) in sufficient detail that others could reproduce it

(Based on “target population“ from the Scope Definition and Pilot action plan with defined improvement areas (Guideline 5.3; Appendix 3 and 6)):

- Describe in narrative the target population (type, age groups, estimated number) and their needs;

-Describe in details the intervention according to the template developed for the Pilot Action Plan; -Add other information that you consider relevant to describe the project (organization, communication aspects, others).

*Target population consists of GPs which provide primary health care services to patients with diabetes. Not all the providers are using the same international MDS standard and are, therefore, not always providing data on their patients of a good quality. Intervention group will consist of 5 urban and 5 rural-area teams which will go through an education on project and MDS/registry and feedback on their MDS performance and whose performance will be used for quantifying awareness increase. Control group will consist of 10 teams which will get letter with information about project and their monitoring but will not get a feedback or an education by LIWG. Their performance will be used for controlling the potential confounding and estimating the influence of education and feedback to data source, i.e. awareness. The third group, consisting of 10 randomly selected and allocated teams, will not receive an information that their panels will be monitored. Their performance will be used for controlling the potential confounding and estimating the influence of all other potential external influences during the study period.*

*The only initial prerequisite for all the groups will be equal distribution of urban and rural teams, while other characteristics will be monitored throughout the analysis. The performance of the selected diabetes QI in the beginning of the pilot will be compared with the performance 6 months after the initial screening. The following diabetes QI will be monitored: BMI, waist and hip circumference, fasting glucose, HbA1C, lipids fractions, albumin/creatinine ratio, systolic and diastolic blood pressure, smoking, alcohol consumption, feet examination and fundoscopic examination.*

*In parallel with this intervention, there will be an actions regarding the MDS standardization, panel improvement (to provide an insight into the health history of the patient) and patient education on their rights and responsibilities as a diabetes patient.*

2. 3. Study of the Intervention(s) :

2.3.1 Approach chosen for assessing the impact of the intervention(s) *(quantitative or qualitative analyses)*

*(based on the Pilot action plan with defined Improvement areas (Guideline 5.3* Appendix 6*) with special focus to key performance indicators)*

-Report the *key performance indicators* described in the Pilot Action Plan;

-Describe the methodology and frequency of data collection, and the stakeholders involved

*Number of teams will be chosen to receive education on registry and feedback with conducted analysis for their patients and data quality. Same number of teams will only receive information regarding project and information that their panels will be monitored during CHRODIS JA+ and additionally same number of teams will be analysed without any intervention. Differences between teams with education and feedback and those that will get only info will help us to quantify impact of raising awareness effort while difference to teams that will be only monitored will indicate level of impact of all other factors that are not part of the intervention (any activity that may influence GPs diabetes care and that may occur simultaneously with project interventions). Change in teams’ baseline performance, measured by share of persons with regularly completed diabetes panel among diabetic patients in care, quality of diabetes panel completeness, and change of chosen diabetes QI within diabetes panel will be measured and assessed using quantitative analyses. Measures will be taken at two time points. Measures taken before the start of our pilot period will be compared with measure taken six months after the end of our pilot period, taking into account possible lag effect. Semi-structured interviews carried out before and after education will be assessed using qualitative methods.*

*As a part of the intervention on governance and education and training level LIWG platform will be used to enable influence on the stakeholders’ processes and activities. Changes in diabetes panel that enable higher level of agreement (or complete) with MDS and monitoring of health status history as well as improving awareness of GPs on and patients of potential benefits from MDS will be assessed using quantitative methods.*

2.3.1 Approach used to establish whether the observed outcomes were due to the intervention(s)

*Sampling method will control some potential confounding. When choosing teams to receive feedback with conducted analysis for their patients and data quality we will take into account rural/ urban ratio since it may influence accessibility of care, level of education and overwork. Other baseline performance characteristics (share of carried out panels, data quality etc.) and general characteristics (population they have in their care, urban-rural area etc.) will be controlled during analysis. Furthermore, we will have control group of teams which will receive information that their baseline performance will be monitored for the purpose of CHRODIS+ JA, but will not receive any feedback or planned education and other control group that will be only monitored through regular statistical data without and intervention. This will allow us to establish whether observed outcomes were due to the intervention, education and feedback, monitoring or due to some other factor concomitantly influencing the target population.*

2. 4. Measures: *Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability*

*(based on the Pilot action plan with defined Improvement areas (Guideline 5.3;* Appendix 6*) with special focus to key performance indicators)*

1. *Share of persons with regularly completed diabetes panel among diabetic patients in care, by team. Values for 2016, 2017 and 2018 will be compared.*
2. *Description and availability of chosen diabetes QI within diabetes panel - BMI, waist and hip circumference, fasting glucose, HbA1C, lipids fractions, albumin/creatinine ratio, systolic and diastolic blood pressure, smoking, alcohol consumption, feet examination and fundoscopic examination in previous 12 months.*
3. *Change in 1st and 2nd measure before and after the intervention – measures taken before the start of our pilot period will be compared with measure taken six months after the end of our intervention period in order to evaluate the result of our intervention (taking into account possible lag effect).*
4. *Changes in diabetes panel that enable higher level of agreement (or complete) with MDS and monitoring of health status history*

2. 5. Chronogram: *Expected timing of the activities of the Change package, scheduling the start and end month (based on the Pilot action plan with defined Improvement areas (Guideline 5.3) with special focus to timeline(s) (Appendix 6)*

*The expected timing of the activities will be 12 months – 6 months for the intervention and 6 months for the follow-up. The activities will start in December 2018 and end in December 2019.*

3. References

*1. Shojania KG, Ranji SR, McDonald KM, Grimshaw JM, Sundaram V, Rushakoff RJ, Owens DK. Effects of quality improvement strategies for type 2 diabetes on glycaemic control: a meta-regression analysis. JAMA. 2006 Jul 26;296(4):427-40.*

*2. Peterson A, Hanberger L, Åkesson K, Bojestig M, Andersson Gäre B, Samuelsson U. Improved Results in Paediatric Diabetes Care Using a Quality Registry in an Improvement Collaborative: A Case Study in Sweden. Neu J, ed. PLoS ONE. 2014;9(5):e97875. doi:10.1371/journal.pone.0097875.*

*3. Burry E, Ivers N, Mahmud FH, Shulman R. Interventions using pediatric diabetes*

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*8. Bu D, Pan E, Walker J, et al. Benefits of information technology-enabled diabetes management. Diabetes Care. 2007;30:1137-1142.*

Appendices

Appendix 1 Individual Pilot Action Plan Report, in summary table

Appendix 2 Local implementation working group definition and stakeholders’ identification, in summary table

Appendix 3 Scope definition

Appendix 4 SWOT analysis, in summary table

Appendix 5 Identification of improvement areas, in summary table

Appendix 6 Pilot action plan in Improvement area (s), in summary table

Appendix 7 Quality Criteria and Recommendations to improve care for people with chronic diseases (QCR Tool), in summary table

*Appendix X*

**Appendix 1**

**Individual Pilot Action Plan Report- summary report** based on SQUIRE 2.0

Please, summarise all the data collected in the Individual pilot action plan. Please, consult also “JA CHRODIS PLIS Guideline on implementation strategy” The source of information to complete the items is stated in italics. The template is based on the adapted version of the SQUIRE 2.0 (<http://squire-statement.org/index.cfm?fuseaction=Page.ViewPage&pageId=504>).

|  |  |
| --- | --- |
| **Introduction** | ***Why did you start?*** |
| 1. Problem Description
 | *Not all the providers are using the same international MDS standard and are not providing data on their patients of a good quality. Therefore, probably not all the patients with diabetes are being treated equally, by the same clinical standards and led through clinical pathways providing similar outcomes.* |
| 1. Available knowledge
 | *Diabetes registries can serve to interventional purposes and are proven to be efficient in quality improvement trough implementation of standardised MDS. They lead to improvements in glycaemic control, monitoring and complication screening rates, reductions in emergency department visits and avoidable hospitalizations, and estimated reductions in health-care expenditures and can be used efficiently especially in comparison with other more expensive health interventions at population level.* |
| 1. Rationale
 | *Well established electronic patient registries improve quality indicators of diabetes control at population level due to better insight in patients’ health status, improved health care delivery (more of and better quality reminders, education, recording information and reporting) and better patient compliance (therapeutic planning, setting goals and following achievements) as well as continuous organisational improvement within and between involved health care providers (clearer functions and responsibilities, communication, evaluation)* |
| 1. Specific aims
 | *To increase use of diabetes control check-list as a MDS within diabetes registry.* |
| **Methods** | ***What will you do?*** |
| 1. Context
 | ***Political and legal****Unclear institutional responsibilities and mandates regarding eHealth and health information systems. There is relatively low awareness of the importance of standardised clinical practice and health information systems****CIPH****CIPH has an important role in strategic planning and implementation of pilot good practices. There is strong scientific evidence of efficiency of interventions with help of diabetes registries. CIPH holds diabetes registry and has a sustainable source of funding. Although, improved reporting practices, if not maintained with good quality feedback to data source tend to decrease in data quality over time (coverage, timeliness, accuracy etc.)****Health care providers****In Croatia, all GPs using “diabetes panel” module within their EHRs. The MDS of diabetes panel is not aligned with CroDiab. The data structure of diabetes panel module within EHR in GPS is easily modifiable and affordable. Although health professionals are educated through various educational platforms which regularly cover diabetes topics, they are generally overworked, not sufficiently informed on panels and how to use them, also some parameters in the “diabetes panel” module are not equally available for all them.****Patients****Diabetes patients are generally highly motivated to attend regular check-ups. There is potentially high interest of diabetic patients to have a better insight in personal health history, status, therapeutic plans, goals and personal achievements. There is relatively low interest of patients in “internal” organisational issues within health care system. Diabetes patients are generally poorly aware of their rights and responsibilities as a diabetes patient, as well as their potential benefits from CroDiab.* |
| 1. Intervention(s)
 | *Target population consists of GPs which provide primary health care services to patients with diabetes. Not all the providers are using the same international MDS standard and are, therefore, not always providing data on their patients of a good quality. Intervention group will consist of 5 urban and 5 rural-area teams which will go through an education on MDS/registry and will get feedback on their previous MDS performance. Changes in their MDS performance will be used for quantifying effect of raising awareness effort. Control group will consist of 10 teams which will get information about project and their monitoring but will not get a feedback or an education by LIWG. Their performance will be used for controlling the potential confounding and estimating the effect of raising awareness effort. The third group, consisting of 10 randomly selected and allocated teams, will not receive an information that their panels will be monitored. That group will be used to indicate level of impact of all other factors that are not part of the intervention (any activity that may influence GPs diabetes care and that may occur simultaneously with project interventions).**The only initial prerequisite for all the groups will be equal distribution of urban and rural teams, while other characteristics will be monitored throughout the analysis. The performance of the selected diabetes QI in the beginning of the pilot will be compared with the performance 6 months after the initial screening. The following diabetes QI will be monitored: BMI, waist and hip circumference, fasting glucose, HbA1C, lipids fractions, albumin/creatinine ratio, systolic and diastolic blood pressure, smoking, alcohol consumption, feet examination and fundoscopic examinationIn parallel with this intervention, there will be an actions regarding the MDS standardization, panel improvement (to provide an insight into the health history of the patient) and patient education on their rights and responsibilities as a diabetes patient.* |
| 1. Study of the Intervention(s)
 | * Approach chosen for assessing the impact of the intervention(s) (quantitative or qualitative analyses)

*Pilot action plan with defined Improvement areas (Guideline 5.3) with special focus to key performance indicators**Number of teams will be chosen to receive education on registry and feedback with conducted analysis for their patients and data quality. Same number of teams will only receive information regarding project and information that their panels will be monitored during CHRODIS JA+ and additionally same number of teams will be analysed without any intervention. Change in teams’ baseline performance, measured by share of persons with regularly completed diabetes panel among diabetic patients in care, quality of diabetes panel completeness, and change of chosen diabetes QI within diabetes panel will be measured and assessed using quantitative analyses. Measures will be taken at two time points and compared within and between groups. Semi-structured interviews carried out before and after education will be assessed using qualitative methods.**As a part of the intervention on governance and education and training level LIWG platform will be used to enable influence on the stakeholders’ processes and activities. Changes in diabetes panel that enable higher level of agreement (or complete) with MDS and monitoring of health status history as well as improving awareness of GPs on and patients of potential benefits from MDS will be assessed using quantitative methods.* * Approach used to establish whether the observed outcomes were due to the intervention(s)

*Sampling method will control some potential confounding. When choosing teams to receive feedback with conducted analysis for their patients and data quality we will take into account rural/ urban ratio since it may influence accessibility of care, level of education and overwork. Other baseline performance characteristics (share of carried out panels, data quality etc.) and general characteristics (population they have in their care, urban-rural area etc.) will be controlled during analysis. Furthermore, we will have control group of teams which will receive information that their baseline performance will be monitored for the purpose of CHRODIS+ JA, but will not receive any feedback or planned education and other control group that will be only monitored through regular statistical data without and intervention. This will allow us to establish whether observed outcomes were due to the intervention, education and feedback, monitoring or due to some other factor concomitantly influencing the target population.* |
| 1. Measures
 | *- Share of persons with regularly completed diabetes panel among diabetic patients in care, by team and availability of accurate indicators**- Trend of chosen diabetes QI within diabetes panel**- Change in 1st and 2nd measure before and after the intervention**- Changes in diabetes panel structure and functionality* |
| 1. Chronogram
 | Expected timing of the activities of the Change package, scheduling the start and end month *The expected timing of the activities will be 12 months – 6 months for the intervention and 6 months for the follow-up. The activities of the Change package will start in December 2018 and end in December 2019.* |

**Appendix 2**

**Local implementation working group definition and stakeholders identification**

Functions and roles preferably covered by the LIWG are stated here. If certain function/role is not represented in LIWG, please give the argument, why.

|  |  |
| --- | --- |
| Functions/roles | Institution, name and surname |
| **Organizer**Plan, prepare, chair and run the group workshopsRun the secretariat (prepare agendas and minutes)Write reports | Croatian Institute of Public Health, Ivan Pristaš, Marija Švajda, Domina Vusio |
| **Experts**Provide knowledge and faculty on specific matters depending on the intervention selected | Croatian Institute of Public Health, Tamara Poljičanin, Marko Brkić, Marija Švajda |
| **Decision makers**Provide strategic visionSupport and sponsorship of the implementation processEliminate bottlenecks during the implementation process | Croatian Institute of Public Health, Tamara PoljičaninMinistry of Health, Dunja Skoko, Sanja KišCroatian Health Insurance Fund, Tatjana Bekić |
| **Front-line stakeholders**Give knowledge and expertise on real-life practice experienceChoose the right type of subject to implement Motivate and empower implementersEquip and support implementers to deal with the implementation | Croatian Family Physicians Coordination, Vjekoslava Amerl ŠakićAssociation of Teachers in General Practice / Family Medicine - Valerija Bralić Lang |
| **Implementers** (can be same individuals as the front-line professionals)Implement the intervention following the agreed planContinuously assess the implementation process Provide input and feedback to the local implementation group |  General practitioners Vjekoslava Amerl Šakić, Valerija Bralić Lang |
| **Patient representatives**Give the input during the pilot action development, implementation, monitoring and evaluation | Representative of diabetes patients associations, Zrinka Mach |

**Stakeholders identification**

Stakeholders are individuals, institutions or organizations that are in any way interested by the activity, program, intervention or policy promoted. In JA CHRODIS PLUS, the stakeholders are interested parties that can include institutions or organizations that come from different fields and distinct expertise and experience (health, education, social, employment, research and Information and Communication Technology (ICT) sectors, NGOs, patients and their associations and civil society, to be as enriching and comprehensive as possible. Although teams can vary in size and composition, each implementation site needs to include the appropriate persons in the group to ensure that all perspectives are covered.

According to the interest, influence and importance for success, the LIWG can consider different levels of involvement of the stakeholders:

Full participation. The stakeholder is fully involved in the decision-making process, but not as part of LIWG.

Consultation. The stakeholder is consulted during the decision-making process and its opinions are then discussed within the LIWG.

Information. The stakeholder is fully informed on decisions and decision-making process.

Passivity. The stakeholder is briefly informed.

|  |  |
| --- | --- |
| Stakeholder | Level of involvement (full participation, consultation, information, passive recipient of the information) |
| Croatian Institute of Public Health (CIPH) | full participation |
| Croatian Ministry of Health (MoH) | full participation |
| Croatian Health Insurance Fund (CHIF) | full participation |
| GPs representatives | full participation |
| Patient representatives | consultation, information |
| Media | passive recipient of the information |

#

**Appendix 3**

**Scope definition**

Please, discuss and define the scope of the Pilot action using criteria from Quality Criteria and Recommendations (found at the back of the document).

You may discuss and define the scope from the focus of all of the criteria, or only the selected criteria that you find the most useful. However, report also arguments, why other criteria were not seen as useful.

Please, keep in mind that Practice design, Target population empowerment, Education and training to promote empowerment and Sustainability and scalability are obligatory for all Pilot actions.

Please check, that at least one of the three criteria from the management perspective (Governance, Interaction with regular and relevant systems or Evaluation) is included.

|  |  |
| --- | --- |
| Item | Description |
| Problem/challenge | Relatively low recorded secondary prevention activities in diabetes in general practitioner teams |
| General purpose of the intervention | To increase use of diabetes control check-list as a tool for improvement of health care in diabetes and minimum dataset within diabetes registry  |
| Target population | All Croatian general practitioners |
| Quality criteria  | **1. Governance**Minimum common data set aligned with international standards and mutually between systems. Clearly defined institutional responsibilities and mandates regarding eHealth and health information systems in Croatia.**2. Practice design**Info to general practitioners on the current and expected use of diabetes control check-list as a minimum dataset within diabetes registry.**3.Target population empowerment** Info on available services at primary health care level (GPs) and the expected benefits and empowerment for their regular use.**4. Education and training**Education and feedback to data sources on their performance and QI.**5. Sustainability and scalability**Ensured sustainable check lists usage and diabetes registry holding. |

# Appendix 4

# SWOT analysis

Based on the scope as defined previously, please perform SWOT analysis of the context of Pilot action using criteria from Quality Criteria and Recommendations (found at the back of the document).You may perform the SWOT from the focus of all of the criteria, or only the selected criteria that you find the most useful. However, report also arguments, why other criteria were not seen as useful. Please, keep in mind that Practice design, Target population empowerment, Education and training to promote empowerment and Sustainability and scalability are obligatory for all Pilot actions. Please check, that at least one of the three criteria from the management perspective (Governance, Interaction with regular and relevant systems or Evaluation) is included.

|  |  |  |
| --- | --- | --- |
|  | **STRENGHTS** | **WEAKNESSES** |
| **INTERNAL**  | **Governance**- 3 years of available routine data collected from EHRs in GPs**Practice design**- “Diabetes panel” module is a useful decision-making tool which meets the administrative needs of Croatian Health Insurance Fund- All GPs are using “diabetes panel” module within their EHRs**Target population empowerment** - GPs are motivated to participate in development of tool to help them in efficient monitoring of diabetic patients **Education and training**- there is system of continuous health professionals education in place that can be used for the pilot purpose- general practitioners are educated through various educational platforms which regularly cover diabetes topics- diabetes patients are generally highly motivated to attend regular check-ups**Sustainability and scalability**- CIPH has an important role in strategic planning and implementation of pilot good practices**Ethical considerations**-“Diabetes panel” module burden is addressed and it has positive benefit to burden ratio | **Governance**- unclear institutional mandates in health information standards in Croatia**Practice design**- “Diabetes panel” module doesn’t provide an insight into the health history of the patient - GPs have no control over their work in the “diabetes panel” module-MDS of diabetes panel is not aligned with CroDiab**Target population empowerment** - some GPs are not informed on what the panels are and how to use them- GPs are generally overworked**Education and training**- diabetes is only until recently in the domain of general practitioners - guidelines for the GPs are constantly changing- diabetes patients are generally poorly aware of their rights and responsibilities as a diabetes patient- the importance of diabetes registry in quality of care not perceived by patients**Sustainability and scalability**- unclear institutional responsibilities and mandates regarding eHealth and health information systems**Ethical considerations**- the need for regular use of Diabetes panel” module is highest in the rural area where education is less frequent |
|  |  |  |

|  |  |  |
| --- | --- | --- |
|  | **OPPORTUNITIES** | **THREATS** |
| **EXTERNAL**  | **Governance**- decision supporting tools in GPs**Practice design**- easily modifiable data structure of diabetes panel module within EHR in GPs**Target population empowerment** - strong evidence of efficiency of interventions with help of diabetes registries**Education and training**- potentially high interest in insight of personal health history, status, goals and achievements of diabetic patients**Sustainability and scalability**- CIPH holds diabetes registry and has a sustainable source of funding**Ethical considerations**- through the education of patients awareness of module benefit can be increased with influence on the better treatment | **Governance**- relatively slow implementation of new technical solutions in GPs**Practice design**- relatively low awareness of the importance of standardised clinical practice and health information systems- some parameters in the “diabetes panel” module are not equally available for all GPs**Target population empowerment** - potentially low motivation due to topics that are covering basic clinical practice (such as “proper washing hands”)**Education and training**- relatively low interest of patients in “internal” organisational issues within health care system**Sustainability and scalability**- decrease in data quality over time (coverage, timeliness, accuracy etc.) due to lack of feedback from reporting authorities |
|  |  |  |
|  |  |

# Appendix 5

# Identification of improvement areas

Based on the SWOT analysis, please

1. Identify potential improvement areas (strategic actions) that will be included in the Pilot action using criteria from Quality Criteria and Recommendations (found at the back of the document). They usually stem out of identified weaknesses of the practice, having in mind the threats as barriers that are outside the control of the LIWG. Improvement areas build on identified strengths as well as on opportunities; although the latest are beyond control of the LIWG, but are potentially helpful.

You may identify improvement areas from the focus of all of the criteria, or only the selected criteria that you find the most useful. However, report also arguments, why other criteria were not seen as useful.

Please, keep in mind that Practice design, Target population empowerment, Education and training to promote empowerment and Sustainability and scalability are obligatory for all Pilot actions. Please check, that at least one of the three criteria from the management perspective (Governance, Interaction with regular and relevant systems or Evaluation) is included.

b) List the potential improvement areas that you have found to be important. You can list as many as you want.

c) Then, score the improvement areas according to their priority (1 = lowest priority, 3= highest priority). Please rank according to the importance those with the highest priority. Agree in LIWG, which of the improvement areas with highest priority and with high rank of importance will be addresses in the Pilot Action Plan (key priorities).

|  |  |  |
| --- | --- | --- |
| Improvement areas | Priority score (1-3) | Ranking |
| * *At decision making level align MDS with international standards and mutually between systems and clearly define institutional responsibilities and mandates regarding eHealth and health information systems in Croatia.*
 | 3 | 1 |
| * *Prepare recommendation for raising awareness of GPs and patients regarding MDS for future implementation*
 | 3 | 2 |
| * *Improving awareness of GPs on potential benefits from MDS and CroDiab, i.e. try to raise awareness of the importance of standardised clinical practice and health information systems*
 | 2 | 3 |
| * *Improving awareness of patients with diabetes on their potential benefits from CroDiab and how to participate within health care system organisation in order to improve their health outcomes.*
 | 1 | 4 |

# Appendix 6

# Pilot action plan in Improvement area (s)

Based on the improvement areas that you identified in the previous step, please design the Pilot action plan:

1. Describe the improvement area
2. Define the objective (s)
3. List the activities (Change package), that you find necessary and feasible to reach the objective(s)
4. Identify the person(s) involved and the one that is responsible
5. Define timeline for all the activities
6. Define the Key performance indicator(s)

You may define elements of pilot action plan from the focus of all of the criteria, or only the selected criteria that you find the most useful. However, report also arguments, why other criteria were not seen as useful.

Please, keep in mind that Practice design, Target population empowerment, Education and training to promote empowerment and Sustainability and scalability are obligatory for all Pilot actions. Please check, that at least one of the three criteria from the management perspective (Governance, Interaction with regular and relevant systems or Evaluation) is included. Evaluation criteria may support the definition of key performance indicator(s).

Please note:

* Several improvement areas may have the same objectives
* It would be advisable that Pilot action plan includes maximum 2 objectives
* The same objective may be related to more improvement areas and to several different criteria
* Each objective may have one or more related activities in the change package

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Improvement area(s)** | **Objective(s)** | **Change Package**Describe the activities  | **Person(s) involved****/responsible** | **Timeline****(months)** | **Key performance indicator(s)** |
| **Align MDS with international standards and mutually between systems and clearly define institutional responsibilities and mandates regarding eHealth and health information systems in Croatia** | Raising awareness of the importance of standardised clinical practice and health information systems | Consultations with decision makers level | Croatian Institute of Public Health, Ivan Pristaš, Tamara Poljičanin, Ministry of Health, Dunja Skoko Poljak, Croatian Health Insurance Fund, Tatjana Bekić | 12 months | Changes in diabetes panel that enable higher level of agreement (or complete) with MDS |
| *Prepare recommendation for raising awareness of GPs and patients regarding MDS for future implementation* | Exploring the most efficient way to raise awareness of GPs and patients through pilot activities | Based on the pilot results in coordination with GP and patients representative preparing the recommendations  | Croatian Institute of Public Health, Domina Vusio, Tamara Poljičanin, General practitioners - Vjekoslava Amerl Šakić, Valerija Bralić Lang, Representatives of diabetes patients associations, Zrinka Mach | 6 months | Prepared recommendation |
| **Improving awareness of GPs on potential benefits from MDS and CroDiab** | Increasing the use of diabetes control check-list as a MDS within diabetes registry. | Organizing an education on potential benefits from MDS and CroDiab | Croatian Institute of Public Health, Marija Švajda, Marko Brkić, General practitioners - Vjekoslava Amerl Šakić, Valerija Bralić Lang,  | 6 months | Share of completed diabetes panels, change in quality of chosen diabetes QI within diabetes panel |
| **Improving awareness of patients with diabetes on their potential benefits from CroDiab and how to participate within health care system organisation in order to improve their health outcomes** | Good quality of recorded and captured data | Making a brochure on rights and responsibilities of diabetes patients | Croatian Institute of Public Health, Marija Švajda, Tamara Poljičanin, General practitioners - Vjekoslava Amerl Šakić, Valerija Bralić Lang, Representatives of diabetes patients associations, Zrinka Mach | 6 months | Share of persons with regularly completed diabetes panel among diabetic patients in care |

**Appendix 7**

**Quality Criteria and Recommendations to improve care for people with chronic diseases (QCR Tool)**

Ref***:*** [***http://chrodis.eu/wp-content/uploads/2017/02/wp7-deliverable-recommendations-final-draft.pdf***](http://chrodis.eu/wp-content/uploads/2017/02/wp7-deliverable-recommendations-final-draft.pdf)

|  |  |
| --- | --- |
| **Criteria**  | **Categories** |
| **Practice design** | The practice aims, objectives and methods were clearly specified |
| The design builds upon relevant data, theory, context, evidence, previous practice including pilot studies |
| The structure, organization and content of the practice were defined, and established together with the target population |
| There was a clear description of the target population (i.e. exclusion and inclusion criteria and the estimated number of participants) |
| The practice includes an adequate estimation of the human resources, material and budget requirements in clear relation with committed tasks |
| There was a clear description of the target population, carers and professionals specific role |
| 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) |
|   |   |
| **Target population empowerment** | 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). |
| The practice considered all stakeholders needs in terms of enhancing/acquiring the right skills, knowledge and behaviour to promote target population empowerment (target population, carers, health and care professionals, policy makers, etc.)  |
|   |   |
| **Evaluation** | The evaluation outcomes were linked to action to foster continuous learning and/or improvement and/or to reshape the practice |
| Evaluation outcomes and monitoring were shared among relevant stakeholders  |
| Evaluation outcomes were linked to the stated goals and objectives  |
| Evaluation took into account social and economic aspects from both target population, and formal and informal caregiver perspectives |
|   |   |
| **Comprehensiveness of the practice** | The practice has considered relevant evidence on effectiveness, cost-effectiveness, quality, safety, etc. |
| The practice has considered the main contextual indicators |
| The practice has considered the underlying risks of the target population (i.e. validated tools to individual risk assessment) |
|   |   |
| **Education and training** | Educational elements are included in the practice to promote the empowerment of the target population (e.g. strengthen their health literacy, self-management, and stress management….etc.) |
| Relevant professionals and experts are trained to support target population empowerment |
| Trainers/educators are qualified in terms of knowledge, techniques and approaches |
|   |   |
| **Ethical considerations** | The practice is implemented equitably (i.e. proportional to needs) |
| The practice objectives and strategy are transparent to the target population and stakeholders involved |
| Potential burdens of the practice (i.e. psychosocial, affordability, accessibility, etc.) are addressed, and there is a balance between benefit and burden |
| Target population rights to be informed, to decide about their care, participation and issues regarding confidentiality, were respected and enhanced |
|   |   |
| **Governance** | The practice included organizational elements, identifying the necessary actions to remove legal, managerial, and financial or skill barriers |
| The contribution of the target population, carers and professionals was appropriately planned, supported and resourced |
| The practice offers a model of efficient leadership |
| The practice creates ownership among the target population and several stakeholders considering multidisciplinary, multi-/inter-sectorial, partnerships and alliances, if appropriate. |
| There was a defined strategy to align staff incentives and motivation with the practice objectives |
| The best evidence and documentation supporting the practice (guidelines, protocols, etc.) was easily available for relevant stakeholders (e.g professionals and target populations) |
| Multidisciplinary approach for practices is supported by the appropriate stakeholders (e.g professionals associations, institutions etc) |
| 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) |
| 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 |
|   |   |
| **Interaction with regular and relevant systems** | The practice was integrated or fully interacting with the regular health, care and/or further relevant systems |
| The practice enables effective linkages across all relevant decision makers and stakeholders  |
| The practice enhances and supports the target populations ability to effectively interact with the regular, relevant systems |
|   |   |
| **Sustainability and scalability**  | The continuation of the practice has been ensured through institutional anchoring and/or ownership by the relevant stakeholders or communities |
| The sustainability strategy considered a range of contextual factors (e.g. health and social policies, innovation, cultural trends and general economy, epidemiological trends). |
| There is broad support for the practice amongst those who implemented it |
| Potential impact on the population targeted (if scaled up) is assessed. |
|  |   |

## Annex 2: Intermediary evaluation report

Intermediate evaluation of Pilot Action against criteria and categories to assess the quality of Pilot Action practices of JA CHRODIS PLUS in WP. Criteria and categories are ranked by weight.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Criteria**  | **Criteria Weight**  | **Categories** | **Category Weight**  | **Current practice****fulfils this category****(yes/no)** | **Justification/explanation of the answer****(a few sentences)** | **Potential improvement of the current practice to achieve the category, if not yet achieved** |
| **Practice design** | 14 | The practice aims, objectives and methods were clearly specified | 19 | Yes |  |  |
| The design builds upon relevant data, theory, context, evidence, previous practice including pilot studies | 18 | Yes | It builds upon research already referenced in WP7 Pilot Action Plan Reporting Croatia and analysis of available panel data |  |
| The structure, organization and content of the practice were defined, and established together with the target population | 14 | Yes | Croatian Family Physicians Coordination, Association of Teachers in General Practice / Family Medicine and 2 GPs were included |  |
| There was a clear description of the target population (i.e. exclusion and inclusion criteria and the estimated number of participants) | 13 | Yes | As referenced in WP7 Pilot Action Plan Reporting Croatia (2.2.2.) |  |
| The practice includes an adequate estimation of the human resources, material and budget requirements in clear relation with committed tasks | 13 | Yes |  |  |
| There was a clear description of the target population, carers and professionals specific role | 12 | Yes |  |  |
| 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 | Yes | Rural-urban area; since the sample is small, we did not want to control too many variables | With more resources (time, money, people) we would be able to cover bigger sample |
|   |   |   | 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 | Yes | GPs representatives included, they gave us feedback on their experiences and needs  |  |
| 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 | Yes | Stakeholders’ representatives (GPs, patients, NHI, MOH) included in all processes and all decisions were made in collaboration with stakeholder |  |
|   |   |   | 100 |  |  |  |
| **Evaluation** | 13 | The evaluation outcomes were linked to action to foster continuous learning and/or improvement and/or to reshape the practice | 31 | No |  | The goal is to link evaluation outcomes to action, which we hope would be realized at the end of the pilot phase |
| Evaluation outcomes and monitoring were shared among relevant stakeholders  | 26 | No |  | Still in the phase of conducting the pilot; it will be shared after we are done with the pilot |
| Evaluation outcomes were linked to the stated goals and objectives  | 25 | No |  | It will be after conducting the pilot |
| 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 | Yes |  |  |
| 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 | Yes | Education of both patients and GPs is the part of the pilot |  |
| Relevant professionals and experts are trained to support target population empowerment | 30 | Yes | Experts from CIPH are going to train target population  |  |
| Trainers/educators are qualified in terms of knowledge, techniques and approaches | 30 | Yes | Experts from CIPH are going to train target population |  |
|   |   |   | 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 | No |  | Depends on the outcomes of the Pilot. If the outcome was good, we plan to do population impact assessment. |
| **Total**  | **100** |   | 100 |  |  |  |

Intermediate evaluation of Pilot Action Practice according to key performance indicators, as defined by Pilot Action Plan

to be prepared by 11th March 2019 and sent to Valentina Strammiello (valentina.strammiello@eu-patient.eu),

Jelka Zaletel (jelka.zaletel@kclj.si ) and Marina Maggini (marina.maggini@iss.it ) and to be included in the Individual

Pilot Action Plan Report at the end of the implementation period.

Please select at least two KPIs from those reported in your Pilot Action Plan

Key performance Indicator 1 [from your Pilot Action Plan]

Definition: Changes in diabetes panel that enable higher level of agreement (or complete) with MDS

At the time of reporting, this indicator is achieved: yes/no

Action(-s) suggested by Partner for improvement related to this indicator:

Key performance Indicator 2 [from your Pilot Action Plan]

Definition: Share of persons with regularly completed diabetes panel among diabetic patients in care, by team and availability of accurate indicators

At the time of reporting, this indicator is achieved: yes/no

Action(-s) suggested by Partner for improvement related to this indicator:

- Education of GP’s

- Education of patients - empowerment

- Activation of financial mechanism on NHI that support panels

Intermediate evaluation of Pilot Action Practice according to indicators that reflect patient involvement

to be prepared by 11th March 2019 and sent to Valentina Strammiello (valentina.strammiello@eu-patient.eu),

Jelka Zaletel (jelka.zaletel@kclj.si ) and Marina Maggini (marina.maggini@iss.it ) and to be included in the Individual

Pilot Action Plan Report at the end of the implementation period.

Patient Involvement Indicator 1 [See your Concept Note and select one]

Definition: At least two representatives of patients/target populations are involved in the identification of the needs/barriers in services access/quality (through a preliminary assessment or during mid-term monitoring);

At the time of reporting, this indicator is achieved: yes/no

Action(-s) suggested by Partner for improvement related to this indicator:

- Ensured through LIWG since a one member is HSDU president

Patient involvement Indicator 2 [See your Concept Note and select one]

Definition: Patients/Target populations receive feedback on the final outcomes of the work done by the LIWG and what happens with their contribution (written feedback is shared with involved representatives and the wider community with examples of success stories);

At the time of reporting, this indicator is achieved: yes/no

Action(-s) suggested by Partner for improvement related to this indicator:

-will be ensured through LIWG since a one member is HSDU president

Overall comments, suggestions and recommendations by Implementer:

## Annex 3: Study visit report

**Rationale of the Pilot:**

In Croatia, there are around 2300 general practitioner teams (GPs) providing primary health care services to more than 300.000 patients with diabetes. Within around 100 of stationary healthcare institutions on secondary and tertiary level there are 7 clinical hospital centres seated in biggest Croatian cities that are providing diabetologist and multi-professional expertise services to the patients with longer history of diabetes and developing multiple complications i.e. comorbidities. All those healthcare providers are required to use internationally accepted health information standards within the field of diabetes using Minimum Data Set (MDS) as part of their routine check-list practice for periodic examination of patients with diabetes as part of secondary health care preventive services. Nevertheless, due to non-consistent health information standards on process and semantic level, not all the providers are using the same international MDS standard and are not providing good quality data (coverage, reliability, accuracy, transparency, timeliness and relevance) on their patients. Therefore, there is an assumption that not all the patients with diabetes are being treated equally, by the same clinical standards and led through clinical pathways providing similar outcomes. There is strong evidence that well established electronic patient registries improve quality indicators of diabetes control at population level. The LIWG strongly believes that causal relationship is due to better insight in patients’ health status, improved health care delivery processes (more of and better quality reminders, education, recording information and reporting) and better patient compliance (therapeutic planning, setting goals and following achievements) as well as continuous organisational improvement within and between involved health care providers (clearer functions and responsibilities, communication, evaluation).

**JA CHRODIS recommendations and criteria - usability, scalability & sustainability**

In terms of usability of JA CHRODIS recommendations and criteria: the LIWG in Croatia shared that it was not really usable for them at this stage, however it was always at the back of their mind when designing and developing the practice. They believed that this tool, developed during the last JA, could be used across countries. They appreciate the tool, however the LIWG needed some education/instructions/manual on how to use the JA CHRODIS recommendations and criteria. The LIWG in Croatia mentioned once again that the tool should be accompanied with a manual.

“JA CHRODIS recommendations and criteria are very useful for controlling communicable diseases and the tool should be improved, however it seems challengeable to be used in country specific countries and contexts. The tool is useful for drafting and writing implementation and additional explanation of each category and examples and he is searching for it now.”

According to the LIWG the native language could be an issue, as non-native English speakers can understand the category completely differently. However, the LIWG had the approach that the categories should be understood in relative terms. Furthermore, the discussions happening during the days of the study visit contributed to understanding the JA CHRODIS recommendations and criteria better and also matching what’s happening in their pilot with the JA CHRODIS recommendations and criteria.

To the question: “If you would not be using the JA CHRODIS recommendations and criteria – what would be different for your work?”

They saw the JA CHRODIS recommendations and criteria as a systematic one. The pilot action would differ how they were different and JA CHRODIS recommendations and criteria are a contact reminder how to write it. It benefits the project and when you have a lot of countries and there is a need to have something like the tool, and it would be much harder without the tool both for implementers and coordinators. There is always a risk to overlook the important parts of the project, however the tool is the guidance. It is a reminder to come back to the categories and to revisit the pilot over and over again.

In terms of sustainability and scalability, the JA CHRODIS recommendations and criteria are a great guidance, the Croatian LIWG see it as some sort of a checklist, mostly to evaluate/define if a practice is a good practice and we developed recommendations…it would be useful to go to the template several times, not only one or twice. We have their plan and we know their plan. The LIWG have to go back and check once again all categories and subcategories. One can use the tool to narrow down the work done. Finally, as with all study visit, the completing the evaluation template would be repeated before the final reporting.

It was important to communicate the difficulties the Croatian team had when filling in the intermediate evaluation; the main complaint was that some categories implied the evaluation of already finished project, and Croatian pilot field research will start in April 2019. Then WP7 leaders and EPF representatives explained that the JA CHRODIS recommendations and criteria are there to navigate and acts like a kind of checklist which checks if everything is covered by the Pilot Action Plan. Evaluation should be conducted in different phases of the project, and that way it should serve as a measurer of quality indicators. The LIWG reached the conclusion that If they track their indicators, they will be aware of how the project develops, and then they can identify if some indicators are not specific enough. It was agreed that it is important to be internally consistent when filling in the Evaluation (e.g. it cannot be mentioned that there is a small sample, and in the Plan, and then report that their intervention will affect all GPs). Sustainability is very important part of the project, and it should be considered much before the project ends. Even in this phase of the project the LIWG should think about what will happen after the project – how are the results going to be disseminated, what type of meetings are going to be organized and who will be presenting the final results.

**Selected PAP KPIs:**

KPI 1 - Definition: Changes in diabetes panel that enable higher level of agreement (or complete) with MDS.
Self-reported status prior the study visit: **not achieved yet.**
KPI 2 - Definition: Share of persons with regularly completed diabetes panel among diabetic patients in care, by team and availability of accurate indicators.
Self-reported status prior the study visit: **not achieved yet.**

**Summary of patient involvement:**

In the Croatian study visit, the head of the national diabetes patient association was involved in the LIWG from the very beginning and the two of the main focus points were: prevention and patient education and participating in this pilot action was of key importance. During the study visit, there was a concrete discussion on the leaflet that was produced and it was aligned with the checklist and you saw the proposal and showed it to a small group with patients with diabetes and they provided feedback and the leaflet will be improved and now it is about dissemination and spreading the leaflet. During the preparation of the informative leaflet, a lot of challenges were encountered, as the LIWG was trying to adapt the leaflet in order to fit it with the needs of approximately 300 000 patients from different age groups and education background and one size does not fit all. There was an agreement that EPF could further assist and help the LIWG to reach out to more patients.

The LIWG has selected the following two indicators that were suggested as potential patient involvement indicators in advance and then self-assessed their own progress prior to the study visit:

Patient Involvement Indicator 1: *At least two representatives of patients/target populations are involved in the identification of the needs/barriers in services access/quality (through a preliminary assessment or during mid-term monitoring);
At the time of reporting, this indicator is achieved:* ***yes****/no*

Patient involvement Indicator 2: *Patients/Target populations receive feedback on the final outcomes of the work done by the LIWG and what happens with their contribution (written feedback is shared with involved representatives and the wider community with examples of success stories);
At the time of reporting, this indicator is achieved: yes/****no***

**Final Agenda - CHRODIS + WP7 Study Visit March 2019 Croatia**



**Participants**

|  |  |
| --- | --- |
| **Name** | **Institution** |
| Jelka Zaletel | Chrodis Plus, National Institute of Public Health Slovania |
| Marina Maggini | Chrodis Plus, Italian National Institute of Health |
| Zuzana Matlonova | Chrodis Plus, MoH Slovakia |
| Lyudmil Ninov | European Patients' Forum |
| Ivana Brkić Biloš | Croatian Institute of Public Health |
| Tamara Poljičanin | Croatian Institute of Public Health |
| Marko Brkić | Croatian Institute of Public Health |
| Ivan Pristaš | Croatian Institute of Public Health |
| Domina Vusio | Croatian Institute of Public Health |
| Marija Švajda | Croatian Institute of Public Health |
| Rui Louriero | European Health Futures Forum |
| Tatjana Bekić | Croatian Health Insurance Fund |
| Vjekoslava Amerl Šakić | GP |
| Valerija Bralić Lang | GP |
| Zrinka Mach | Croatian Alliance of Diabetes Associations  |
| Tereza Šarić | Promeritus Counselling Director |

## Annex 4: Final evaluation report

Key performance indicator indicator 1

Definition - Changes in diabetes panel that enable higher level of agreement (or complete) with MDS; LIWG defined/ approved final version of MDS and as a indicator comparison of defined MDS and MDS currentlly in used was performed.

At the time of reporting, this indicator is achived: yes/**no**

Interpretation and future suggestions action (-s) suggested by Partner with Pilot Action for improvement related to this indicator:

Notes – till the end of the project we hope that changes will be accepted by CHIF

Key performance indicator indicator 2

Definition - Share of persons with regularly completed diabetes panel among diabetic patients in care, by team and availability of accurate indicators (what data was collected, who was collecting the data, when was the data collected, how was the data collected /explain data sources and quantitative/qualitative methods used):

At the time of reporting, this indicator is achived: yes/no

Interpretation and future suggestions action (-s) suggested by Partner with Pilot Action for improvement related to this indicator:

Notes – analyses in progress

**Finall evaluation of Pilot Action implementation is reported also against JA CHRODIS set of Criteria**

Final evaluation of Pilot Action against criteria and categories to assess the quality of Pilot Action practices of JA CHRODIS PLUS in WP. Criteria and categories are ranked by weight.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Criteria**  | **Categories** | **Current practice****fulfills this category****(yes/no/partially)** | **Justification/explanation of the answer** | **Potential improvement of the current practice to achieve the category** |
| **Practice design** | The practice aims, objectives and methods were clearly specified | Yes | Methods were adjusted both to aim/ objective and data availability and quality | More comprehensive and detailed data and better data quality would enable the use of more sophisticated methods  |
| The design builds upon relevant data, theory, context, evidence, previous practice including pilot studies | Yes | It builds upon research already referenced in WP7 Pilot Action Plan Reporting Croatia and analysis of available panel data |  |
| The structure, organization and content of the practice were defined, and established together with the target population | Yes | Croatian Family Physicians Coordination, Association of Teachers in General Practice / Family Medicine and 2 GPs were included | Patients and doctors might have been included directly, and not through the representatives (gathering patients’ and doctors’ inputs directly through the focus groups) |
| There was a clear description of the target population (i.e. exclusion and inclusion criteria and the estimated number of participants) | Yes | Inclusion and exclusion criteria were clearly defined, and participants were randomly selected. |  |
| The practice includes an adequate estimation of the human resources, material and budget requirements in clear relation with committed tasks | Yes | The estimation of the human resources, material and budget requirements was in line with the total budget. |  |
| There was a clear description of the target population, carers and professionals specific role | Yes |  |  |
| 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) | Yes | Rural-urban area; since the sample is small, we did not want to control too many variables | With more resources (time, money, people) we would be able to cover bigger sample which would enable us to control for public GPs and GPs in concession  |
|   |   |  |  |  |
| **Target population empowerment** | 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). | Yes | GPs representatives included, they gave us feedback on their experiences and needs. GPs are left with educational leaflets for patients.  |  |
| 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.)  | Yes | Stakeholders’ representatives (GPs, patients, NHI, MOH) included in all processes and all decisions were made in collaboration with stakeholders. | Diabetologists, due to organizational issues in diabetologists associations, were not formally included.Nurses were not included in the project, partly because they do not have formal associations in primary healthcare that would represent them. However, the pilot research showed they have major role in communicating with diabetic patients and data input. |
|   |   |  |  |  |
| **Evaluation** | The evaluation outcomes were linked to action to foster continuous learning and/or improvement and/or to reshape the practice | Yes | The goal is to link evaluation outcomes to action, which would be realized at the end of the pilot phase. |  |
| Evaluation outcomes and monitoring were shared among relevant stakeholders  | Yes | Evaluation outcomes and monitoring will be shared with relevant stakeholders after we are done with the pilot.  | Due to organizational issues in diabetologists associations, they were not formally included, but the results of this pilot action will be shared with them.  |
| Evaluation outcomes were linked to the stated goals and objectives  | Yes  | It will be after conducting the pilot. |  |
| Evaluation took into account social and economic aspects from both target population, and formal and informal caregiver perspectives | Yes  |  |  |
|   |   |  |  |  |
| **Comprehensiveness of the practice** | The practice has considered relevant evidence on effectiveness, cost-effectiveness, quality, safety, etc. |  |  |  |
| The practice has considered the main contextual indicators |  |  |  |
| The practice has considered the underlying risks of the target population (i.e. validated tools to individual risk assessment) |  |  |  |
|   |   |  |  |  |
| **Education and training** | 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. ) | Yes | Education of both patients and GPs is the part of the pilot | Additional education of nurses would be advisable due to their involvement in the whole process.  |
| Relevant professionals and experts are trained to support target population empowerment | Yes | Experts from Croatian Institute of Public Health have educated GPs that have been the part of intervention group. | After analysing the results, Croatian Institute of Public Health will make guidelines/ propositions for education of both GPs and nurses, on national level. |
| Trainers/educators are qualified in terms of knowledge, techniques and approaches | Yes |  |  |
|   |   |  |  |  |
| **Ethical considerations** | The practice is implemented equitably (i.e. proportional to needs) |  |  |  |
| The practice objectives and strategy are transparent to the target population and stakeholders involved |  |  |  |
| Potential burdens of the practice (i.e. psychosocial, affordability, accessibility, etc.) are addressed, and there is a balance between benefit and burden |  |  |  |
| Target population rights to be informed, to decide about their care, participation and issues regarding confidentiality, were respected and enhanced |  |  |  |
|   |   |  |  |  |
| **Governance** | The practice included organizational elements, identifying the necessary actions to remove legal, managerial, and financial or skill barriers |  |  |  |
| The contribution of the target population, carers and professionals was appropriately planned, supported and resourced |  |  |  |
| The practice offers a model of efficient leadership |  |  |  |
| The practice creates ownership among the target population and several stakeholders considering multidisciplinary, multi-/inter-sectorial, partnerships and alliances, if appropriate. |  |  |  |
| There was a defined strategy to align staff incentives and motivation with the practice objectives |  |  |  |
| The best evidence and documentation supporting the practice (guidelines, protocols, etc.) was easily available for relevant stakeholders (e.g professionals and target populations) |  |  |  |
| Multidisciplinary approach for practices is supported by the appropriate stakeholders (e.g professionals associations, institutions etc) |  |  |  |
| 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) |  |  |  |
| 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 |  |  |  |
|   |   |  |  |  |
| **Interaction with regular and relevant systems** | The practice was integrated or fully interacting with the regular health, care and/or further relevant systems |  |  |  |
| The practice enables effective linkages across all relevant decision makers and stakeholders  |  |  |  |
| The practice enhances and supports the target populations ability to effectively interact with the regular, relevant systems |  |  |  |
|   |   |  |  |  |
| **Sustainability and scalability**  | The continuation of the practice has been ensured through institutional anchoring and/or ownership by the relevant stakeholders or communities | Yes/ No | We are preparing scripts that would enable us the automatization of generating feedback to the GPs, about their panel data. | We will give the recommendations of implementing that feedback into GPs central health records system. However, here we need the support from Croatian Health Insurance Fund. Based on the intervention results, guidelines for the education on national level will be made.  |
| The sustainability strategy considered a range of contextual factors (e.g.health and social policies, innovation, cultural trends and general economy, epidemiological trends). | Yes | One of the KPI’s are changes in diabetes panel that enable higher level of agreement with MDS.  |  |
| There is broad support for the practice amongst those who implemented it | Yes |  |  |
| Potential impact on the population targeted (if scaled up) is assessed. |  |  | Not applicable because our pilot action does not focus on this perspective but we plan to present the results of the pilot action to the ones who will then do a population impact assessment. |
| **Total**  |   |  |  |  |

## Annex 5: Barriers and Enablers identified during the implementation of selected***Quality Criteria and Recommendations,*** and Suggestions for future implementations

|  |  |  |  |
| --- | --- | --- | --- |
| **Quality Criteria and Recommendations** | **Barriers** | **Enablers** | **Suggestions for future Implementations** |
| **1. Practice design** | * More comprehensive and detailed data and better data quality would enable the use of more sophisticated methods
* MDDS module doesn’t provide an insight into the health history of the patient
* GPs have no control over their work in the MDDS module
* MDDS is not aligned with CroDiab
* Relatively low awareness of the importance of standardized clinical practice and health information systems
* Some parameters in the MDDS module are not equally available for all GPs
 | * Large quantity of available data - all GPs are using MDDS module within their EHRs
* Lots of stakeholders included – lots of different perspectives
* Clear definition of target population
* Both GPs and patients included
* Rural-urban area sample
 | * Patients and doctors might have been included directly, and not through the representatives (gathering patients’ and doctors’ inputs directly through the focus groups)
* With more resources (time, money, people) we would be able to cover bigger sample which would enable us to control for public GPs and GPs in concession
 |
| **2.Target population empowerment**  | * Diabetologists, due to organizational issues in diabetologists associations, were not formally included.
* Nurses were not included in the project, partly because they do not have formal associations in primary healthcare that would represent them. However, the pilot research showed they have major role in communicating with patients with diabetes and data input.
 | * Stakeholders’ representatives (GPs, patients, NHI, MOH) included in all processes and all decisions were made in collaboration with them.
* GPs are motivated to participate in development of tool to help them in efficient monitoring of patients with diabetes
* Strong evidence of efficiency of interventions with help of diabetes registries
 | * Find a way to include diabetologists and nurses, regardless of the organizational issues.
 |
| **3. Evaluation** | * Due to organizational issues in diabetologists associations, they were not formally included, but the results of this pilot action will be shared with them.
 | * Evaluation outcomes are linked to action
* Evaluation outcomes and monitoring will be shared with relevant stakeholders
 |  |
| **4. Comprehensiveness of the practice** |  |  |  |
| **5. Education and training** | * Intervention showed that nurses have a major role in dealing with patients with diabetes and data input, but they were not educated.
 | * Education of both patients and GPs
* Experts from Croatian Institute of Public Health have educated GPs that have been the part of intervention group.
 | * Additional education of nurses would be advisable due to their involvement in the whole process.
 |
| **6. Ethical considerations** | * The need for regular use of MDDS module is highest in the rural area where education is less frequent
 | * MDDS module burden is addressed and it has positive benefit to burden ratio
 |  |
| **7. Governance** | * Unclear institutional mandates in health information standards in Croatia
* Relatively slow implementation of new technical solutions in GPs
 | * 3 years of available routine data collected from EHRs in GPs
 |  |
| **8.Interaction with regular and relevant systems** |  |  |  |
| **9.Sustainability and scalability** | * Unclear institutional responsibilities and mandates regarding eHealth and health information systems
* Decrease in data quality over time (coverage, timeliness, accuracy etc.) due to lack of feedback from reporting authorities
 | * Scripts that would enable the automatization of generating feedback to the GPs, about their MDDS data.
* We will give the recommendations of implementing the feedback into GPs central health records system. However, here we need the support from Croatian Health Insurance Fund. Based on the intervention results, guidelines for the education on national level will be made.
 | * Changes in MDDS, which are one of the objectives of this project, would enable higher level of agreement with internationally accepted minimum data set.
 |

## Annex 6: Sustainability and Replicability/Transferability

**The continuation of the practice has been ensured through institutional anchoring and/or ownership by the relevant stakeholders or communities:**

MDDS and the Registry have from before been a part of CHIF’s and CIPH’s regulatory system. The Registry is regulated by law and it is obligatory for all doctors. We have used current framework as a starting point, in order to ensure sustainability. All changes have been implemented in amending bylaw acts, that is internal stakeholders’ procedures (feedback to GPs from CHIF).

**The sustainability strategy considered a range of contextual factors (e.g. health and social policies, innovation, cultural trends and general economy, epidemiological trends).**

We have used mechanisms (CIPH, Ministry of Health, CHIF) that cover all Croatian residents, so that everyone can benefit from changes we will introduce.

**There is broad support for the practice amongst those who implemented it**

LIWG has included all stakeholders.

**Potential impact on the population targeted (if scaled up) is assessed.**

Number of patients covered by MDDS has increased.

*You may also describe your results from these perspectives:*

**Institutional: describe if, as effect of the activities, there was a further involvement of key institutions at the sub national and national level and the related effects in terms of strategies, policies regarding the project’s objectives and expected results;**

National committee for strategy and treatment of patients with diabetes will include the results into strategy of treatment.

**Stakeholder’s involvement: describe the involvement of beneficiaries, institutions and actors important for the development and continuation of the activities beyond the implementation;**

Through LIWG and National committee for strategy and treatment of patients with diabetes, all stakeholders were included.

**Intersectoral collaboration: if relevant, describe the involvement of relevant sectors (health, social, community, others);**

**Allocation of Resources: describe if, as effect of the project activities, funding and resources were allocated to continue the activities beyond the implementation;**

At the moment, no funding and resources were allocated to continue the activities beyond the implementation. However, activities in that direction have been initiated and they will be continued.

**Organizational changes: describe if, as effect of the activities, decisions of changes in the design and delivery of services were taken.**

Decisions of changes in the design and delivery of services have been changed through the changes in MDDS.

**Replicability/Transferability: a successful transferability of the practice maybe facilitated by a clear definition of the context, sustainability, intersectorality and participation of stakeholders.**

This project can be replicated in other countries, or on other MDDS.

## Annex 7: Essential elements of pilot action report

Please describe the component(s) of the **Quality Criteria and Recommendations** implemented:

* Study design relied upon large quantity of available MDDS data. Thanks to multiple stakeholders included, whole range of different perspectives was covered.
* Target population (GPs) was empowered by education on MDDS usage and active participation in professional training. Stakeholders’ representatives were included in all processes. Experts from Croatian Institute of Public Health have educated GPs that have been the part of intervention group.
* The outcomes and monitoring will be shared with all relevant stakeholders.
* The practice was implemented equitably. MDDS module burden was addressed and it had positive benefit to burden ratio. The objectives and strategy were transparent to both target population and stakeholders involved.
* The continuation of the practice was ensured by changes in MDDS, which would enable higher level of agreement with internationally accepted minimum data set.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **General Objective (Specific Aim):** to improve the management of diabetes according to international standards | **Process Indicators** | **Outcome****Indicators** | **Outcome****Indicators** | **Sources of information** |
|  |  | **Baseline**(2018) | **Current value**(2019) |  |
| **Specific Objectives*** **SO1.** Toimprove GPs awareness and practice in diabetes monitoring
* **SO2.** To improve patients understanding on the importance of yearly check-ups

**SO3.** To harmonize diabetes information systems and coordination mechanisms according to international standards  |  | * Average

number of patients with filled MDDS per GP (20.2)  | * Average number of patients with filled MDDS per GP (30.8)
* Representatives of Patients Associations participated through all phases of the implementation
* Revised Croatian Health Insurance Fund specification; specification of additional chapter regarding diabetes in Yellow book
 | * Semi-structured qualitative interviews with GPs
* Databases that are part of diabetes registry
* Minutes from talks with patient representatives/ other stakeholders
* Leaflets of regular diabetes monitoring
* Croatian Conference of People with Diabetes proceedings
* “Dijabetes” magazine articles
* JA-CHRODIS Recommendations document
 |
| **Activities (change package)*** **SO1**

1.1 Qualitative interviews to explore GPs attitudes towards MDDS1.2 Develop educational material and train GPs on the use of MDDS1.3 Develop and disseminate feedback reports to GPs about their work  | * 8/10 GPs trained on MDDS /expected
* 8/10 qualitative interviews with GPs conducted/planned
* Elaborated feedback report template
 | * Average number of patients with fulfilled MDDS per GP (20.2)
 | * Average number of patients with fulfilled MDDS per GP (30.8)
 | * Semi-structured qualitative interviews with GPs
* Databases that are part of diabetes registry
* Feedback reports to GPs
 |
| * **SO2**

2.1 Develop leaflets on the importance of regular diabetes monitoring 2.2 Distribute leaflets to patients through GP’s 2.3 Disseminate the information and material during the Croatian Conference of People with Diabetes2.4 Develop articles about importance of regular diabetes monitoring in “Dijabetes” magazine  | * 2000/ 2000 leaflets developed/ distributed for patients
* Information and leaflets disseminated during the Conference
* 30000/

30000 magazine distributed/ expected |  | • Representatives of Patients Associations participated through all phases of the implementation  | * Minutes from talks with patient representatives
* Leaflets of regular diabetes monitoring
* Croatian Conference of People with Diabetes proceedings
* “Dijabetes” magazine articles
 |
| * **SO3**

3.1 Align MDDS with international standard3.2 Define institutional responsibilities3.3 Strengthen coordination among stakeholders through LIWG platform | * Involved key stakeholders and Committees from National level
 | * Specification on MDDS by CHIF
* Yellow book
 | * Revised CHIF specification
* Specification of additional chapter regarding diabetes in Yellow book
 | * Minutes from meetings with GPs, experts, front-line stakeholders, National committee for strategy and treatment of patients with diabetes
* JA-CHRODIS Recommendations document
 |

Summarize the **mayor Barriers and Enablers** identified during the implementation of the **Quality Criteria and Recommendations**

**Enablers**

* JA CHRODIS recommendations and criteria were very helpful in the process of planning and it served as a navigator and check list which ensured that all important elements were covered by the practice. Besides, it **has eased** the project tracking in the execution phase, because it made us aware how the project develops, and helped to identify if some indicators were not specific enough.
* Large quantity of data was available and multiple stakeholders were involved in all processes.
* The target group in this research was very broad (patients and GPs; rural and urban areas were covered).
* The study generated recommendations for changes in GPs central health records system, which would contribute to better diabetes monitoring and better care for patients with diabetes.

**Barriers**

* The use of JA CHRODIS recommendations and criteria were a bit unclear during intermediate evaluation, since some categories implied the evaluation of already finished project, and Croatian pilot field research did not start at that moment. The wording of the tool was sometimes abstract and not clear.
* Due to organizational issues, some possible stakeholders were not formally included in the project (diabetologists and nurses).
* Awareness about the importance of standardized clinical practice and health information systems is relatively low. Even when the decision about implementation of new technical solutions in GPs practices is made, the implementation is still relatively slow.

Please describe the major **Results of the Implementations**

**-Benefits for Patients** (improved access to care, health status and quality of life):

* Patients were educated on their rights and responsibilities. Leaflets about importance of regular diabetes monitoring were developed and distributed.
* Qualified professionals from LIWG (GPs, patients, National Health Insurance Fund, Ministry of Health) participated in creating the leaflet in order to strengthen patients’ health literacy and self-management. The intervention was supposed to improve quality of care and to nudge patients into stronger involvement in treatment process and care.

**-Stakeholders and Policy Makers Involvement and Actions:**

* Through LIWG, different stakeholders were involved (CIPH, Ministry of Health, CHIF); that enabled involvement in all regular organizational processes, and usage of current frameworks and processes whenever possible.
* The National committee for strategy and treatment of patients with diabetes will include the results into a national strategy.

**Suggestions for future Implementations,** **Sustainability and Replicability/Transferability of the Quality Criteria and Recommendations**

* All important stakeholders and future implementors should be included through the LIWG.
* Involvement in all regular organizational processes should be ensured by using current frameworks and processes whenever possible.