

ORIGINAL ARTICLE / ОРИГИНАЛНИ РАД

Regulatory and clinical perspective on patient access to antidiabetic medicines in Slovenia

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SUMMARY

Introduction/Objective Three novel classes of antidiabetic medicines have been introduced into the market in the last decade, namely dipeptidyl peptidase-4 inhibitors, glucagon-like peptide-1 receptor agonists, and sodium-glucose co-transporter 2 inhibitors. Many factors influence patient access to these medicines and their utilization in clinical practice: these need to be explored.

The aim of the study was to gain an insight into patient access to antidiabetic medicines in Slovenia from a regulatory and clinical point of view.

Methods A focus group with five Slovenian experts (representatives of regulatory bodies and prescribers of antidiabetic medicines) was performed in January 2019. The discussion was audiotaped upon obtaining written consent from the experts and transformed into a verbatim transcript. Two researchers independently analyzed the content of the discussion, using NVivo 11 to identify main themes and subthemes.

Results Slovenia provides satisfactory patient access to antidiabetic medicines; however, prescribing restrictions and unequal access to diabetologists in the Slovenian regions may limit patient access to novel antidiabetic medicines. Prescribing restrictions should be aligned with the new evidence on cardiovascular benefit of some antidiabetic medicines. A national registry of patients with diabetes should be established in order to obtain reliable data on patient outcomes and improve the quality of patient care.

Conclusion Patient access to antidiabetic medicines could be significantly improved not only in Slovenia but also in other countries by changing prescribing restrictions, establishing national registries of patients with diabetes, and involving multidisciplinary teams in diabetes care.

Keywords: diabetes mellitus; antidiabetic medicines; patient access; focus groups; diabetes care

INTRODUCTION

Slovenia has a social Bismarck-type health insurance system, which is mainly financed through compulsory health insurance provided by the Health Insurance Institute of Slovenia (HIIS) and mainly funded by payroll taxes. The HIIS is also involved in medicine reimbursement decision-making. The Reimbursement Committee evaluates applications for medicine reimbursement and makes a recommendation, while the HIIS makes the final decision [1]. All antidiabetic medicines in Slovenia are fully covered by compulsory insurance; however, even for these medicines the HIIS can introduce various measures to control medicine expenditure, e.g., prescribing restrictions, reference pricing.

The estimated prevalence of diabetes in Slovenia is 6.9% and every year about 4.7 in 1000 people start antidiabetic therapy [2]. Three novel classes of antidiabetic medicines have obtained marketing authorization in the EU since 2006, namely dipeptidyl peptidase-4 inhibitors (DPP-4i), glucagon-like peptide-1 receptor agonists (GLP-1RA), and sodium-glucose co-transporter 2 inhibitors (SGLT2i). A recent study, which evaluated patient access to novel antidiabetic medicines in 11 European countries, showed that, in 2016, the proportion of novel antidiabetic medicines consumption in Slovenia was lower than in most other

European countries included in the study [3]. The uptake of novel antidiabetic medicines in Slovenia was similar to that in Sweden and Italy, accounting for less than 10% of total antidiabetic medicines consumption, while in Spain and Austria it accounted for more than 25%. There may be many factors affecting patient access to antidiabetic medicines in Slovenia that should be investigated in order to plan appropriate measures to optimize patient access to these medicines and their outcomes.

The aim of the study was to gain an insight into patient access to antidiabetic medicines in Slovenia from a regulatory and clinical point of view.

METHODS

A semi-structured focus group with five Slovenian experts was performed in January 2019. The Consolidated Criteria for reporting Qualitative Research (COREQ) were followed when conducting and reporting on this focus group [4].

Research team

The research team consisted of four members working in an academic environment: two faculty professors, a postdoctoral researcher with a PhD in pharmacoeconomics, and a

Received • Примљено:
January 25, 2021

Revised • Ревизија:
June 18, 2021

Accepted • Прихваћено:
June 30, 2021

Online first: July 2, 2021

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Table 1. A set of questions used to lead a discussion

<p>Patient access to antidiabetic medicines and utilization of antidiabetic medicines in Slovenia</p> <p>List positive aspects of patient access to antidiabetic medicines and utilization of antidiabetic medicines in Slovenia.</p> <ul style="list-style-type: none"> • From the clinical perspective • From the system perspective <p>List key challenges of patient access to antidiabetic medicines and utilization of antidiabetic medicines in Slovenia.</p> <ul style="list-style-type: none"> • From the clinical perspective • From the system perspective <p>Influence of differences in patient access to antidiabetic medicines on health outcomes</p> <p>What impact do differences in patient access to antidiabetic medicines have on health outcomes?</p> <p>Opportunities for improvement</p> <p>What are the most important measures to improve patient access to antidiabetic medicines and diabetes management in Slovenia?</p> <ul style="list-style-type: none"> • At system level • At clinical practice level
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second-year doctoral student. The researchers are familiar with qualitative study designs and have conducted several focus groups and other types of qualitative studies [5, 6, 7].

Selection of participants

A purposive sampling technique was used with the aim to gather a heterogeneous group of experts who do not only have an in-depth insight into the healthcare system and patient access to antidiabetic medicines, but also the ability to influence diabetes management in Slovenia.

To obtain the regulatory point of view, we invited representatives of two institutions involved in medicines' regulation, namely the HIIS and the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP). To obtain the clinical perspective, we invited representatives of physicians (diabetologists and general practitioners) who work as clinicians with patients with diabetes and who have been actively involved in the development, implementation, and monitoring of the Slovenian national diabetes program. One of the key objectives of the program is to ensure access to comprehensive, integrated, equal, effective, and safe patient care, which also includes provision of patient access to antidiabetic medicines [8]. Initially, seven experts were invited to participate in the discussion via e-mail: one from each of the two regulatory bodies and five physicians. Two physicians could not participate in the discussion due to other obligations. The focus group consisted of five experts:

- Two diabetologists with more than 20 years of experience in managing patients with diabetes, working at two of the leading Slovenian hospitals in different regions (D1, D2);
- A representative of general practitioners working at a community health center with more than 10 years of experience in family medicine, and a member of the coordination working group at the Ministry of Health that is responsible for the implementation of the national diabetes program (GP) [8];
- A representative of the HIIS from the Department for Medicines with more than 20 years of experience in medicine reimbursement decision-making (HIIS);
- A representative of JAZMP from the department focusing on access to medicines, health technology assessment, and medicine pricing (JAZMP).

Study design

A semi-structured panel discussion was held in an academic environment in January 2019. The discussion was facilitated by a postdoctoral researcher, who was previously trained in facilitating discussion by the faculty professors. The faculty professors observed the discussion and the doctoral student took notes on non-verbal communication. The discussion lasted one and a half hours and was audio-taped upon obtaining written consent from all the participants. No ethical approval was required for this study.

The discussion began with a brief introduction of each focus group member. After the introduction, the facilitator posed a set of open-ended questions, which are listed in Table 1. The questions were based upon literature review and the results of a pharmacoepidemiological analysis that evaluated patient access to novel antidiabetic medicines in 11 European countries [3]. At the end of the discussion, the experts had the opportunity to expose any additional comments or suggestions.

Data analysis

A verbatim transcript of discussion was made by the facilitator of the focus group. It was subjected to content analysis with NVivo 11 qualitative data analysis computer software package (QSR International, LLC, Burlington, MA, USA) to identify main themes and subthemes of the discussion. Two researchers independently coded the data based on key expressions. Each researcher developed a separate coding tree with main themes and subthemes. After comparing the coding trees, they reached an agreement on the final themes and subthemes. Then one of the researchers set a new theme hierarchy based upon the agreement, while the second researcher reviewed the final coding hierarchy.

RESULTS

Four main themes were derived from the discussion, which are presented in Tables 2, 3, and 4, with key quotes from participants.

Table 2. Quotes supporting themes Patient Access to Antidiabetic Medicines and Factors that Influence Patient Access to Antidiabetic Medicines

Patient Access to Antidiabetic Medicines
<i>Patient access to antidiabetic medicines in Slovenia</i>
[JAZMP]: "Slovenia provides good patient access to medicines, not only in the field of diabetes, but in other fields as well."
[D1]: "Patients, who benefit the most, with best expected health outcomes, have access to medicines. Patients in whom smaller benefit is expected do not have such access to medicines. I assume that the greatest benefits with regard to health outcomes are covered with our access to medicines."
<i>Comparison of patient access to antidiabetic medicines in Slovenia and other countries</i>
[D1]: "Slovenia provides better patient access to antidiabetic medicines compared to the countries of the former Yugoslavia (e.g., Croatia, Serbia) and Eastern Europe; however, in terms of patient access to novel antidiabetic medicines, Slovenia is still a little behind compared to some other countries [e.g., Spain, Austria, Germany]."
[JAZMP]: "Some smaller European countries, e.g., Cyprus, Malta, already have problems with the availability of older medicines. I would like to emphasize that the Reimbursement Committee is trying to do its best to enable good patient access to older medicines."
<i>Lower prescribing rate of insulin in Slovenia compared to Nordic countries</i>
[D1]: "A lot of insulin, basal insulin, is being prescribed in Nordic countries."
[D2]: "Swedes routinely monitor HbA1c levels and introduce insulin when target HbA1c levels cannot be achieved using oral antidiabetic medicines."
[D1]: "Slovenian patients often remain on triple therapy, which is expensive. And triple combination therapy is allowed by the health insurance institute, whereas Swedes initiate insulin earlier in the course of type 2 diabetes."
<i>The proportion of novel antidiabetic medicines consumption is lower than in other countries</i>
[HIS]: "With regard to utilization of novel antidiabetic medicines, Slovenia is comparable to Sweden, but not to Austria and Spain."
[D1]: "Sweden has higher consumption of GLP-1RA compared with Slovenia."
Factors that Influence Patient Access to Antidiabetic Medicines
<i>Prescribing restrictions</i>
[GP]: "Some groups of patients benefit from novel antidiabetic medicines. Prescribing restrictions are influenced by medicine prices and the number of patients with type 2 diabetes; however, they are necessary for the sustainability of the healthcare system."
[JAZMP]: "The Reimbursement Committee is trying to set prescribing restrictions so that patients most in need and patients with greatest expected benefits get the medicines."
[D2]: "What has been bothering me for several years is that certain medicines can be prescribed only by diabetologists. Some Slovenian regions provide poorer patient access to diabetologists, which automatically affects patients' access to medicines that can be prescribed only by diabetologists."
[D1]: "New evidence in diabetology represents a huge challenge. New studies of some novel antidiabetic medicines showed benefit in terms of treatment outcomes in patients with established cardiovascular disease. This evidence is so important that it will be challenging not to provide certain patients with these medicines or to treat them with older medicines without this evidence."
<i>Medicine prices</i>
[HIS]: "Older medicines are generally a bit more expensive in Slovenia, because the market is small, which makes it harder to negotiate. And there is only one or two manufacturers, and we are really careful in order to keep them on the market. However, apparently we are better negotiators for novel medicines."

D1 – diabetologist 1; D2 – diabetologist 2; GP – general practitioner; HIS – representative of the Health Insurance Institute of Slovenia; JAZMP – representative of the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia; GLP-1RA – glucagon-like peptide-1 receptor agonists

Table 3. Quotes supporting theme Influence of Patient Access to Antidiabetic Medicines on Patient Outcomes

Influence of Patient Access to Antidiabetic Medicines on Patient Outcomes
<i>Treatment approach to improve patient outcomes</i>
[D2]: "Multifactorial approach had the greatest influence on patient outcomes. Not only diabetes but also lipids, blood pressure, and other measures."
[D1]: "Cardiocentric approach will be crucial in the following years. In addition to multifactorial approach, also choosing the right medicine with regard to these outcomes."
[D1]: "Studies with DPP-4i did not show benefits, but they are safe in the early stage in addition to metformin. However, for such a diagnosis (established cardiovascular disease) SGLT2i and GLP-1RA are more appropriate."
<i>Outcomes of patients with diabetes in Slovenia</i>
[HIS]: "Cardiovascular outcomes of Slovenian patients are significantly improving. The mortality rate is decreasing rapidly. We have global indicators. With the exception of amputations for which I don't know where we stand, we are doing very well with regard to global health indicators, those most important ones."
[HIS]: "We need to know what the incidence of the second most important outcome [amputations] is. I find it unacceptable that the medical profession has no data on the incidence of amputations."
[D1]: "The medical profession does not have this data. This is divided among several specialties and the acknowledgment of that."
[D2]: "We also need data on the incidence of blindness, end-stage kidney failure, etc."

D1 – diabetologist 1; D2 – diabetologist 2; GP – general practitioner; HIS – representative of the Health Insurance Institute of Slovenia; DPP-4i – dipeptidyl peptidase-4 inhibitors; GLP-1RA – glucagon-like peptide-1 receptor agonists; SGLT2i – sodium-glucose co-transporter 2 inhibitors

Patient access to antidiabetic medicines

From the experts' point of view, Slovenia provides satisfactory patient access to antidiabetic medicines. Slovenia provides good patient access to older antidiabetic medicines, which should not be taken for granted. In addition, Slovenia provides better patient access to antidiabetic

medicines than other countries of the former Yugoslavia and Eastern Europe, while it is still a little behind with regard to patient access to novel antidiabetic medicines when compared to some other EU countries, e.g., Spain, Austria, and Germany. Furthermore, Slovenia has a lower prescribing rate of insulins than the Nordic countries, especially Sweden. The experts also highlighted the problem

Table 4. Quotes supporting theme Suggestions for Improving Patient Access to Antidiabetic Medicines

Suggestions for Improving Patient access to Antidiabetic Medicines
<i>Change in prescribing restrictions</i>
[D1]: "It is important to change prescribing restrictions in order to provide better patient access to medicines." [D1]: "Now that we have evidence of cardiovascular benefit, Slovenia should open the door at least a little bit for patients at high risk, high cardiovascular risk. Especially for SGLT2i." [HIS]: "According to this discussion, SGLT2i are a group of medicines for which it would be reasonable to open the door at least a little bit. This is the group from which everyone would benefit the most." [D2]: "GPs are qualified to prescribe DPP-4i and SGLT2i. These medicines have more or less evaluated safety profiles, so safety aspects should not be a barrier for prescribing." [GP]: "GPs are generally somewhat reluctant to prescribe novel antidiabetic medicines. Additional training on these medicines should be provided to GPs. In such a case, we would probably start prescribing these medicines. Nevertheless, physicians prefer to prescribe medicines with which they are familiar. They know what the side effects are and what to expect."
<i>Establishment of national registry</i>
[D2]: "Until we have a registry, we won't have reliable data on amputations." [D2]: "What has been missing in Slovenia for several years is a unified registry of patients with diabetes. This should be a national project. Until we have a registry, we won't know what is going on with diabetes in Slovenia." [GP]: "I would like to refer to the nurses in the FMRCs. I think that in the future we could have a complete national registry. Nurses should write down all patient data once a year. Or this data could be collected elsewhere. We need a joint system. There is such a mess of data, some data is here and some data is there. Some patients are registered in reference clinics, some are not."
<i>Involvement of other potential medicine prescribers</i>
[D2]: "Nurses in FMRCs should be legally and professionally enabled to change therapy. England is a good model of this practice... Nurses in foreign countries titrate medicines, they don't prescribe them. The prescription is still written by a physician." [JAZMP]: "Nurses don't have in-depth knowledge of pharmacotherapy... Pharmacists have more knowledge of pharmacotherapy than nurses. In my opinion, we need to consider multidisciplinary teams."
<i>Improvement of the concept of FMRCs</i>
[D2]: "A lot of money is spent for very little benefit. That's what bothers me about the concept of FMRCs. However, I think the basic idea of involving FMRCs in the management of patients with diabetes was excellent." [HIS]: "The potential of FMRCs is unexploited and the concept is not clear." [HIS]: "Nurses in the FMRCs are providing individual counseling. I think it would be reasonable to perform group education for patients with diabetes. The concept of FMRCs should be upgraded."

D1 – diabetologist 1; D2 – diabetologist 2; GP – general practitioner; HIS – representative of the Health Insurance Institute of Slovenia; JAZMP – representative of the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia; DPP-4i – dipeptidyl peptidase-4 inhibitors; FMRC – family medicine reference clinic; SGLT2i – sodium-glucose co-transporter 2 inhibitors

that in Slovenia, triple combination therapy is often used instead of insulin (Table 2).

Factors that influence patient access to antidiabetic medicines

The panel agreed that prescribing restrictions are necessary for the sustainability of the healthcare system, but pointed out that they limit patient access to novel antidiabetic medicines. Some antidiabetic medicines, namely DPP-4i and SGLT2i, can only be prescribed by diabetologists, but patients in Slovenia do not have equal access to diabetologists, which affects their access to these medicines. In addition, the experts agreed that new evidence on cardiovascular benefit of certain antidiabetic medicine groups will pose a challenge for both decision-makers and prescribers of antidiabetic medicines in order to provide access to these medicines for patients with established cardiovascular disease. On the other hand, the representative of JAZMP argued that Reimbursement Committee sets prescribing restrictions so that patients most in need and those with greatest expected benefits have access to medicines.

Another factor that may influence patient access to antidiabetic medicines are medicine prices. In comparison with other countries, older medicines are generally more expensive in Slovenia, while novel antidiabetic medicines are less expensive (Table 2).

Influence of patient access to antidiabetic medicines on patient outcomes

The experts agreed that the multifactorial treatment approach has the greatest influence on the outcomes of patients with diabetes. In their opinion, in the future, antidiabetic medicine will be selected based on the cardiovascular risk of the individual patient. Patients with established cardiovascular disease will be treated with medicines with proven cardiovascular benefit, namely SGLT2i and GLP-1RA.

The experts also discussed the influence on outcomes of patients with diabetes in Slovenia. They agreed that both mortality rates and the number of people with diabetes who experience cardiovascular events in Slovenia have been decreasing in recent years. Yet, they pointed out the lack of data on other outcomes, namely amputations, retinopathies, and kidney failure (Table 3).

Suggestions for improving patient access to antidiabetic medicines

The experts expressed the need to change prescribing restrictions, especially for SGLT2i, to provide these medicines to patients at high cardiovascular risk. They also argued that GPs should be able to prescribe DPP-4i and SGLT2i to ensure more equal patient access to these medicines.

One of the diabetologists suggested involving other healthcare professionals in prescribing antidiabetic medicines. Another expert emphasized the need to establish multidisciplinary teams in diabetes care. One attempt to do this was the introduction of family medicine reference clinics (FMRCs) at the primary level of the healthcare system. The general opinion of the experts was that the implementation of FMRCs was an excellent idea; however, they agreed that their potential is unexploited.

The experts repeatedly stressed the need to establish a Slovenian national registry of patients with diabetes in order to obtain more reliable data on these patients' outcomes (Table 4).

DISCUSSION

The participants agreed that Slovenia provides satisfactory patient access to antidiabetic medicines that is comparable with most European countries. Some countries, such as Spain, Austria, and Germany, provide better patient access to novel antidiabetic medicines than Slovenia [3]. However, Slovenia provides good patient access to older antidiabetic medicines, while some smaller European countries already had problems with the availability of older antidiabetic medicines, especially metformin.

The most important factor that may affect patient access, especially to novel antidiabetic medicines, is prescribing restrictions. Several prescribing restrictions apply to novel antidiabetic medicines, e.g., SGLT2i and DPP-4i can only be prescribed by diabetologists and neither of these groups of medicines can be used as first-line therapy. Another antidiabetic medicine group, GLP-1RA, could also be prescribed by GPs, but only to patients with a body mass index equal to or greater than 30 kg/m² who are already receiving maximum doses of dual oral combination therapy [9]. However, GPs are reluctant to prescribe GLP-1RA due to lack of knowledge about these medicines.

Due to unequal access to diabetologists across Slovenian regions, patients living in regions with poorer access to diabetologists (especially in eastern Slovenia) may have poorer access to DPP-4i and SGLT2i [10]. Prescribing restrictions of SGLT2i and GLP-1RA should be changed to align with new evidence on the cardiovascular benefit of some medicines of the SGLT2i and GLP-1RA drug classes [11].

In subsequent years, cardiovascular prognosis will probably be the key factor influencing the choice of antidiabetic medicine for individual patients. Cardiovascular outcomes and mortality rates of patients with diabetes in Slovenia are improving, but there is a lack of reliable data on other outcomes, especially amputations. A national registry of patients with diabetes is needed, following the example of, e.g., Sweden and Denmark [12, 13]. Sweden has the best diabetes care in Europe and its national registry is a key factor in the quality of patient care [14]. The experts saw the potential for establishing a registry in Slovenia using FMRCs, where nurses could set up and maintain a national registry of patients with diabetes. FMRCs have been established to provide preventive screening for some chronic

diseases (including diabetes), to identify and monitor risk factors, and provide patient education [15]. They play an important role in detecting diabetes early and in providing early access to care for these patients, including early access to antidiabetic medicines that can be prescribed by a GP. In the experts' opinion, the concept of FMRCs was promising but should be upgraded. One area for improvement is in providing group rather than individual education for patients with diabetes. The model of FMRCs may serve as a basis for involving multidisciplinary teams in diabetes care and improving patient care.

The present study provides insight into patient access to antidiabetic medicines from a regulatory and clinical point of view and identifies factors that influence it. In addition, it proposes measures to improve patient access to antidiabetic medicines and patient outcomes, which apply not only to Slovenia but also to other countries. Our study has some important strengths. COREQ criteria were followed for performing and reporting this study. To ensure study validity, the discussion was audiotaped and transcribed verbatim. Two coders independently identified main themes and subthemes of the discussion and jointly interpreted the results.

Nevertheless, some limitations arise when interpreting the findings. First, the study involved only one focus group; however, the group members represented key stakeholders (regulatory bodies and clinicians), who not only have an in-depth insight into patient access to antidiabetic medicines, but also the ability to influence diabetes management in Slovenia. The number of representatives of regulatory bodies with specific knowledge on the study topic in Slovenia is limited, which makes it more difficult to conduct series of focus groups with different representatives of regulatory bodies; doing so would most likely not add to the results. We could conduct another focus group including only representatives of clinicians, but in this case different stakeholders would not be able to interact and discuss each other's opinions, which is one of the main advantages of focus groups. Second, although the focus group facilitator encouraged all participants to express their opinions, some clinical aspects were discussed more specifically by diabetologists only. Third, transcripts and study findings were not returned to the experts for additional feedback and confirmation. However, all four researchers who attended the focus group discussed the study findings. During the discussion, no specific questions arose regarding the interpretation of the study results.

CONCLUSION

Slovenia provides satisfactory patient access to antidiabetic medicines; this is mainly affected by prescribing restrictions and unequal access to diabetologists across Slovenian regions. The most important measure to improve patient access to antidiabetic medicines, not only in Slovenia but also in other countries, is changing prescribing restrictions. In addition, national registries of patients with diabetes should be established to monitor patient outcomes.

Multidisciplinary teams should be involved in diabetes care. The Slovenian model of FMRCs may serve as a basis for establishing multidisciplinary teams; however, the activities of these clinics should be clearly defined from the beginning at the national level, involving representatives of all stakeholders in diabetes care.

ACKNOWLEDGEMENT

The authors would like to thank all the experts that participated in the focus group.

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Conflict of interest: None declared.

Regulatorna in klinička perspektiva dostupnosti antiidiabetika bolесnicima u Sloveniji

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САЖЕТАК

Увод/Циљ У последњој деценији уведене су три иновативне врсте антидијабетика, а то су инхибитори дипептидилне пептидазе-4, аналози глукагона слични пептиду-1 и инхибитори натријума и глукозе 2. Неколико чињеница утиче на доступност ових лекова болесницима, те треба истражити њихову употребу у клиничкој пракси.

Циљ студије био је да се стекне увид у доступност антидијабетика болесницима у Словенији са регулаторне и клиничке тачке гледишта.

Метод Фокусна група са пет словеначких стручњака (представници регулаторних тела и корисници антидијабетика) састала се у јануару 2019. године. Дискусија је снимљена звучним записом, а после добијања писмене сагласности стручњака направљен је писани транскрипт. Двоје истраживача су независно анализирали садржај дискусије, користећи NVivo 11 да идентификују главне теме и подтеме.

Резултати Словенија пружа задовољавајући ниво доступности антидијабетика болесницима, међутим, ограничења у прописивању лекова и неједнак приступ дијабетолозима у словеначким регионима могу ограничити приступ болесника иновативним антидијабетичарима. Ограничења у прописивању лекова треба ускладити са новим доказима о кардиоваскуларним предностима одређених антидијабетика. Потребно је успоставити национални регистар болесника са дијабетесом како би се добили поуздани подаци о исходима лечења и побољшао квалитет неге болесника.

Закључак Неопходно је побољшати доступност антидијабетика болесницима не само у Словенији већ и у другим земљама променом ограничења за прописивање лекова, успостављањем националног регистра болесника са дијабетесом и укључивањем мултидисциплинарних тимова у лечење дијабетеса.

Кључне речи: дијабетес; антидијабетичари; приступ болесницима; фокусна група; лечење дијабетеса