# Implementation Strategy for the Development and Implementation of Standard Clinical Guidelines and Standard Guidelines for Prevention

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## Introduction

**The Strategic framework for health 2014-2030** (hereinafter referred to as the Strategic Framework) was approved by the Slovak Government on 18 December 2013 and constitutes a basic document to guide Slovakia's public health policy in the medium and long-term[1].

**One of the important tools and indicators used in the "Strategy" are standard clinical guidelines for general and specialised outpatient and inpatient care and prevention in selected priority therapeutical areas. The aim of their development and introduction into practice is to provide a more detailed specification of competences of individual providers, and to harmonise and standardise diagnostic, therapeutic and preventive guidelines in selected priority areas.** It is accompanied not only with cuts in ineffective spending caused by insufficient coordination and existing duplicities, but also with the enhancement in quality, effectiveness and accessibility of health care services provided to patients as they will be able to receive more health care services from a single treating physician, in one place and time.

The public health in Slovakia shows a number of negative deviations compared to other EU Member States, as also evidenced by the statistical data of the National Health Information Centre (NHIC) and international comparisons. [2,3]

A shorter Healthy Life Year at Birth indicator for the Slovak population compared to the EU average (53.4 years for Slovak males against 61.3 years in the EU28 translate into an eight year negative difference; the situation is similar for females)[4] results in an early leaving of the labour market and social exclusion of persons at retirement age.

Life Expectancy - 72.2 years for males and 79.4 for females in 2011 - is below the European Union average (77.3 years for males and 83.1 years for females in 2011).

Crude Death Rate - Slovakia's crude death rate of 9.6‰ is close to the European Union average (9.7‰ in 2011).

Infant Mortality Rate - Slovakia's infant mortality rate of 4.9‰ (2011) exceeds the European Union average by 0.9 percentage points. The lowest infant mortality rates are reported for Scandinavian countries, namely Norway (2.3‰ in 2011) and Finland.

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[1] Health Ministry: Strategic framework for health for 2014 – 2030. Available online at: http://www.health.gov.sk/?strategia-v-zdravotnictve

[2] NHIC: Slovak Health Yearbook 2012. pg. 213. Available online at: http://www.nczisk.sk/Publikacie/Edicia_roceniek/Pages/default.aspx

[3] Ibid. International data taken from the World Health Organization's European Health for All database (HFA-DB), update of July 2013.

[4] EUROSTAT: Healthy life years statistics. Available online at: http://epp.eurostat.ec.europa.eu/statistics_explained/index.php/File:Healthy_life_years,_2012_(years)_YB14_II.png

Cardiovascular Death Rate - a comparison of death rates standardised for European population shows high numbers in the case of cardiovascular diseases. Slovakia's data for 2011 (515.7 for males and 337.6 for females) are nearly double the values reported for the European Union.
(*In 2013, the NHIC conducted a comprehensive review of causes of death using the databases of the Slovak Statistical Office for 2011. The revised standardised cardiovascular death rate for 2011 fell to 447.8 (for males) and 291.0 (for females) per 100,000 population).*
Deaths from Malignant Tumours - With deaths from malignant tumours at 273.9 per 100,000 population (2011) for males, Slovakia ranks among the countries with higher mortality rates in this category, while 114.6 deaths per 100,000 population (2011) for females put it in the bottom part of the list. For the whole of the EU, deaths from malignant tumours stand at 219.8 (2011) for males and 128.9 (2011) for females per 100,000 population.

According to OECD data, Slovakia has currently the lowest score under the health care efficiency indicator, while it moved around the OECD average level in 2003.[5] Slovakia has reported a largest decline in this indicator of all countries under review.

The key causes behind the low efficiency of Slovakia's health care sector include shortcomings in medical prevention and missing and/or insufficient uniform standards for medical diagnostic , treatment and missing standards for prevention. Available high-quality and effective prevention is prerequisite to improvements in cost-effectiveness of the health care sector.
Only 32% of the total of adult capitation patients undergoes preventive check-ups at a general practitioner[6]. The lack of uniform preventive check-up practices which would systematically cover prevention of all of the most serious conditions also contributes to a lower effectiveness of preventive check-ups. The low quality and efficiency in health care services is equally affected by the absence of, and/or insufficiently prepared uniform (standardised) clinical guidelines that would reflect the latest medical knowledge and expertise and ensure effective links between clinical guidelines at all levels of the health care system with the focus on reinforcing competences in primary outpatient care.

With respect to different levels of health care providers, the establishment of a primary general outpatient care network, serving as a "gate keeper" for the entire health care system, is pivotal in order to provide better access to quality and effective health care. Based on the experience from other EU countries, a functioning primary general outpatient health care network is able to resolve as much as 80% of cases without a need to refer them to higher health care system levels (specialised outpatient care and inpatient care), while the current figure stands below 30% in Slovakia. This translates into a high number of unnecessary doctor's consultations (visits by patients), with an average yearly number of 11.0 visits in Slovakia compared to an OECD average of 6.6 only).[7]. If the aforementioned problems are not

[5] For more detail see: IFP MF SR : Málo zdravia za veľa peňazí: Analýza efektívnosti slovenského zdravotníctva (Less Health for More Money: Efficiency in Slovak Health Care Sector) (December 2012), pg.16-18. Available online at: https://www.finance.gov.sk/Default.aspx?CatID=8789
[6] Source: VšZP health insurance company
[7] OECD: OECD Health Statistics 2013 - Frequently Requested Data. Available online at: http://www.oecd.org/els/health-systems/oecdhealthdata2013-frequentlyrequesteddata.htm

addressed at the system level, the long-term efficiency of health care in Slovakia will not improve and the pressure for higher health care spending will constantly grow (with the government lacking the necessary resources due to an adverse demographic development and the need of fiscal consolidation). Inevitably, this will make health care services less accessible (for example, by making them less affordable due to the increased demand for private spending in the form of co-payments by patients). Consequently, public health will deteriorate, regional discrepancies will grow and social exclusion of the most vulnerable groups of population at risk of poverty will increase.

Developing and implementing uniform standard guidelines for preventive practices at the level of primary outpatient care will help improve the quality of preventive practices (ensuring access to the same-quality medical prevention across the whole of Slovakia) and increase the number of preventive check-ups. Increasing the number of preventive check-ups will positively contribute to early diagnosis of the most severe diseases and conditions, thus enabling their quicker, more effective and less costly treatment. **Standard guidelines for prevention will primarily focus on effective prevention of the socially most serious types of diseases, such as cardiovascular, oncology, endocrine and metabolic disorders and neurodegenerative diseases.**

Developing and implementing uniform clinical diagnostic and therapeutic guidelines for the most severe and most frequent diseases and conditions at all levels of the health care system will enhance the quality and efficiency of therapeutic treatment and ensure access to the same-quality health care services across the whole of Slovakia.

## 1. Current situation

### 1.1 Definition, aim and methodology for the development of standard clinical guidelines

The terminology on clinical recommendations, standards, protocols or algorithms is often used inconsistently in practice. This results in misunderstanding the aim, application and obligatory nature of these documents for their users in practice. To that end, for the purposes of the present document and for the needs of the future practice, we will build on the terminology used in the applicable Slovak legislation and will try to describe some legal as well as practical aspects of its use in the Slovak Republic.

Act No. 576/2004 Coll. on health care, health care related services and on amendments to certain acts as amended (hereinafter referred to as Act No. 576/2004 Coll. on health care) sets out the competences of the Ministry of Health of the Slovak Republic:

"The Ministry of Health of the Slovak Republic (hereinafter the Ministry) provides professional guidance, within the scope of its competence, on the provision of health care, **issues standard diagnostic guidelines and standard therapeutic guidelines**, and coordinates research activates in the health care sector and the application of research outcomes in practice."[8]

**Definition of clinical guidelines (recommendations) by the National Institute for Health and Care Excellence (NICE)**, one of the most renowned UK institutions that prepare clinical guidelines:

- **Clinical guidelines** are recommendations by NICE on the appropriate treatment and care of people with specific diseases and conditions within the NHS. They are based on the best available evidence. While clinical guidelines help health professionals in their work, they do not replace their knowledge and skills.

- **Aim of NICE clinical guidelines/recommendations:**
  Good clinical guidelines aim to improve the quality of health care. They can change the process of health care and improve people's chances of getting as well as possible.
  (NICE) Clinical guidelines can:
  - provide recommendations for the treatment and care of people by health professionals,
  - be used to develop standards to assess the clinical practice of individual health professionals,
  - be used in the education and training of health professionals,
  - help patients to make informed decisions,
  - improve communication between patient and health professional.[9]

**Slovak generally binding regulations do not contain a more detailed definition of the aim and content of standard diagnostic and therapeutic guidelines.** However, if we compare aforementioned, it is

[8] §45(1)(b), (c) and (e) of Act No. 576/2004 Coll. on health care, health care related services and on amendments to certain acts as amended (hereinafter only referred to as Act No. 576/2004 Coll. on health care)
[9] NICE: About clinical quidelines. Available online at:
http://www.nice.org.uk/aboutnice/whatwedo/aboutclinicalguidelines/about_clinical_guidelines.jsp

evident that Slovak law-makers apply a narrower approach and the aim of standard diagnostic and therapeutic guidelines is rather that of a regulation than a recommendation under the Health Care Act. While the Slovak Health Care Act (Act No. 576/2004 Coll.) treats the expressions "standard" as legislative terms, NICE considers that clinical guidelines "can be used" (i.e., does not have to be used) to develop standards, giving this option as one of the possible ways of their application.

The Health Ministry, therefore, prepared in 2008 the "**Concept for development of standard diagnostic and therapeutic guidelines**", adopted by Government resolution No. 628 of 17 September 2008[10] (hereinafter the Concept). Under this Concept, the Health Ministry issues standard diagnostic and therapeutic guidelines (SDTG) in the form of a ministry guidance and publishes them in its official journal, available to public at the Health Ministry website. **The Concept contains a more detailed definition and aim of standard diagnostic and therapeutic guidelines, provides a framework description (in points) of the methodology for their development and updates, application, control and monitoring, and implementation in practice.** The Concept has proposed a basic SDTG structure to develop professional ministry guidance and also notes the need for a uniform methodology approach and statutes to govern the work of working groups. The methodology for the development and review of SDTG and the statutes of working groups as proposed in the Concept have so far not been prepared, even though the SDTG published by the Health Ministry following the adoption of the Concept more or less keep the proposed structure.

**The Concept-based definition of standard diagnostic and therapeutic guidelines:**

- **Standard diagnostic and therapeutic guidelines:**

1) are an integral part of the overall system of quality in the provision of health care services;
2) represent the required level of diagnostic and therapeutic guidelines that are desirable, attainable and serving as a benchmark for current diagnostic and therapeutic guidelines;
3) will define the norms to ensure the quality in the provision of health care and set out the minimum requirements on ensuring a higher level of quality and safe health care, as well as its scope and content;
4) will systematically be developed and updated (professional guidance) for health professionals to use them in order to make right decisions and be oriented in the provision of health care;
5) will be approved by the Health Ministry and published in the form of professional guidance in the Health Ministry Official Journal;
6) will be published on a website.

**The Concept-based aim of standard diagnostic and therapeutic guidelines:**

- **Standard diagnostic and therapeutic guidelines:**

[10] SLOVAK GOVERNMENT RESOLUTION No.628 of 17 September 2008: Concept for development of standard diagnostic and therapeutic guidelines. Available online at: http://www.rokovania.sk/Rokovanie.aspx/RokovanieDetail/458

1) will provide health care providers and health professionals with recommendations on an appropriate and standard practice for the diagnosis, treatment and care of patients;
2) serve to develop objective criteria to assess the standard, quality and safety of health care provided by health care providers;
3) are used in the ongoing and further education and training of health professionals;
4) can be used by the Health Ministry to determine priorities and improvements in the efficiency and effectiveness of the health care system;
5) help to improve communication between health professional and patient;
6) make it easier for patients to acquire relevant information about diagnostic and therapeutic procedures necessary for the provision of informed consent to a diagnostic and therapeutic intervention;
7) serve as a basis for health insurance companies (hereinafter HIC) to contract health care services;
8) serve as a basis for recommendations on diagnostic and therapeutic procedures for HIC medical experts;
9) serve as a basis for the Health Care Surveillance Authority (hereinafter HCSA) to assess the quality of health care.

## 1.2 Past and current situation in SDTG development and application in Slovakia

The need to describe and harmonise applied clinical procedures (guidelines) occurred relatively soon after the 1989 social transformation in Slovakia. Slovak expert community and government authorities were inspired by the ongoing implementation and application of such recommendations in neighbouring countries. The first standard therapeutic and diagnostic procedures published in book form and, later, the SDTG published in the "Methodology papers" series used a medicine-based-on-evidence approach and followed a wider concept of clinical guidelines as descriptions of procedures and practices that constitute "*lege artis*" procedures at the time of their development. They are generally accepted by medical experts and other stakeholders as medical procedures recognised as possible and recommended, albeit not compulsory, at a given point in time.

### 1.2.1 Standard diagnostic and standard therapeutic guidelines published in book form

Between 1997 and 2002, these efforts resulted in the publication of the first of the series of SDTG prepared by experts in various fields of medicine. The Health Ministry commissioned the Slovak Medical Association to develop standard therapeutic and diagnostic guidelines (procedures). A coordinating body responsible for the development, review and external examination of individual chapters of standards guidelines was the then Institute for Preventive and Clinical Medicine (IPCM). Supervised by professor Tomáš Trnovec and professor Rastislav Dzúrik, the guidelines were published in two separate books: **Štandardné terapeutické postupy (Standard therapeutic guidelines)**(Martin: Osveta, 1997) and **Štandardné diagnostické postupy (Standard diagnostic guidelines)**(Martin: Osveta, 1998).

### 1.2.2 Methodology papers on rational pharmacotherapy of the Central committee for rational pharmacotherapy and drug policy of the Ministry of Health of the Slovak Republic (renamed Standard diagnostic and therapeutic guidelines from 2009)

**The Methodology papers on rational pharmacotherapy** were published for several years. The algorithm for the development of methodology papers was approved by a Health Ministry board.[11] **The Methodology papers on rational pharmacotherapy** were published under the supervision of the Central committee for rational pharmacotherapy and drug policy from 1998. The methodology papers were edited by professor J. Holomáň of the Slovak Medical University, who still heads their editorial board. Despite their title, implying they only deal with pharmacotherapy issues, their content covered much wider areas, including aetiology, epidemiology, diagnostics and therapy (i.e., other than pharmacology-based approaches to treatment). The methodology papers provided professional recommendations (guidance) for first-contact doctors and specialists designed to improve the level and quality of rational pharmacotherapy and treatment of individual diseases. Initially, they were published in *Lekársky obzor* and *Farmaceutický obzor* medical journals, later by the Herba publishing house. The methodology papers published before January 2008 can still be found at the Health Ministry website ("Material and documents" section); the last methodology paper published on the website (Issue 45) is from 2008.

The Methodology papers series still continues. Starting with Issue 46 of March 2009, with the title "**Standard diagnostic and therapeutic guideline**" (subtitled "Methodology paper on rational pharmacotherapy"), they are published by the Herba publishing house until now. The Health Ministry committee for rational pharmacotherapy and drug policy is no longer active. In line with the Health Ministry organisational rules, the rational pharmacotherapy is currently managed by the Drug pricing and drug policy department. **The Standard diagnostic and therapeutic guidelines (subtitled "Methodology paper on rational pharmacotherapy") published by the Herba publishing house now only represent an expert, though respected, medical publication.**

### 1.2.3 Standard diagnostic and therapeutic guidelines published by the Health Ministry as professional guidance in the ministry's Official Journal

As mentioned earlier, the Slovak Government approved the "**Concept for development of standard diagnostic and therapeutic guidelines"** in September 2008. **In line with the Concept, the SDTG are issued in the form of professional guidance published in the Health Ministry Official Journal.** Since 2008, the Health Ministry has published around 45 guidelines on procedures and practices to be applied in the diagnostic and treatment of various diseases and conditions. Some of these guidelines were repeatedly reviewed and/or updated to include new medical knowledge and related new procedures and therapies.

[11] HSR: Report by the Health Ministry for government discussion, pg.7. Available online at: http://hsr.rokovania.sk/data/att/30175_subor.rtf.

## 2. Main present issues

The previous chapter described the history of recurring attempts at standardising clinical guidelines and institutionalising their development in Slovakia. **In spite of all the efforts made so far and outputs already implemented, the continuity has not been preserved in this area.** The developed standard diagnostic and therapeutic guidelines do not play such a major role as they do in some other, more advanced health systems (UK, the Netherland, Germany, Australia, etc.). **Clinical recommendations or SDTG are not systematically applied in the medical practice in Slovakia.** The causes are varied.

**SDTG are not developed, updated and applied systematically.** Professional ministry guidelines are only in place for some selected therapeutic areas and diagnoses, but often no SDTG exist at all.

The absence of SDTG then leads to an **unclear assignment of competences** in some areas, not only between first-contact doctors and specialists, but also with respect to unclearly defined responsibilities of health care providers and some uncertainty as to what kind of necessary health care a patient with a particular problem is entitled. **The issues of quality and equal access to health care also occur.** The ambiguity in diagnostic and treatment may then result, in addition to the application of inappropriate medical procedures and consequent complaints and forensic problems, in economic losses and useless "bullying" of patients.

Some associations of Slovak medical professionals therefore publish their own clinical recommendations by adopting and adapting international recommendations (European, US, world-wide recommendations by relevant associations of medical experts, etc.) and, in some cases, by developing their own local recommendations for their members. The development of such recommendations should not, however, serve to substitute state-recognised standard procedures - professional guidelines as required under the Health Care Act. They do not comply with the procedure adopted in the Concept, no unified methodology for their development has been defined (or methodology is not always available to the public) and they are not officially published. But in the situation when no other recommendations exist, even such consensus-based recommendations by experts can serve as important practical guidance that defines, at a given stage, what is considered an appropriate practice in a particular field of medicine and, as such, they can serve as a reference source where necessary.

The aforementioned "Methodology papers" (later renamed "Standard diagnostic and therapeutic papers"), originally published with the authorisation by the Health Ministry and still being published by the Herba publishing house, have also served this purpose. The professional community is accustomed to them, their form is well established and experts involved in their development consider them the "right" standard. Some duplicity and ambiguity has therefore arisen, even though the topics they cover only partially overlap with SDTG published as professional ministry guidance. The thing is that the professional community often does not even learn about the existence of professional guidance - the SDTG published in the Health Ministry Official Journal.

This situation gives rise to a certain controversy inside the professional community; some health professionals feel disconcerted and call for a uniform approach, while others prefer the freedom of choice from a handful of options, yet others remain neutral or even sceptical. However, this often only holds until they have encountered a real problem with the provided health care (a recently increasing number of complaints or still more frequent lawsuits initiated by patients against health care providers).

Following chapters will seek to identify and analyse areas of concern and, subsequently, propose measures to eliminate deficiencies.
Areas of concern:

**2.1 Legislative framework and legal form (obligatory nature and enforceability of SDTG)**
**2.2 Methodology and competence (development, adaptation, implementation and revision of SDTG in practice)**
**2.3 Prioritising in SDTG development**
**2.4 Payment mechanisms**
**2.5 Practical implementation of SDTG**
**2.6 Institutionalisation of development and surveillance over SDTG**
**2.7 Patients´ needs**
**2.7 Financing**

## 2.1 Legislative framework and legal form (obligatory nature and enforceability of SDTG)

Pursuant to §4(3) of Act No. 576/2004 Coll. on health care, health care providers are required to provide health care "properly"[12], i.e., they have to take all the actions necessary to determine the diagnosis and proper treatment while taking into consideration "the current level of knowledge of medical science". In addition, elsewhere in the same act, in §45(1)(b) and (c), the Health Ministry is authorised to provide professional guidance on the provision of health care and the publication of SDTG. The original intent pursued by the legislator when construing the legislation in question was to guarantee the "proper" provision of health care by means of standardised medical interventions. However, such a strict wording was later abandoned, §3(2) of the Act was recast[13] and the condition that the proper provision of health care pursuant to §4(3) requires a list of indicated medical interventions for individual diseases was left out.
The reason was that even several years from the adoption of the Health Care Act the list of medical interventions and corresponding standard diagnostic and therapeutic guidelines covering the whole range of indications was not available. The practice proved that the wording of the Act was too stringent and overambitious in this respect. Other advanced countries which have much larger capacities

[12] "The provider shall provide health care properly. The health care is deemed to be provided properly if all medical practices are performed in order to properly diagnose a disease and provide timely and effective treatment in order to restore the health of an individual or improve conditions of an individual while taking into consideration the current level of knowledge of medical science."
[13] Amended by Act No. 489/2008 Coll.

established for quality management and development of clinical guidelines and standards than Slovakia have also undergone a similar development. The reason is not only the complexity and extent of that approach, but also specific aspects of the medicine as a science dynamically developing and changing over time.

In order to objectively assess the quality of health care provided, quality standards with indicators must be in place, but a thorough consideration also needs to be given to the extent of their obligatory nature and their corresponding form, also taking into account the entitlement to and enforceability of medical interventions by patients, providers and insurance companies, as well as patient's and doctor's need for an individual approach.

Comparison of some aspects of SDTG published as professional guidance (or generally binding regulation)

| | **Professional guidance issued by the Health Ministry (not constituting** a generally binding regulation) | **Act, degree, measure, government regulation** (**constituting** generally binding regulations) |
|---|---|---|
| **Legal force** (obligatory nature and enforceability) | Protection of rights and liability cannot directly be claimed before a court for the breach of provision of professional guidance<br><br>Has a nature of a recommendation or application tool that defines what is **currently** considered a "lege artis" procedure in a particular field of medicine.<br><br>**A more flexible framework better suits the nature of the medical science and its dynamic changes** | **Protection of rights and liability can be claimed before a court** |
| *Risks:* | *The professional guidance has no sufficient authority, therefore sufficient protection of rights and liability is not ensured* | ***May lead to an enormous increase in the number of lawsuits over non-provision of health care in compliance with a regulation and, consequently, of legal actions seeking compensation for damage Legal actions may be brought by all involved parties (patient, provider, insurance company)*** |
| **Flexibility in development and revision** | **Less formal approach**<br>**More flexible**<br>**Faster** | More formal approach |
| *Risks:* | *Quality issues*<br>*Lack of authority* | *A risk that the guideline (procedure) may be obsolete or even incorrect*<br><br>*Possible discrimination - some fields will be regulated, some will not - it is impossible to develop the necessary number of guidelines in a short time* |

| | | |
|---|---|---|
| **Public oversight** | A public review procedure is not required - but a document may be subject to a different form of expert or public consultations | **External review procedure and, if needed, discrepancy procedure <u>is a must</u> - a higher level of public oversight** |
| *Risks:* | *Quality issues*<br>*Lack of authority*<br>*Lack of consensus* | *Over-interference by the general public and the risk a professional/expert issue changes into a political one* |

**Based on the analysis of possible risks, we therefore do not recommend issuing SDTG in the form of a generally binding regulation (decree and/or measure),** except for some special cases where SDTG may concern a rather sensitive issue, such as ethical principles. In that case it might be advisable to adopt a guideline in the form of a separate law. **We consider also necessary to complete the law with SDTG definition**.

In order to preserve the necessary professional authority and formal nature of SDTG issued by the Health Ministry, we recommend drawing up a detailed methodology for their development and methodology would be issued as a generally binding regulation - decree. **It should provide for sufficient transparency and discussion necessary in order to ensure that a document based on which SDTG are to be developed is accepted by relevant experts and professionals. The legislation will specify the aim, content and form of SDTG and define the procedure for their development, adaptation, implementation, revision and publication.** Particular SDTG will be further issued in the form of professional guidance (or other appropriate form) published by the Health Ministry in the ministry's Official Journal to show the ministry supervision to recipients.

### 2.2 <u>Methodology and competence</u>
### (development, adaptation, implementation and revision of SDTG in practice)

The development and revision of SDTG requires enormous expert capacities. It is therefore necessary to propose a methodology that would take into account, in an acceptable manner, scientific developments in a particular field of medicine and align local possibilities and established practice with such developments. Even if a portion of guidelines is taken over from international sources, local review, consultations and adaptation will always be required, in particular to consider and incorporate local specifics and needs.

**We deem it absolutely necessary to draw up a detailed standard methodology for the development, adaptation, implementation and revision of SDTG right at the very beginning of the process aimed at developing new SDTG.** The underlying considerations for the preparation of the methodology are contained in the Concept for SDTG development; experience and methodologies prepared by renowned international institutions may also serve as a source of inspiration.

**The methodology should also involve the principles and options for the selection of topics to be covered by new SDTG, procedures to be used in adaptation and revision of the existing SDTG, and the**

**status of and a procedure for nominating experts and reviewers to a working group. Attention should also be paid to identifying and resolving possible conflicts of interests of expert working group members.**

**The possibility to subject the prepared document to a public review is also an important component of the methodology.** We suggest that the methodology also specifies a procedure and competences regarding the review of a draft document by relevant stakeholders, i.e., it should specify in advance a sufficiently transparent approach to how comments and proposed modifications will be handled, who and how will decide on accepting and possible incorporation of such comments and modifications, in order to eliminate possible unauthorised inputs and influence by lobbyists.

We suggest that domestic and foreign experts be invited to participate in the preparation of the methodology to ensure its quality, credibility and consensual character so that it is not questioned later.

### 2.3 Prioritising in SDTG development

It is necessary to specify priority areas on which the SDTG development should focus. We recommend applying several different criteria that will not only reflect the priorities set under the Strategic Framework, but also the needs of other groups of stakeholders - especially experts in a relevant field of medicine, health insurance companies, control bodies and patients. The methodology for prioritising and selecting up-to-date topics for the development of new and revision of existing SDTG should be included in the preparation of the methodology for SDTG development mentioned above. **We propose that SDTG are preferentially developed for those therapeutic fields and diagnoses that have a considerable impact on selected indicators of public health in Slovakia as specified in the Strategic Framework (Table 1 - cardiovascular system, oncology, metabolic disorders), and possibly combined with other selected criteria.**

Examples of criteria used for prioritising topics in the world:

**SIGN (Scottish Intercollegiate Guidelines Network)** [14]

Guideline topics selected for inclusion in the SIGN programme are chosen on the basis of the burden of disease, the existence of variation in practice, and the potential to improve outcome. The following criteria are considered by SIGN in selecting and prioritising topics for guideline development

- Areas of clinical uncertainty as evidenced by wide variation in practice or outcomes.
- Conditions where effective treatment is proven and where mortality or morbidity can be reduced.
- Iatrogenic diseases or interventions carrying significant risks.
- Clinical priority areas for strategic aims of NHS Scotland.
- The perceived need for the guideline, as indicated by a network of relevant stakeholders.

[14] SIGN 50: A guideline developer´s handbook - Quick reference guide. Available online at: http://www.sign.ac.uk/guidelines/fulltext/50/index.html

**Recommendation (2001)13 of the Council of Europe - Developing a methodology for drawing up guidelines on best medical practices** [15]

- Prioritisation of guideline topics may be based on:
  - epidemiology of health problems;
  - health inequalities;
  - variations in the provision and quality of care;
  - emergence of new technologies, or other factors that create a need for high quality, updated information.
- The existence of presently available evidence-base guidelines should be considered in the prioritisation of topics for development.

**The CDP-PL methodology for the development of guidelines of the Czech Society of General Practice (SVS ČLS JEP)** [16]

- risk-carrying procedures (frequent errors, risky interventions)
- new scientific knowledge, changes in diagnostic and treatment practices
- economic relevant (price, frequency, both)

**Prioritising criteria proposed for Slovakia:**

1. **Public health** (number of patients by diagnosis - analysing data from the NHIC and insurance companies)
2. Social implications of diseases – **Priority health objectives** under the Strategic Framework
3. Innovation requiring prompt implementation in practice
4. Risk-carrying interventions
5. **Gate-keeping and enhancing** competences of general practitioners (analysing data from insurance companies)
6. **Cost-effectiveness of diagnostic and treatment** by diagnoses (analysing data from the NHIC + insurance companies)

### 2.4 Payment mechanisms serving as incentives

If the SDTG are also supposed to serve as an incentive mechanism to encourage general practitioners to provide the widest possible range of services and specialists to further extent the offer of their specialist interventions, it is advisable to re-design, at least partly, payment mechanisms applicable in the general and specialised outpatient care to a combined system of fee-for-service and capitation-based payments.

[15] COUNCIL of EUROPE: Rec(2001)13 Council of Europe Developing a methodology for drawing up guidelines on best medical practices. Available online at: http://www.leitlinien.de/mdb/edocs/pdf/literatur/coe-rec-2001-13.pdf

[16] SVS ČLS JEP: Metodika CDP-PL pro tvorbu doporučeného postupu SVS ČLS JEP (The CDP-PL methodology for the development of SVS ČLS JEP guidelines). Available online at: http://www.svl.cz/doporucene-postupy/centrum-pro-spravu-doporucenych-postupu-pro-prakticke-lekare-cdp-pl/

A financially neutral effect of such changes can be achieved by transferring a portion of interventions from specialised outpatient care to general outpatient care providers. The changes will have to be managed gradually, with the involvement of affected stakeholders (Health Ministry, general outpatient care providers, specialised outpatient care providers), so that their outcome is generally recognised and accepted and the changes are not counter-productive.

**The adoption of changes and their positive acceptance is likely to be supported by an inflow of younger general practitioners from a resident program and the integrated health care project, as well.**

## 2.5 Practical implementation of the SDTG

In this section, the SDTG implementation means, in the broad sense:

2.5.1. Dissemination (physical and knowledge-based)
2.5.2. Practical use (putting into practice – implementation in the strict sense)
2.5.3. Assessment (quality and impact)

### 2.5.1 Dissemination of SDTG

The medical community needs to be adequately, continuously and systematically informed about the purpose and availability of clinical recommendations (guidelines) and SDTG.

In terms of "visibility" it is important that SDTG be structured in a defined and distinguishable format while maintaining the continuity of SDTG development and revisions.

Any new SDTG should be actively disseminated and promoted by:

- the Ministry of Health of the Slovak Republic
- professional medical associations
- healthcare providers
- health insurance companies
- patients' associations (where applicable)
- HCSA

Where necessary and practicable, the dissemination and implementation should also be backed by training courses for health professionals (for instance, in the case of preventive programmes, it may be necessary to provide training to health professionals who will be implementing the programme, or instruct patients on proper preventive procedures).

Training courses may be organised by professional medical associations, healthcare providers or their organisations as part of further compulsory training (conferences, seminars, e-learning) or by training agencies.

**Currently, the dissemination of SDTG primarily relies on voluntary activities of particular professional medical associations or communities. In some cases, there are also other involved or concerned entities (health insurance companies, patients' associations, Health Ministry) which take part in the dissemination of SDTG. However, these activities are not performed systematically, but rather as "ad hoc" actions depending on the preferences and needs of interest groups.**

2.5.2 **Practical use (putting into practice)**

2.5.3 **Assessment (quality and impact)**

**The planning of activities with respect to putting SDTG into practice (implementation in the strict sense) and subsequent assessment of the quality of standards and measuring their impacts on pre-defined health objectives is not currently implemented in Slovakia.**

## 2.6 Institutionalisation of SDTG development

Slovakia has not yet set up an institution to systematically deal with the development and revision of SDTG at such level of detail that is common in some countries – the UK, NL, USA or New Zealand. The Health Ministry (the Health Care Department at the Health Section, or the Health Policy Institute) will therefore fulfil the role of a process promoter and coordinator of experts responsible for the technical content of the SDTG. In cooperation with the responsible employees of the Health Ministry, the Ministry's key experts will address external experts (nominated by professional organisations under the Slovak Medical Association) and prepare the technical part of SDTG in line with the assignment and methodology. The Health Ministry should oversee the alignment of SDTG's technical content with other strategic health and health care provision objectives in Slovakia. The introduction of SDTG in certain areas should have a significant impact on costs associated with the provision of health care (costs of diagnosis, medicinal products, preventive medicine procedures) in both directions and, therefore, involvement of other experts or general public (external review procedure) in the preparation and commenting on the guidelines is advisable.

**The possibility to establish an independent organisational unit at the Health Ministry or a public institution systematically dealing with the development and revision of the SDTG or overseeing and facilitating their practical implementation needs to be considered and proposed.**

**We recommend that the development of SDTG becomes institutionalised in this wave (the fifth already) to ensure that, in the future, the development of SDTG does not come to a halt and that the SDTG issued so far be regularly assessed, abandoned or renewed under the leadership of professionals in order to preserve the necessary level of expertise in terms of content and formal requirements.**

## 2.7 Patients´needs

In the case that Slovakian patient himself or his close person is not healthcare professional, his access to medical information is very often severely hindered and limited. It is above the scope of this realisation strategy to analyse all reasons of this information asymmetry. But from the patient point of view it is certainly beneficiary if he could get as much as possible information because the patient is in the same time the object of provided healthcare services and also subject to whom belongs the rights to obtain healthcare service, he is customer and consumer. It concerns not only accessibility, quality and financial

aspects of provided services, but also the right guaranteed by law " to obtain the care properly"[17]. Problems with lack of information which have patients in Slovakia could be partially caused by missing, unaccessible or not up to date standard clinical guidelines for diagnostic, treatment or prevention. The consequence is that provided healthcare interventions could differ depending on regional practices, type or specialisation of healthcare provider. The main reasons why the patients have a need and why they are looking for information on standards are following:

#### 2.7.1 **competences**

Absence of standard clinical guidelines do in certain areas cause unclear division of competences not only between primary care doctor and specialists, but also among specialists themselves or several different types of healthcare providers. Patient has not sufficient information which doctor and what healthcare facility is responsible to deliver care. If the patient is refused and send elsewhere, the consequence could be delay, improper practice and damage to patient´s health.

#### 2.7.2 **right to obtain particular care**

This is about healthcare providers´ obligation to deliver on not deliver particular care and doubts connected with patient's right to obtain particular care for particular health problem.

#### 2.7.3 **access, equality and quality**

Standard clinical guidelines and standard guidelines for prevention help to eliminate possible shortcomings in quality, accessibility and equality of provided healthcare services.

#### 2.7.4 **forensics reasons**

Standardisation of care helps to solve eventual conflicts via court or out-of-court way.

### 2.8 **Financing**

One of the serious reasons behind interruptions and fluctuations in the development of SDTG lies in insufficient organisational and personnel background which is closely associated with financing. So far, Slovak experts involved in the development of SDTG have been doing it for free and out of their passion for medicine or for a symbolic reward. Under such circumstances it is difficult to invite a foreign expert, buy a licence, the necessary literature, etc. It is also more difficult to remain independent and keep the necessary distance from the interest groups concerned.

**Restarting the development of SDTG in Slovakia with the help of EU funds is therefore a unique opportunity which should not be missed. Simultaneously, it is also necessary to find a way how the activities related to the development of SDTG and preventive programmes will be financed from national funds when support from EU funds is no longer received, so that there are no further interruptions due to a lack of personnel and financial capacities.**

[17] §4(3) of Act No. 576/2004 Coll. on health care :"The provider shall provide health care properly. The health care is deemed to be provided properly if all medical practices are performed in order to properly diagnose a disease and provide timely and effective treatment in order to restore the health of an individual or improve conditions of an individual while taking into consideration the current level of knowledge of medical science."

## 3. Key indicators

3.1 **SDTG**

- **% of patients treated in the future in accordance with standard clinical guidelines by**
  - **general practitioners**
  - **specialists**

  **Checked against data from NHIC and health insurance companies + sample survey**
- **Number of the new and innovated clinical guidelines established in healthcare system**

3.2 **Prevention**

- **% of patients who underwent some form of preventive medicine procedure based on standard clinical guidelines**

  **Checked against data from NHIC and health insurance companies + sample survey**
- **Number of the new and innovated guidelines for prevention established in healthcare system**

## 4. Strategic objectives

Strategic objectives are based on objectives defined in the Strategic framework for health 2014–2030[18]

### 4.1 Standard diagnostic and therapeutic guidelines

Current situation:

Absence or insufficiency of prepared standard clinical guidelines which reflect the latest level of knowledge in medicine and assure effective connection through all levels of healthcare delivery system (further HC only).

Expected outcomes:

SDTG will be primarily focused on diagnostic and therapy the most serious and frequent diseases on all levels of healthcare (ambulatory and hospital care). SDTG will be newly developed or revised/innovated for all relevant levels of HC. Special care will be dedicated to force competences and services on the level of the primary ambulatory care. SDTG will be issued and available for public in the form of professional guidance (or other appropriate form) published by the Health Ministry in the ministry's Official Journal. Education on proper application of standard clinical guidelines in medical practice will be assured for healthcare professionals In relevant cases.

### 4.2 Standard guidelines for prevention

Current situation:

Absent or not sufficiently harmonized guidelines for preventive examination (hereinafter PE only) lowering effectiveness of medical prevention. Low % of patients got through PE. High numbers of unnecessary doctors visits compared to OECD average.

Expected outcomes:

Guidelines for prevention will be developed as guidelines for relevant levels of HC. Execution and effectiveness of medical prevention will be strengthened, accessibility to equal quality of medical prevention on whole area of Slovak Republic will be assured and number of PE will be increased. Increased number of PE will improve early disease diagnostic and consequently it will be possible to treat diseases faster, more effective and cheaper. In relevant cases the education on proper application of standard preventive guidelines in medical practice will be provided for healthcare professionals.

[18] Health Ministry: Strategic framework for health for 2014 – 2030. Available online at: http://www.health.gov.sk/?strategia-v-zdravotnictve

**Indicators and time frames according to the** Strategic framework for health 2014–2030

| Area of concern | Indicator | Unit of measure | Current situation | Target situation | Target deadline |
|---|---|---|---|---|---|
| **1.**<br>**SDTG development and revision** | % of patients treated in accordance with standard clinical guidelines by general outpatient care and specialised outpatient care facilities | **%** | 0% | 50% | 2030 |
| | % of patients treated in accordance with standard clinical guidelines in hospitals | **%** | 0% | 50% | 2030 |
| | Number of the new and innovated clinical guidelines established in healthcare system | number | 0 | 120 | 2030 |
| **2.**<br>**Prioritising in SDTG development**<br>- general practitioners<br><br><br><br>-specialists<br>- hospitals | Essential hypertension<br>Dyslipoproteinaemia<br>Diabetes<br><br>Other diagnoses are to be specified based on the new methodology<br><br>To be specified based on the new methodology | | | | Q1 2015<br>Q1 2015<br>Q3 2015<br><br>by 2020<br><br><br><br>by 2020 |
| **3.**<br>**Prevention**<br>cardiovascular<br>neurodegenerative<br>oncology | Increasing the share of patients who undergo preventive check-ups by general practitioners for adults | **%** | 32% | 60% | by 2030 |
| | Number of the new and innovated guidelines for prevention established in healthcare system | number | 0 | 4 | 2030 |
| **4.**<br>**Payment mechanisms** | capitation – general practitioners<br><br><br><br><br><br><br>fee-for-service specialists | | 100%<br><br><br><br><br><br><br>100% | 85% capitation + 15% services<br><br>70% capitation + 30% services<br><br><br><br>+15% savings from general outpatient care<br><br>+30% savings from general outpatient care | by 2016<br><br>by 2018<br><br><br><br>Based on priorities and needs until 2016<br><br>by 2018 |

## 5. Measures

**Areas of concern and proposed measures:**

**5.1 Legislative framework and legal form (obligatory nature and enforceability of SDTG)**

**5.2 Methodology and competence (development, adaptation, implementation and revision of SDTG in practice**

**5.3 Prioritising in SDTG development**

**5.4 Payment mechanisms**

**5.5 Practical implementation of SDTG**

**5.6 Institutionalisation of development and surveillance over SDTG**

**5.7 Patients´ needs**

**5.8 Financing**

### 5.1 Legislative framework and legal form

**(obligatory nature and enforceability of SDTG)**

**Measures and the method of their implementation:**

**5.1.1 In the first step it is necessary to develop a methodology for the development, adaptation, revision and implementation of SDTG and complete the law with SDTG definition. The methodology should be published in the form of a generally binding regulation – a decree.**

- In order for the decree to be published and the law complete, it is necessary to amend Act No. 576/2004 Coll. on health care and supplement the provision of § 2 with SDTG definition and of § 45(1)(c) with an enabling clause for its publication.
  **Deadline: Q2–Q3 2014**
- The methodology needs to be sufficiently detailed and should be developed in cooperation with national and foreign experts.
- **Deadline: Q1 2015**

**5.1.2 Extending the scope of competence of general practitioners by allowing them to submit a request for continuing health care for their patients to health insurance companies. According to the current wording of the Act, only specialists are authorised to propose continuing health care (dispensary).**

- It is necessary to amend Act No. 581/2004 Coll. on health insurance companies, health care supervision and on amendments to certain acts as amended; **specifically, §6(1)(i) should be added.**
  **Deadline: Q2–Q3 2014**
- It is necessary to amend Decree No.127/2014 Coll. on continuing healthcare (dispensary) and add there preferred diagnosis.
  **Deadline: 2-3 Q 2014**

## 5.2 Methodology and competence

**(development, adaptation, implementation and revision of SDTG in practice)**

**Measures and the method of their implementation:**

**5.2.1** Setting up an expert group to develop the methodology for the implementation of SDTG
**Deadline: Q3 2014**

**5.2.2** Development of methodology
**Deadline: Q4 2014**

**5.2.3** Publication of the methodology in the form of a decree (generally binding regulation)
**Deadline: Q1 2015**

## 5.3 Prioritising in SDTG development

**Measures and the method of their implementation:**

**5.3.1** Preparation of the methodology for SDTG development which will also include the methodology for the selection of new topics and procedures for the revision or abandoning of SDTG and preventive medicine guidelines (PMG)

**5.3.2** A more detailed analysis of epidemiologic data and costs

**5.3.3** SDTG for general practitioners – hypertension, dyslipidemia, diabetes
**Deadline: 2014 – Q2 2015**

**5.3.4** Preparation of a publishing programme for SDTG and PMG based on the methodology, always one year in advance

**5.3.5** Implementation of SDTG and PMG development in accordance with the programme
**Deadline: 2Q 2015 – 2020**

Example 1: Analysis of 30 top-ranking diagnoses, by cost, 2011,

Source: NHIC and the General Health Insurance Company

| **ICD code** | **Σ EUR** | **Diagnosis** |
|---|---|---|
| I10 | 77 018 928 | Essential (primary) hypertension |
| I25 | 30 692 826 | Chronic ischemic heart disease, unspecified |
| E11 | 23 314 655 | Type 2 diabetes mellitus, non-insulin dependent |
| E78 | 20 697 561 | Pure hypercholesterolemia |
| E10 | 19 604 982 | Type 1 diabetes mellitus, insulin dependent |
| D66 | 19 022 696 | Hereditary factor VIII deficiency |
| C50.9 | 15 590 835 | Malignant neoplasm of breast of unspecified site |
| J45 | 15 079 287 | Asthma |
| G35 | 14 805 129 | Multiple sclerosis |
| I11 | 13 804 670 | Hypertensive heart disease |
| I11.9 | 13 157 782 | Hypertensive heart disease without heart failure |
| M81 | 12 913 688 | Osteoporosis without current pathological fracture |
| C61 | 12 004 630 | Malignant neoplasm of prostate |
| J30 | 11 340 481 | Vasomotor and allergic rhinitis |
| N40 | 11 168 915 | Enlarged prostate |
| F20 | 9 726 203 | Schizophrenia |
| C20 | 9 248 202 | Malignant neoplasm of rectum |
| C64 | 9 021 502 | Malignant neoplasm of kidney, except renal pelvis |
| G20 | 9 000 852 | Parkinson's disease |
| M05 | 8 906 526 | Rheumatoid arthritis with rheumatoid factor |
| I25.0 | 8 867 394 | Chronic ischemic heart disease |
| K30 | 8 863 661 | Functional dyspepsia |
| C50 | 8 497 849 | Malignant neoplasm of breast |
| C50.4 | 8 398 355 | Malignant neoplasm of upper-outer quadrant of breast |
| I70.2 | 8 392 642 | Atherosclerosis of native arteries of the extremities |
| L40 | 7 999 298 | Psoriasis |
| M54 | 7 487 041 | Dorsalgia |
| N18 | 6 768 092 | Chronic kidney disease |
| H35.3 | 6 359 698 | Degeneration of macula and posterior pole |
| J45.0 | 6 132 912 | Predominantly allergic asthma |

Example 2: Analysis of 30 top-ranking diseases, by prevalence, 2011

Source: NHIC and the General Health Insurance Company

| ICD code | **ID** | **Diagnosis** |
|---|---|---|
| I10 | 784 894 | Essential (primary) hypertension |
| M54 | 401 494 | Dorsalgia |
| I25 | 389 480 | Chronic ischemic heart disease, unspecified |
| E78 | 357 594 | Disorders of lipoprotein metabolism and other lipidemias |
| J06 | 328 985 | Acute upper respiratory infections |
| J04 | 287 999 | Acute laryngitis and tracheitis |
| J30 | 284 314 | Vasomotor and allergic rhinitis |
| J20 | 252 115 | Acute bronchitis |

| | | |
|---|---|---|
| K30 | 242 387 | Functional dyspepsia |
| I11 | 232 773 | Hypertensive heart disease |
| J03 | 217 558 | Acute tonsillitis |
| J02 | 194 120 | Acute pharyngitis |
| H10 | 169 310 | Conjuctivitis |
| I11.9 | 163 061 | Hypertensive heart disease without heart failure |
| E11 | 157 247 | Type 2 diabetes mellitus, non-insulin dependent |
| F48 | 147 208 | Other nonpsychotic mental disorders |
| N30 | 146 134 | Cystitis |
| J01 | 140 692 | Acute sinusitis |
| J45 | 134 411 | Asthma |
| I70 | 128 003 | Atherosclerosis |
| I83 | 124 019 | Varicose veins of lower extremities |
| L30 | 121 929 | Other and unspecified dermatitis |
| M81 | 120 492 | Osteoporosis without current pathological fracture |
| Z25 | 115 624 | Need for immunization against other single viral diseases |
| N76 | 110 098 | Other inflammation of vagina and vulva |
| J00 | 108 509 | Acute nasopharyngitis |
| Z25.1 | 104 293 | Need for immunization against influenza |
| M51 | 94 213 | Other intervertebral disc disorders |
| K29 | 91 916 | Gastritis and duodenitis |
| D50 | 91 284 | Iron deficiency anaemia |

**SDTG for general practitioners:**

As regards the planned extension of the scope of general practitioners' competences, it is necessary to start developing the selected **SDTG by targeting the needs of general practitioners** in advance, because the implementation deadline for the key area "Health: general outpatient care" is set for 2014. Redefining the scope of general practitioners' competences through legislation will have to be backed by SDTG that will also play the role of a significant driver of change, including modifications to the payment mechanisms of insurance companies.

| **Prioritising in SDTG development** General practitioners | Diagnosis | Target deadline |
|---|---|---|
| | • Hypertension<br>• Dyslipoproteinaemia<br>• Diabetes | Q! 2015<br>Q1 2015<br>Q3 2015 |
| | Other diagnoses (SDTG) are to be specified based on the new methodology | by 2020 |

### 5.4 Payment mechanisms: capitation versus fee-for-service

**Measures and the method of their implementation:**

Prepare, on an ongoing basis and in connection with the individual SDTG, the proposals for modifications in payments, if any, so that physicians and health insurance companies are incentivised to implement SDTG in practice as soon as possible. Maintain budgetary neutrality whenever possible. Negotiations with health insurance companies will be part of the SDTG development process, if the implementation of SDTG requires changes in the payment mechanisms or additional costs.

**Deadline: continuously**

### 5.5 Practical implementation of SDTG

**Measures and the method of their implementation:**

The methodology for the development of SDTG will also include a chapter on implementation strategy and the follow-up clinical audit of the use and monitoring of the results in SDTG implementation. Every individual SDTG will be assessed on a case-by-case basis depending on whether it includes measurable targets, criteria and indicators allowing the assessment of its impact, or whether only the "soft parameters" such as its dissemination will be monitored. **Interlinking the development of SDTG with other quality management tools for healthcare provision in the future is a must.**

**Deadline: continuously**

### 5.6 Institutionalisation of development and surveillance over SDTG

**Measures and the method of their implementation:**

In order to be able to receive EU funding, an **organisational unit will have to be established** as an expert background for the project which will ensure its coordination in technical terms (selecting the topics and organising their preparation), as well as in operational terms (the spending of funds and the reporting of costs).

**The technical part of this organisational structure should remain within the ambit of public administration (Health Ministry or a public institution) even after support from EU funds is no longer received, so that the continuity in the administration of the already-developed SDTG is not interrupted again, thus causing SDTG to lose their value by becoming obsolete, as has been the case on several occasions in the past.**

**Deadline: Q2 2015**

### 5.7 Patients 'needs

**Measures and the method of their implementation to points:**

2.7. 1. competences
2. 7.2. right to obtain particular care
2.7.3. access, equality and quality
2.7.4. forensic reasons

Fulfilment of patients 'needs is possible to manage via:

**5.7.1.** Participation of roof patient organisations on preparation of methodology (decree).
**Deadline: 3Q2014-1Q2015**

**5.7.2.** Participation of roof patient organisations on setting of priorities and creation of edition plan for SDTG and standard guidelines for prevention.

**5.7.3.** Participation of patients on implementation of SDTG and standard guidelines for prevention - If the cooperation with patients is appropriate.

**5.7.4.** Publication and accessibility of SDTG and standard guidelines for prevention for professionals and lay public via all available channels.
**Deadlines 5.7.2-4: continuously**

### 5.8 Financing and Indicative budget

**Measures and the method of their implementation:**

The financing of the project for the period between Q2 2015 - 2020 is proposed through the drawing funds under the Human Resources Operational Programme
**Deadline: Q2 2015 - 2020**
Subsequently, the continued financing of the project will have to be ensured from national funds **sufficiently in advance.**
**Deadline: 2019 at the latest, during the preparation of the 2020 state budget**

The Human Resources Operational Programme for the 2014 - 2020 programming period [19]
PRIORITY AXIS 3: Social inclusion

**IP 3.2. Improving access to affordable, sustainable and high quality services, including public health care and social services of in general interest**
Specific objective 3.2.2:

[19] GOVERNMENT RESOLUTION No. 229/2004 of 14 May 2014. The Human Resources Operational Programme for the 2014 - 2020 programming period – draft. Available online at: http://www.rokovania.sk/Rokovanie.aspx/BodRokovaniaDetail?idMaterial=23534

**Improving the availability of high quality health care by standardising clinical guidelines and preventive medicine guidelines**

- Development and implementation of new and innovative preventive medicine guidelines
- Development and implementation of new and innovative standard clinical guidelines, primarily focused on the most frequent and serious types of diseases

Supported activities:

Under specific objective 3.2.2, two types of activities will be supported – development and implementation of new and innovative preventive medicine guidelines and clinical guidelines.

Preventive medicine guidelines will primarily focus on effective prevention of the socially most serious types of diseases, such as cardiovascular, oncology, endocrine and metabolic disorders and neurodegenerative diseases. Separate procedures will be designed for each type of disease and incorporated into standard preventive medicine guidelines at relevant levels of the health care system. This activity will enhance the effectiveness of preventive medicine.

Clinical guidelines will primarily focus on diagnosis and treatment of the most severe and most frequent diseases and conditions at all levels of the health care system (both outpatient and inpatient care). A cross-cutting approach will be pursued in the development or innovation of clinical guidelines, and a special attention will be paid to reinforcing competences and enhancing services at the level of primary outpatient care in this context. The standardisation of clinical guidelines will contribute to enhancing the regional availability of safe and high-quality health care.

Standardised guidelines will be publicly available in the form of professional guidance or in a similar manner through the Health Ministry's Journal.

In relevant cases, the activities will also include training of health professionals in order to ensure the correct application of standardised guidelines in medical practice.

Activities will be implemented in the form of national projects coordinated by the Ministry of Health of the Slovak Republic.

# Indicative budget for the implementation of the project between 2015 -2020

**Estimated costs of the development and implementation of 1 SDTG**

**Direct expenditure**

| | Number | Costs - estimate (€) | Total costs (€) | | | | |
|---|---|---|---|---|---|---|---|
| Expert group member | 5 | 5 000 | 25 000 | 637 | Services | 637027 | Bonuses to employees beyond the scope of employment contract |
| Evaluation group member | 3 | 5 000 | 15 000 | | | | |
| Working group meeting | 5 | 500 | 2 500 | | | 637007 | Travel expenses other than those of internal staff |
| Evaluation group meeting | 2 | 500 | 1 000 | | | 637006 | Compensation |
| Technical documents (research) | 1 | 5 000 | 5 000 | | | 637011 | Studies, expert opinions, assessments |
| Consumables and supplies | 1 | 200 | 200 | 633 | Supplies | 633006 | General supplies |
| Activity coordinator | 3 | 2 040 | 6 120 | 600 | Current expenditure | 610620 | Personnel costs |
| **Total direct expenditure** | | | **54 820** | | | | |

**Indirect expenditure**

| | | | | | |
|---|---|---|---|---|---|
| Project management | 15% | | 8 223 | 910 | Lump-sum indirect expenditure |
| Publicity | 5% | | 2 741 | | |
| **Total indirect expenditure** | | | **10 964** | | |

| | |
|---|---|
| **Total cost of 1 SDTG (direct + indirect expenditure)** | **65 784** |
| **Total cost of 100 SDTG** | **6 578 400** |

**Estimated costs of the development and implementation of 1 PMG**

**Direct expenditure**

| | Number | Costs - estimate (€) | Total costs (€) | | | | |
|---|---|---|---|---|---|---|---|
| Expert group member | 15 | 20 000 | 300 000 | 637 | Services | 637027 | Bonuses to employees beyond the scope of employment contract |
| Evaluation group member | 9 | 20 000 | 180 000 | | | | |
| Working group meeting | 15 | 2 000 | 30 000 | | | 637007 | Travel expenses other than those of internal staff |
| Evaluation group meeting | 6 | 1 500 | 9 000 | | | 637006 | Compensation |
| Technical documents (research) | 1 | 15 000 | 15 000 | | | 637011 | Studies, expert opinions, assessments |
| Consumables and supplies | 1 | 1 000 | 1 000 | 633 | Supplies | 633006 | General supplies |
| Activity coordinator | 3 | 360 | 1 080 | 600 | Current expenditure | 610620 | Personnel costs |
| **Total costs of preparation of 1 PMG** | | | **536 080** | | | | |

**Indirect expenditure**

| | | | | | |
|---|---|---|---|---|---|
| Project management | 15% | | 80 412 | 910 | Lump-sum indirect expenditure |
| Publicity | 5% | | 26 804 | | |
| **Total indirect expenditure** | | | **107 216** | | |

| | |
|---|---|
| **Total costs of 1 PMG (direct + indirect expenditure)** | **643 296** |
| **Total costs of 4 PMG** | **2 573 184** |

| | | |
|---|---|---|
| **Total cost of 100 SDTG + 4 PMG** | **9 151 584** | **EUR** |

## Conclusions

Clinical Guidelines have a deserved place in Slovak medical practice. Various Slovak associations of medical practitioners and their members create guidelines in relevant fields of practice, or assimilate guidelines from international organisations and professional bodies. The state (Ministry of Health) also contributed to the development of guidelines in Slovakia. The ministry introduced, under its legal role and responsibility to supervise an appropriate delivery of healthcare services, the legal concept of standard diagnostic and therapeutic guidelines. These concepts were initially published as methodology papers and later in the form of professional guidance, published in the Journal of the Ministry of Health.

Although the need to create SDTG has legal foundations and their necessity and benefits were repeatedly officially declared, aforementioned attempts were not reflected in practice and real support of development of guidelines. The preparation of SDTG has not been up to this day sufficiently personally, organisationally and financially secured, which led to a certain degree of unsystematic approach and creation of guidelines ad hoc.

The question of quality of provided healthcare services and satisfaction of patients is increasingly becoming a pressing matter even in Slovakia. Hence, the quality and standardisation of guidelines to facilitate delivery of health services is a must even today and will have a growing importance in the future.

**Therefore, it is particularly important to consider following points:**

- **Finalise legislative framework and form of SDTG, introduce a definition of SDTG and publish a uniform methodology for their development, revision, implementation and audit as a generally binding regulation – a decree.**
- **Ensure systematic creation and continual supervision over SDTG in the form of institutionalisation of sufficient financing from the national sources.**
- **Align the development of SDTG with national healthcare and financial targets.**
- **Incorporate SDTG into overall system of quality management of provided healthcare services in the Slovak Republic.**

The opportunity to restart the development of SDTG in Slovakia via financial help from the EU funds is a unique chance that needs to be exploited. Simultaneously, it is vital to consider financing from national sources in order to ensure that SDTG and preventive programmes will not be interrupted again, once EU funds are spent after 2020.