National guidelines for management of cervical squamous intraepithelial lesion:

A survey of European Federation for Colposcopy members

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Highlights:

- Guidelines support clinicians to follow evidence-based practice;
- Correct management of intraepithelial lesions (SIL) reduce the risk of cervical cancer;
- Most EFC member countries have national guidelines for management of cervical SIL.

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Abstract

Objectives: The management of women with cervical squamous intraepithelial lesions (SIL) is fundamental to prevention of cervical cancer in an organized cervical screening programme. Clinical guidance should improve quality of care and clinical effectiveness if developed and implemented appropriately. This survey provides an update on the current situation of national guidelines for management of cervical SIL among member countries of European Federation for Colposcopy (EFC).

Study design: A questionnaire was sent to representatives of each member country of EFC. The questionnaire contained questions on: guidelines for management of cervical SIL of the National Societies/Associations of Colposcopy or others national societies/associations including the development and the consultation processes; guidelines for management of lower genital tract diseases; and the regulations in each country for colposcopy practice.

Results: We received responses from all 34 member countries. Thirty countries reported a national guideline for management of cervical SIL that were developed by, or in conjunction with, their national societies or associations of colposcopy. In most cases there was adherence to the recommended steps for guideline development: they were developed by a multi-disciplinary group of specialists (29 countries) and society members were consulted before publication (21 countries). A small number of countries (8) reported to have guidelines for the management of lower genital tract dysplasia (e.g. vulval disease) developed by other national societies. In most countries (26) the

colposcopists are obliged to follow the guidelines but this is regulated in only 6 countries. In 12 countries (35%) the colposcopists need to be certified by the national society of colposcopy in order to practice.

Conclusion: There are advances in the development and provision of country specific guidance on the management of cervical SIL. Most EFC member countries have national guidelines that were developed using a clear methodology, are updated according to progresses in the field and are accessible online to current practitioners. These guidelines support colposcopists to follow evidence-based practice and provides understanding of best practice in guideline development and access.

Keywords: guidelines; cervical squmaous intraepithelial lesions; management cervical SIL; society of colposcopy; management vulvar diseases.

Introduction

The main role of cervical screening is to reduce the risk of cervical cancer through the detection and treatment of high-grade cervical squamous intraepithelial lesions (SIL) [1]. Treatment of SIL (previously known as cervical intraepithelial lesions) depends on various factors, including histological grade, size of lesion the patient's age, fertility plans, other medical conditions, and last but not least, the preference of the patient [2]. The terminology cervical intraepithelial neoplasia (CIN) was replaced with SIL ("low-grade" or "high-grade) in 2012 after the Lower Anogenital Squamous Terminology (LAST) consensus (Table 1) [3]. According to LAST project "this terminology is familiar to clinicians, because it parallels the terminology of the Bethesda System cytologic reports [3]. However, some clinicians feel that the previous cervical intraepithelial neoplasia (CIN) classification with high-grade disease subdivided into

CIN2 and CIN3 is more clinically relevant with the advent of conservative management of CIN2, particularly in young women [4]. Biopsy results using SIL terminology may be further qualified using “intraepithelial neoplasia”.

Today, clinical guidelines are the mainstay of quality assured medical practice. They aim to translate the best evidence into clinical practice. They should consist of systematically developed statements that help healthcare practitioners to diagnose, treat or even prevent diseases. Guidelines are usually developed by scientific societies or associations by consensus from a multi-disciplinary team.

At the time of the survey, the EFC comprised 38 national colposcopy societies or associations from 34 countries in Europe and neighboring regions along with 5 associated countries (Figure 1). The EFC aims to promote the best possible standards of colposcopy, cervical and lower genital tract pathology in Europe. Supporting high quality colposcopy services and using minimum standards of training for colposcopy throughout Europe are essential. The management of SIL requires a balance between interventions that prevent possible progression to cancer whilst avoiding overtreatment since some SIL lesions can spontaneously regress and excessive treatment can increase obstetrical morbidity.

Although a set of European colposcopy standards and guidelines were developed as part of the Europe Against Cancer Program in 2008, many countries use their own guidelines or those from other countries [5-7]. These guidelines can differ in a variety of ways, including content, scope, and developmental process. The aim of this paper

was to evaluate how guidelines for the management of SIL and lower genital tract disease were developed amongst EFC member countries.

Material and methods

A semi-structured questionnaire consisting of 40 questions was sent to representatives of each EFC member country. The principle lines of enquiry were whether there were agreed national guidelines for SIL management; who produced them; the guideline developmental process; the up-date process of the guidelines; and whether there were guidelines relating the management of other lower genital pre-invasive disease. In addition, there was enquiry as to whether colposcopists had to be licensed or registered in order to practice and whether compliance with the guidelines was monitored.

Results

We received responses from representatives of all 34-member countries. Thirty countries reported having national guidelines for management of SIL (Austria, Belgium, Croatia, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Israel, Ireland, Italy, Latvia, Lithuania, Moldova, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovenia, Spain, Sweden, Switzerland, The Netherlands, UK and Ukraine) (Table 2). In 29 countries, the guidelines were developed either by, or in close co-operation with, the national colposcopy society whilst in one other (Romania) the guideline development did not involve the EFC member society. The guidelines were introduced prior to 2000 in 6 countries, 7 during 2000-2009, 12 in the period 2010-2015 and in 5 after 2015. Apart from in Iceland, they were developed by a multi-disciplinary group. In 13 countries, the group had representations from colposcopy, gynaecology, cytopathology and public health. Five countries only had representation from gynaecology and colposcopy with the remainder including cytopathology but not

public health. Twenty-one countries were able to confirm consultation with their membership on the draft guidance. Most countries reported having a process for formal review to ensure that they reflect current evidence at 3-8 year intervals but 9 countries did not. The interval for revision differs from society to society. In some countries (The Netherlands) they are revised periodically every year (if needed), while in other countries the revision is longer (5-7 years).

Twenty two countries reported an up-date of the guideline since 2015 (Austria, Finland, Germany, Greece, Hungary, Iceland, Israel, Italy, Latvia, Moldova, Poland, Serbia, Slovenia, Spain, Sweden, Switzerland, Romania, Russia, The Netherlands, UK, Ukraine).

Eight countries (Croatia, Estonia, Finland, Germany, Greece, Latvia, Norway and Spain) included guidelines for the management of vulvar diseases.

In most countries (n=23) the colposcopists were expected to follow the guidelines but this is not regulated in all of them. In 6 countries (Croatia, Estonia, Ireland, Russia, Slovenia and the UK) evidence of clinical practice is submitted to demonstrate compliance. In 12 countries (Croatia, Finland, Greece, Hungary, Ireland, Italy, Latvia, Russia, Serbia, Slovenia, UK and Ukraine) colposcopists are certified by the national colposcopy society; however, only in 10 countries is certification mandatory in order to practice colposcopy.

Discussion

The Institute of Medicine defines clinical guidelines as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for

specific clinical circumstances" [8]. They aim to promote high quality medical practice because they are based on the strongest available scientific evidence but availability, support and adherence are also necessary steps.

A successful cervical screening programme requires not only accurate detection of cervical abnormalities but also their appropriate management. Several national and international bodies have developed guidelines on this issue including the World Health Organization (WHO), American Society of Colposcopy and Cervical Pathology (ASCCP), National Health Service (NHS) England. Such recomendations provide guidance and local organizations can implement amendments appropriate to the local setting. However, these should be well documented [9]. National guidelines are in general particularly important when regional variations exist in managing a condition.

Our survey has found that most countries have their own guidelines. While in some countries they were introduced several decades ago (Austria, 1994, UK- 1997) in others they were quite recently developed (Hungary and Iceland 2017, Ukraine 2018, Russia 2019).

In addition to using systematic literature review methodology, guidelines need to be developed transparently and in such a way that all professional stakeholders are involved. Key topics need to be agreed by a multidisciplinary group of relevant stakeholders. We have identified that the majority of guidelines followed these principles although none mentioned patient or public involvement and this importance of such input should be highlighted for future revisions, as service users are key to compliance and uptake.

With only one exception (Iceland) the national guidelines for management of SIL were developed by a group of specialists. In most of the countries this was truly multidisciplinary. In five countries (Estonia, Latvia, Lithuania, Moldova and Russia) the guidelines resulted from the cooperation between gynecologists and colposcopists. Moreover there are countries where guidelines were developed in conjunction with other societies. For example, in Spain the guidelines are a consensus document written by all the national societies involved in cervical cancer screening.

Not all representatives knew all the past details, but most countries involved interaction with members of the colposcopy society at the draft stage. This is essential to ensure ownership and future compliance of the practitioners who will be required to follow such advice.

Earlier or international guidance tended to be produced in English but the development of national guidelines in that country's language probably promotes increased usage. However, an English translation can be beneficial in order to make comparisons between EFC countries and allow other countries to access them. To this end, Austria, Greece, Poland, Spain also have guidelines in English, and the Finish guidelines have an English summary. An essential component of a successful guideline is to be available in an accessible format. As we work in a digital era the possibility of immediate accessing free the guideline on the Internet can be considered a mandatory step. Almost in all cases the national societies of colposcopies have these guidelines available on Internet so they can be downloaded.

Due to the rapid accumulation of evidence on new technologies and prevention strategies, review and updating of the current guidelines is essential. Guidelines need to be updated to take into account emerging evidence and this can be addressed by setting revision dates when the guideline committee will review new evidence. Panels of experts in the field should be involved to identify any changes in the interventions available. International associations can play an important role by giving important signals regarding the need for an updating process and from this starting point each national society can adapt and update their guidelines according to local policy and resources. In general, the best practice is to include a scheduled review update. However, this can be inflexible and can result in either a full update being performed prematurely (even if no new evidence appears in that period), or produced too late (in a rapid evolving field) [10]. Consequently, some guidelines stated that they will be updated whenever this is needed. Also, we need to keep in mind that if the guidelines are correctly produced and respect the methodology they can take time and expertise to produce them. Since 2015, revision took place in 22 (73%) countries indicating that most countries are following best practice.

Seven countries included guidelines for the management of lower genital tract dysplasia (e.g. vulval disease). This important trend reflects the growing realization that the sites of preinvasive disease throughout lower genital tract should be considered collectively rather than in isolation.

The colposcopy training is usually related to national medical training structure that has particularities for each country [11]. Our study showed that in twelve European countries, doctors performing colposcopy have to some form of registration by the

colposcopy society. Other countries have introduced methods of voluntary accreditation based on examination or curriculum vitae (Portugal, Spain). In most European countries, colposcopists are expected to follow colposcopic guidelines but only in 6 countries (Croatia, Estonia, Germany, Ireland, Russia, UK) require colposcopists to submit evidence. Also it is advisable that all national programs should include quality measures in their National Programs according to international quality measures [12]. This role in supporting or quality assuring colposcopists is a significant opportunity for colposcopy societies. Assessment of compliance with guidelines and providing feedback is best undertaken at regionally or nationally level rather than at a European level.

According to this study national societies of colposcopy played over the years an important role in the development of national guidelines. The EFC, as an 'umbrella' federation, can further support national societies by encouraging the principles of best practice which include membership of a multidisciplinary team, patient and society member engagement and requirement for review and updating. By working together under the umbrella of the EFC, European colposcopy societies can support each other with such quality improvement initiatives.

Conclusion

The majority of EFC member countries have developed national guidelines for management of SIL using a clear methodology. In most cases these are updated according to progresses in the field and are accessible to current practitioners.

Conflict of interest

None.

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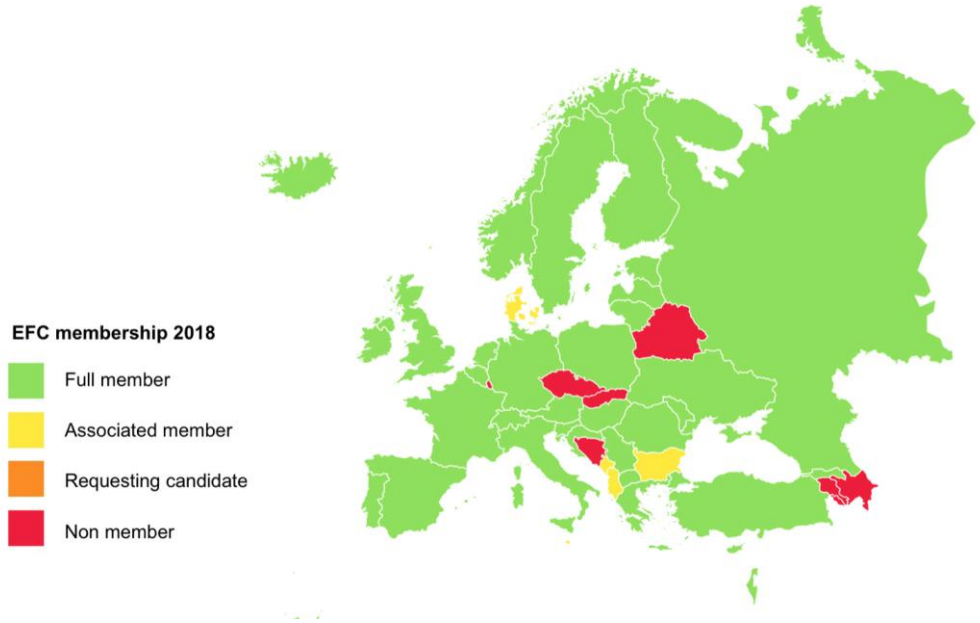

Figure 1. EFC membership 2018

Natural history model	Histology			Cytology
	Dysplasia nomenclature	*CIN nomenclature*	*LAST nomenclature*	*The Bethesda system*
	Negative	Negative		NILM
	Squamous atypia	Squamous atypia		ASC-US
Infection	Mild dysplasia	CIN 1	LSIL	LSIL
	Moderate dysplasia	CIN 2		
Precancer			HSIL	HSIL
	Severe dysplasia Carcinoma in situ	CIN 3		
Cancer	Carcinoma	Carcinoma		Carcinoma

Table 1. Comparison between dysplasia, CIN and LAST nomenclature for cervical squamous intraephitelial lesions.

	Country	Guidelines for management of SIL	When where the guidelines introduced	When the guidelines were last time updated
1.	**Austria**	Yes	1994	2018
2.	**Belgium**	Yes	2011	2011
3.	**Croatia**	Yes	2012	2012
4.	**Cyprus**	No		
5.	**Estonia**	Yes	In the late 1990s	2013
6.	**Finland**	Yes	2006	2019
7.	**France**	Yes	2002	2016

8.	**Georgia**	Yes	2010	2010
9.	**Germany**	Yes	Many years ago	2015
10.	**Greece**	Yes	2015	2015
11.	**Hungary**	Yes	2017	2017
12.	**Iceland**	Yes	2017	2017
13.	**Ireland**	Yes	2009	2014
14.	**Israel**	Yes	2010	2017
15.	**Italy**	Yes	2002	2019
16.	**Kosovo**	NO		
17.	**Latvia**	Yes	2015	2015
18.	**Lithuania**	Yes	2004	no
19.	**Macedonia**	No		
20.	**Moldova**	Yes	2015	2019
21.	**Norway**	Yes	1995	2019
22.	**Poland**	Yes	2016	2016
23.	**Portugal**	Yes	2011	2014
24.	**Romania**	Yes	2009	2019
25.	**Russia**	Yes	2019	2019
26.	**Serbia**	Yes	2013	2017
27.	**Slovenia**	Yes	2012	2019
28.	**Spain**	Yes	2015	2015
29.	**Sweden**	Yes	1980’s	2018

30.	**Switzerland**	Yes	2004	2018
31.	**The Netherlands**	Yes	2012	2020
32.	**Turkey**	No		
33.	**Ukraine**	Yes	2018	2019
34.	**United Kingdom**	Yes	1997	2019/2020

Table 2. EFC country members- information regarding the existence of national guidelines for management of SIL, when were introduced and updated.