Evaluation of a training course for general practitioners within the melanoma multimedia education programme of the Italian Melanoma Intergroup: a study protocol

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Abstract

The text discusses the role of general practitioners (GPs) in the prevention and early diagnosis of melanoma, a type of skin cancer. It highlights the need for GPs to be able to recognize suspicious skin lesions and refer patients to specialist dermatology centers. However, many GPs lack comprehensive training in diagnosing melanoma. The text mentions that various training courses have been conducted for GPs, but their impact on clinical practice has been limited. The MelaMEd Programme is an e-learning course developed by the Italian Melanoma Intergroup (IMI). The programme aims to provide GPs with comprehensive knowledge of melanoma prevention, diagnosis, and treatment. It includes an e-learning section, and a dedicated platform called MelaMEd platform, which offers a multimedia atlas of melanoma. The objective of the study is to evaluate the impact of the MelaMEd programme on GPs' diagnostic accuracy, knowledge of melanoma, and management of suspicious lesions. The methodology involves administering pre-training and post-training questionnaires to participants, assessing their diagnostic skills and evaluating the training course's effectiveness. The study aims to demonstrate the effectiveness of the MelaMEd programme in improving GPs' ability to recognize and manage melanoma. It also seeks to identify areas for improvement and recommend interventions to enhance diagnostic accuracy. The results will be analyzed statistically using descriptive, univariate, and multivariate analysed methods.

Introduction

The role of general practitioners in the prevention of melanoma

Several public information and education initiatives on self-skin surveillance have been carried out in many European nations throughout the years. Although very confusing, these initiatives have shown to significantly improve the time to diagnosis and survival from cutaneous melanoma.[1]

The primary prevention for skin malignancies, the clinical recognition of "suspicious melanoma" and the identification of patients at risk of melanoma are the recommended strategies by Europe's Beating Cancer Plan[2] and by Italian and international guidelines.[3-6]

According to these recommendations, general practitioners (GPs) and also pediatricians play an active role in the referral pathway to the dermatology center. Being the natural "link" between patients and the specialist reference centers, GPs must be able to recognize the skin lesions with clinical-morphological characteristics that are consistent with early-stage melanoma. Additionally, they must be at least somewhat familiar with the entire fundamental melanoma diagnostic-therapeutic pathway. In other words, their role is mainly to select the high-risk population and perform a preliminary differential diagnosis, *i.e.,* to select patients susceptible to specialist diagnostic investigation. Nonetheless, many GPs lack comprehensive training in diagnosis, patient selection, and the diagnostic-therapeutic pathway for skin malignancies, especially melanoma.

A recent review has collected the results of training courses for GPs on melanoma prevention. Interventions were heterogeneous and varied widely in the design and teaching methods, with live or online courses lasting from 5 minutes to 24 months.[7] Whilst several initiatives have demonstrated significant improvements in melanoma knowledge and expertise, only a few studies have revealed positive changes in clinical practice through histological review.[7]

The adequate triage of skin lesions and the knowledge of the essential basis of the melanoma diagnostic-therapeutic pathway allow an effective and efficient cooperation between GPs and specialist structures. According to the Italian Oncology Plan 2023-2027, the training of healthcare workers is considered "one of the best investments to guarantee high levels of performance" and "highly dynamic training interventions are recommended because they concern a continuously evolving sector with regards to care models, technological innovations and the indispensable aspects of humanization and respect for the person".[8] For these reasons, the importance of multimedia technologies in education has been highlighted and the widespread adoption of multimedia e-learning tools has been recommended. In Italy, the effect of formal training on GPs has been seldom evaluated and the impact of multimedia educational programme has never been investigated.[9,10]

The MelaMEd Programme and the evaluation of its training impact

The Melanoma Multimedia Education (MelaMEd) programme, one of the projects developed by the Italian Melanoma Intergroup (IMI), aims to provide physicians, mainly general practitioners, with a comprehensive understanding of the primary and secondary prevention of cutaneous melanoma and a broad overview of diagnostic and therapeutic procedures. The MelaMEd programme is hosted on a dedicated platform: an educational area which includes an e-learning section, with training courses accrediting Continuing Medical Education (CME) points.[11]

This multimedia training course is aimed at building up, at a local level, a network between multidisciplinary teams dealing with melanoma and healthcare workers. In particular, this training course has been recommended to GPs, healthcare workers who are part of multidisciplinary melanoma teams and those dealing, at a local level, with the management of patients with melanoma.

The MelaMEd programme provides the knowledge and experience that will enable participants to recognize skin lesions requiring specialist dermatological consultation by applying validated methods. Recent scientific evidence on the association between the trend of annual dermatology outpatient visit rates, skin biopsy rates and melanoma incidence rates has demonstrated a limited selection of the population at risk and of suspicious melanoma by GPs.[12] This epidemiological data undoubtedly represents an important basis for the implementation of specific training courses in the management of the diagnostic and therapeutic pathway of melanoma. These premises also highlight the need to carry out an evaluation of the training course and represent the rationale for this protocol.

Objective

In the field of prevention, the expression *demonstration project* refers to projects in which a preventive tool of proven or accepted effectiveness (a dietary correction, a test for early diagnosis, etc.) is used in practice with the aim to "show something and explain how it works".[13,14] The evaluation of these projects is essentially descriptive, and the MelaMEd programme has similar characteristics. We plan to provide a teaching activity on a large scale to a potentially very large number of subjects, *i.e.* in a real rather than experimental situation. To establish if and how this preventive strategy works, we have identified as a primary objective the MelaMEd programme impact evaluation in terms of improvement in 1) diagnostic accuracy (recognition of suspicious lesion), 2) basic knowledge of the disease, and 3) management of suspicious lesion. Our secondary objective is to gather useful information about how to enhance diagnostic accuracy and fundamental knowledge of melanoma. To address the first point, we will identify the areas in which the basic knowledge of melanoma needs to be strengthened. To address the second point, we will assess the factors that may influence the accuracy of the diagnosis and recommend appropriate intervention.

Study design

The MelaMEd programme

The MelaMEd programme consists of a dedicated asynchronous e-learning course entitled "Early diagnosis and management of the therapeutic diagnostic pathway of melanoma". The asynchronous e-learning course includes, among the educational contents, a link to the MelaMEd platform, a website developed by IMI devoted to melanoma diagnosis and treatment. Direct access to the MelaMEd platform is possible from the asynchronous e-learning course.

The asynchronous e-learning course is free of charge and is delivered on behalf of the Federazione Nazionale degli Ordini dei Medici Chirurghi e degli Odontoiatri (FNOMCeO), a national association including all the Italian community of physicians and dentists. The asynchronous e-learning course was activated on 1 June 2022 and available until 31 December 2023.

The asynchronous e-learning course has included video presentations, with audio and visual information on the following topics: identification of risk groups, sun exposure pattern, photoprotection, melanoma diagnosis using the mainly clinical Prediction Rules as ABCDE,[15,16] EFG,[17] and the "Ugly Duckling" sign,[18,19] histopathological diagnosis, surgical and medical therapy and finally interactive clinical cases in the various spectrums of melanoma progression with the related decision-making points.

For each topic, MelaMEd programme has an interactive function which allows the user to further explore any aspect of the course material available in 'switching' modality with the MelaMEd platform.

The MelaMEd programme is a real revolution in the panorama of multimedia medical training, offering interaction and integration functions connecting the asynchronous e-learning format and the MelaMEd platform.

The MelaMEd platform

The MelaMEd platform[11] is a vast virtual library, a multimedia atlas, free of charge, quick to access and easy to consult. Divided into fundamental chapters containing iconographic documentation of the clinical, dermoscopic and histological aspects of melanocytic pathology, the platform is aimed at raising awareness of the importance of identifying melanoma at an early stage. The MelaMEd platform also details surgical and medical treatments, stage and prognosis according to the latest guidelines accredited by Italian National Health Authority and by other European and international organizations.[3-5]

More specifically, the MelaMEd platform is divided into 10 chapters: epidemiology, risk factors, with particular attention to ultraviolet radiation (chapters 1, 2 and 3), clinical and differential diagnosis of melanoma facilitated by the use of non-invasive cutaneous techniques (chapters 4, 5, 6 and 7), histological diagnosis, medical and surgical therapy, staging, prognosis (chapters 8 and 9) and finally the most frequently asked questions from patients, with related answers (chapter 10). Each multimedia chapter includes a combination of more than one media type such as text, symbols, pictures, audio, video, with the use of static and dynamic images, as well as links to the most recent literature and the most updated official websites. The MelaMEd platform's contents and descriptions are listed in Table 1.

Phases of the study

Figure 1 illustrates an outline of the project. The project is divided into the following phases: 1) presentation of the project

Table 1. Number, name and description of the chapters included in the MelaMEd platform.

Number	Name	Description
1	Epidemiology	Epidemiology of melanoma in terms of incidence, mortality and survival that reports the main references at international and national level
2	Risk factors	Comprehensive review of following mainly risk features: genetic, phototypes, melanocytic nevi, ABCDE and EFG rules, ugly duckling sign
3	Sun exposure, mole and the melanoma risk	Description of endogenous, or inherited, risk factors, and exogenous, or independent, risk factors. Photo-protection and tips to ensure correct sun exposure
4	Diagnosing melanoma	Explanation of self-examination importance and of the GP and dermatologist role
5	Clinical diagnosis of melanoma	Description and iconographic documentation of the different clinical spectrum of melanoma and special clinical forms related to degree of pigmentation and/or location
6	Clinical differential diagnosis	Description and iconographic documentation of the different clinical spectrum of benignmelanocytic lesions (nevi) and benign or malignant non-melanocytic lesions
7	Early diagnosis with instrumental assessment	Dermoscopy analysis and other non-invasive instrumental methods such as sequential dermoscopy, total body photography and confocal microscopy. Dermoscopical and histopathological correlations. Description and iconographic documentation of the clinical and dermoscopical melanocytic nevi, melanoma and benign or malignant non-melanocytic lesions
8	Histological diagnosis	Histopathological and molecular diagnosis of melanoma and melanocytic lesions recommended by WHO Classification of Skin Tumours 4th edition
9	Surgery, staging, prognosis and treatment	Comprehensive review of surgical treatment, staging, prognosis, follow-up and treatment topics
10	Questions patients ask	List of the most frequently asked questions from patients, with the related answers

GP, general practitioner.

Figure 1. Name and description of the MelaMEd programme phases.

synopsis to the IMI centers, 2) communication of participation in the project by the IMI centers 3) administration of a pre-training questionnaire about the basic knowledge of the disease, the recognition and management of suspicious lesions, 4) administration of the training course, 5) administration of a post-training questionnaire to those participants who have filled in the pre-training questionnaire, and 6) comparison of pre- and post-training answers to evaluate the training course impact.

Inclusion and exclusion criteria

All GPs, resident GPs and pediatricians of the healthcare system areas of the IMI centers are eligible. Participation is optional and, in case of participation, it is mandatory for participants to provide personal data processing consent, after reading and understanding the information on the processing of personal data according to EU Regulation 679/2016. There are no exclusion criteria.

Materials and Methods

Pre-training and post-training questionnaire

The pre-training questionnaire is administered to eligible participants via Google Forms. To maximize the number of eligible people filling in the questionnaire, the coordinating center and each participating center arrange, in several calendar dates, a webinar to present the "MelaMEd project", inviting in the meantime the participants to fill in the questionnaire. The link to the questionnaire should, therefore, be provided to the participants via email in advance. We have chosen Google Forms because it allows to easily fill in the questionnaire via smartphone. Each eligible person will also receive a numerical code, required in both the pre- and post-training questionnaires. This code is used to match the answers during the analysis.

The questionnaire includes 7 multiple choice theoretical questions about the prevention of skin tumors and 10 images of skin tumors to be evaluated indicating 1) whether the lesion is benign or malignant, 2) one of 4 possible diagnoses, 3) whether the patient should be referred to a specialist for a medical consult and possible excision (Supplementary Table 1). The 10 images of pigmented lesions have been selected according to two criteria: (1) they are present in the MelaMEd platform, and (2) they reflect pigmented lesions commonly observed in general practice. These criteria allow us to assume that the participants' diagnostic skills observed in the questionnaire can be generalised to routine medical practice.

In the post-training questionnaire (Supplementary Table 1), the same questions as those included in the pre-training one will be administered, together with 10 additional questions on the Likert scale for the training course global evaluation.[20]

Questionnaire validation

Each question in the pre- and post-training questionnaires was extrapolated from recommendations by international publications[7,17,19-22] and from clinician guidelines by the National Health Institute and European organizations.[3-5] Furthermore, 20 people randomly chosen among those eligible have been asked via Google Forms for feedback about the clarity and understandability of each question. This methodology ensures that all the respondents understand the questions they are reading, strengthening the results.[23] Questions that have been evaluated include the 7 theoretical questions and the 10 questions about the images, for a total of 17 questions. For the majority (14 out of 20) of participants, all the 17 questions (100%) were asked in a clear and understandable way. For the remaining 6 participants, there were from 1 to 3, out of 17, not clear and understandable questions (Supplementary Table 2). Furthermore, 9/17 questions were clear and understandable for 20 (100%) of participants, 6/17 questions for the 95%, and, lastly, 2/17 questions were clear and understandable for the 90% of participants. These figures guarantee the strength of the results, once available.

Consent to personal data processing

The project handles participants' data, including name, last name, email address and workplace. Participants will be provided with an information form in accordance with EU Regulation 679/2016 regarding the processing of personal data. At the beginning of the pre-training questionnaire, participants will be asked to confirm that they have read and understood the information form and whether they authorize their data processing. Should a respondent decline authorization, the survey will instantly end, excluding the participant from the training course impact evaluation but not preventing the access to the asynchronous e-learning course and to the MelaMEd platform. An alert is shown before the questionnaire automatic closure, warning participants in case they accidentally denied permission.

Statistical analysis

Descriptive, univariate, and multivariate analysis of the questionnaire responses will be used to assess how the training programme improved the participants' diagnostic performance.

The percentages of correct answers for the theoretical questions given before and after the training will be compared.

As for the answers to the questions relating to images, we will compare the percentages of correctly diagnosed cases of benign or malignant melanoma, the percentages of correct diagnoses, and the percentages of referrals to dermatologists before and after training. With reference to the answers to the global evaluation questions, the frequency distribution will be calculated.

The Wilcoxon signed-ranks test will be used to compare the pre-training and post-training medians, and the McNemar test for paired data will be used to compare the pre-training and post-training proportions. We will use logistic regression models to investigate possible factors which might affect the accuracy of the diagnosis.

Conclusions

Results will be published via (inter)national peer-reviewed journals, and the findings of the study will be communicated using a comprehensive dissemination strategy aimed at healthcare professionals, in particular GPs, resident GPs and pediatricians.

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Online Supplementary

Supplementary Table 1. Question and answers of the pre-training and post-training questionnaires. The right answer is underlined.
Supplementary Table 2. Distribution of the number of clear and understandable questions from the pre- and post-training questionnaire. Questions that has been evaluated include the 7 theoretical questions and the 10 questions about the images, for a total of 17 questions.

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