



## Smart e-Skin Cancer Care in Europe During and after the Covid-19 Pandemic: a Multidisciplinary Expert Consensus

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**ABSTRACT** **Introduction:** Melanoma is the deadliest of all the skin cancers and its incidence is increasing every year in Europe. Patients with melanoma often present late to the specialist and treatment is delayed for many reasons (delay in patient consultation, misdiagnosis by general practitioners, and/or limited access to dermatologists). Beyond this, there are significant inequalities in skin cancer between population groups within the same country and between countries across Europe. The emergence of the COVID-19 pandemic only aggravated these health deficiencies.

**Objectives:** The aim was to create an expert opinion about the challenges in skin cancer management in Europe during the post COVID-19 acute pandemic and to identify and discuss the implementation of new technologies (including e-health and artificial intelligence defined as “Smart Skin Cancer Care”) to overcome them.

**Methods:** For this purpose, an *ad-hoc* questionnaire with items addressing topics of skin cancer care was developed, answered independently and discussed by a multidisciplinary European panel of experts comprising dermatologists, dermato-oncologists, patient advocacy representatives, digital health technology experts, and health technology assessment experts.

**Results:** After all panel of experts discussions, a multidisciplinary expert opinion was created.

**Conclusions:** As a conclusion, the access to dermatologists is difficult and will be aggravated in the near future. This fact, together with important differences in Skin Cancer Care in Europe, suggest the need of a new approach to skin health, prevention and disease management paradigm (focused on integration of new technologies) to minimize the impact of skin cancer and to ensure optimal quality and equity.

## Introduction

Skin cancer and particularly keratinocyte skin cancer is diagnosed more commonly than all other malignancies combined. A systematic review showed a 33% increase in keratinocyte skin cancer cases between 2007 and 2017. Most of this increase (20%) could be attributed to a change in the population age structure, and 13% to population growth [1].

Patients with melanoma often go late to the specialist. Moreover, treatment is delayed for many reasons (delay in patient consultation, misdiagnosis by general practitioners, and/or limited access to dermatologists). These facts, together with the increase of the cost-of-illness of melanoma in Europe [2,3], remark the importance to enhance prevention (ie, primary prevention: reduction of ultraviolet light exposure, and secondary prevention: earlier detection of melanoma).

In addition to these necessary improvements, relevant inequalities in skin cancer between population groups within the same country and between countries across the European region have been reported. Limitation in the number of skin cancer experts and access to dermatologists, access to skin cancer centers, availability of diagnostic techniques (ie, dermoscopy, digital monitoring, reflectance confocal microscopy, optical coherence tomography), availability of Mohs surgery in complex skin carcinoma, availability of systemic therapies, reimbursement constrains, among others [4-6].

The notable disparity in the prognosis of melanoma across Europe is correlated with significant differences in healthcare

expenditure [7,8]. According to data from recent studies in Europe, a large percentage of patients have restricted access to innovative medicines for metastatic melanoma [9]. Moreover, there is limited number of dermatologists in many European regions. There are tight health budgets and this situation is unlikely to improve in the next few years. The public healthcare pathways in many European countries rely on general practitioners triaging patients before referral to dermatologists with patients in private healthcare having the ability to go directly to dermatologists.

In 2019 a document of the EuroHealthNet highlighted the need for health policies that guarantee universal access to high-quality care and eradicate health inequalities in the European Union (EU), which are estimated to cost €980 billion per year [10].

The emergence of the COVID-19 pandemic and the post COVID-19 acute pandemic has postponed planned medical and surgical activities, may lead to delays in the diagnosis and treatment of skin cancer and could aggravate the health deficiencies previously described [11-13].

## Objectives

The aim of this study was to describe the challenges in skin cancer management in Europe during the post COVID-19 acute pandemic and to identify and discuss the implementation of new technologies (including e-health and artificial intelligence defined as “Smart Skin Cancer Care”) to overcome them.

## Methods

A panel of multidisciplinary European experts (total of 12 experts) comprising 4 dermatologists (UK N = 1, Germany N = 1, and Italy N = 2), five dermato-oncologists (Italy N = 1, Spain N = 2, Greece N = 1, and France N = 1), patient advocacy representatives (Spain N = 1), digital health technology experts (Switzerland N = 1), and health technology assessment (Spain N = 1) experts was selected for the formulation of this document. The experts were selected by the study coordinator and this selection was done based on their expertise in the different disciplines.

The experts countries were France, Germany, Greece, Italy, Spain, and the UK. It has been considered that the experts represent countries with different provisions for skin cancer care in Europe.

An ad hoc questionnaire with items addressing challenges and opportunities that the post COVID-19 pandemic offer in skin cancer management was developed (see Appendix 1) and was answered independently by all the experts in three meetings on-line.

During the three meetings on-line, the questionnaire was answered and the discussions were set up in June 2020. As a result of these discussions, a multidisciplinary expert opinion about challenges and opportunities during the post COVID-19 pandemic in skin cancer management was created and reviewed by all the experts in October-November 2020.

## Results

Challenges and opportunities that the post COVID-19 pandemic offer in skin cancer management in Europe: clinical statements.

### Statement 1

A universal access of the European Union (EU) citizens to specialists, modern diagnostics and treatments, skin cancer centres, and personalized medicine is needed, especially, in a situation of overload of health care systems and restricted health budgets, which has been aggravated by the COVID-19 pandemic. Some of these changes include better predictive genotypic and phenotypic biomarkers or a combination of them (deep phenotyping) to help selecting individuals more accurately for screening, diagnosis, treatment, and follow-up. Moreover, more efficient clinical trials guided by translational research and the collaboration of pharmaceutical companies are required. The development of networks of referral centers in coordination with local hospitals to improve effective translational research and to facilitate enrolment of patients is crucial.

### Statement 2

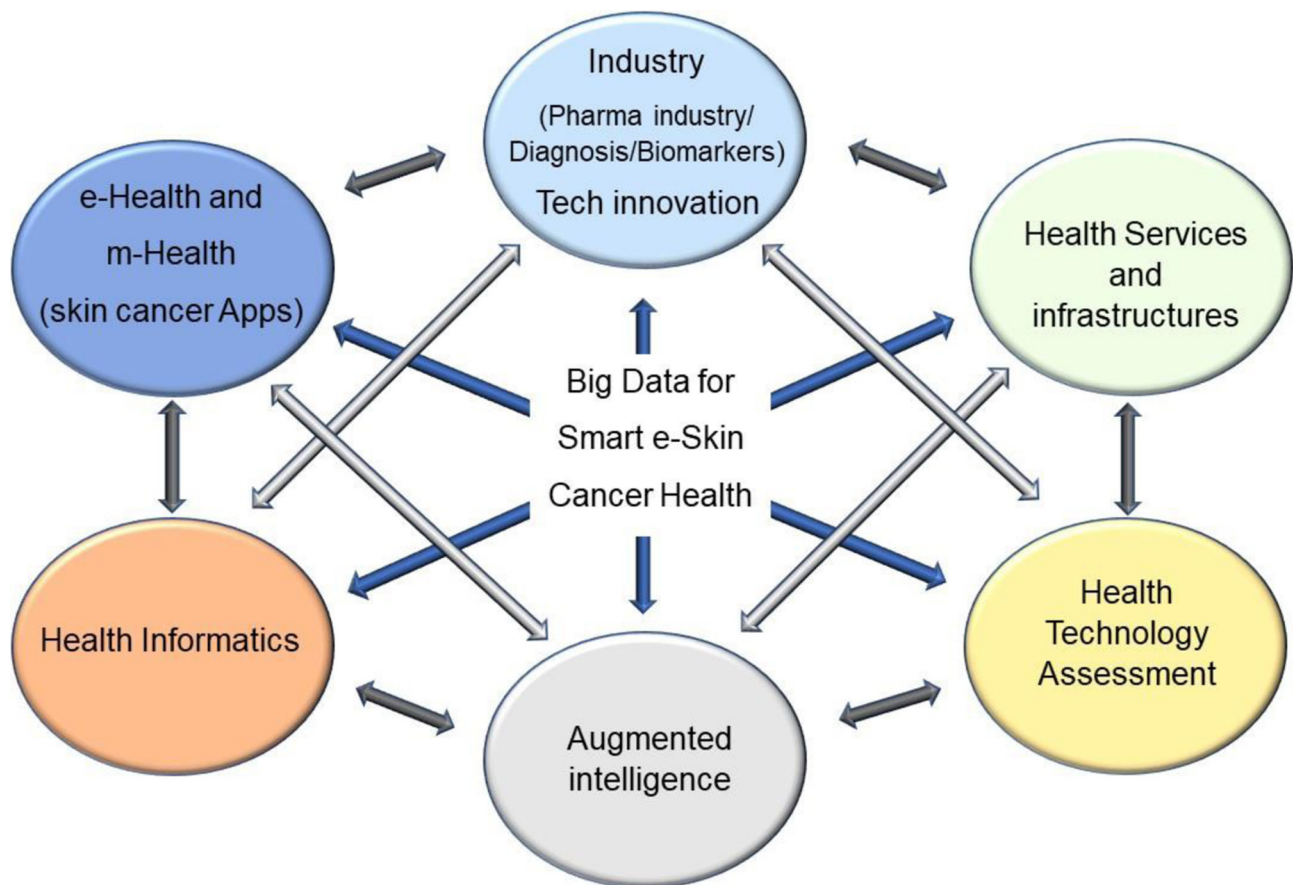
A more equitable health system should be developed by implementing new strategies and technology (e-health and others) (that will improve efficiency and reduce costs), providing high-quality skin cancer care and ensuring transparency. Artificial intelligence applications in some healthcare systems may entrench existing social and economic biases and perpetuate inadvertent discriminatory practices [14]. Thus, appropriate EU policies should be promoted to decrease inequalities among different populations and countries in Europe.

### Statement 3

A fast implementation of digital medicine in clinical practice is crucial to overcome the scenario of shortage of dermatologists in most European countries. Smart Skin cancer care consists of e-Health (electronic health) technologies including m-Health (mobile health) services, electronic record management, smart home services, and intelligent and connected medical devices for patients and health professionals in skin cancer (see Figures 1 and 2). Deep learning, which leverages artificial neural networks and learn complex mappings between inputs (eg images) and outputs (eg diagnosis) [15,16] has shown an accuracy non-inferior to dermatologists and superior to primary care physicians [17-21]. The involvement of dermatologists in the development of these digital technologies, together with other disciplines such as anthropologists or sociologists should be also considered to help associate them with human perspectives and values, while ensuring good acceptance when launched. Moreover, the collaboration of general practitioners with teledermatology is also needed since it has shown similar clinical outcomes to conventional consultation in dermatology clinics, and improved satisfaction from both patients and care providers [22-24].

### Statement 4

A more proactive disease management by the citizen/patient should be encouraged. The use of “smart” digital health technologies offers new opportunities to educate citizens and patients to improve their care without constraints of distance, location, and time, while expanding the patient/citizen’s capabilities and empowerment, which is recognized as an important part of the integrated care provision. Ensuring proper education in digital health for their conditions can improve clinical care, treatment adherence, patient satisfaction, and health outcomes [19]. The new strategies for education will require the introduction of online learning settings in skin cancer and new digital technologies. Effective policies to support empowerment of patients are needed.



**Figure 1.** Big data for smart skin cancer health. Industry (pharma, biomarkers, devices for diagnosis of skin cancer), Health services and infrastructures, Health (Skin Cancer) Technology Assessment, Artificial Intelligence/Augmented Intelligence (Natural language processing, Diagnosis using images and pathology, prognosis, precision medicine, epidemiology), Health informatics (Standards for e-Health), e-Health (Telemedicine, prescription, monitoring, etc.), m-Health (Skin cancer Apps: education, triage, diagnosis, monitoring of patients). Adapted from [https://ec.europa.eu/info/sites/info/files/mazzucato\\_report\\_2018.pdf](https://ec.europa.eu/info/sites/info/files/mazzucato_report_2018.pdf)

### Statement 5

Digital health education for health professionals is an efficient and convenient learning mode, a promising solution to enhance patient-related outcomes, to support health care staff by reducing their workload, to improve the careers coordination, meet the increasing demand and address the shortage of highly trained dermatologists. The results of a survey targeted toward European medical students showed that 85% of them consider that more digital health education should be implemented in the medical curriculum. This study concluded that there is a lack of digital health-related formats in medical education and a perceived lack of digital health literacy among European medical students [25]. Therefore, implementation of digital Health education in the medical curriculum is essential to enable a meaningful digital transformation of healthcare systems [26].

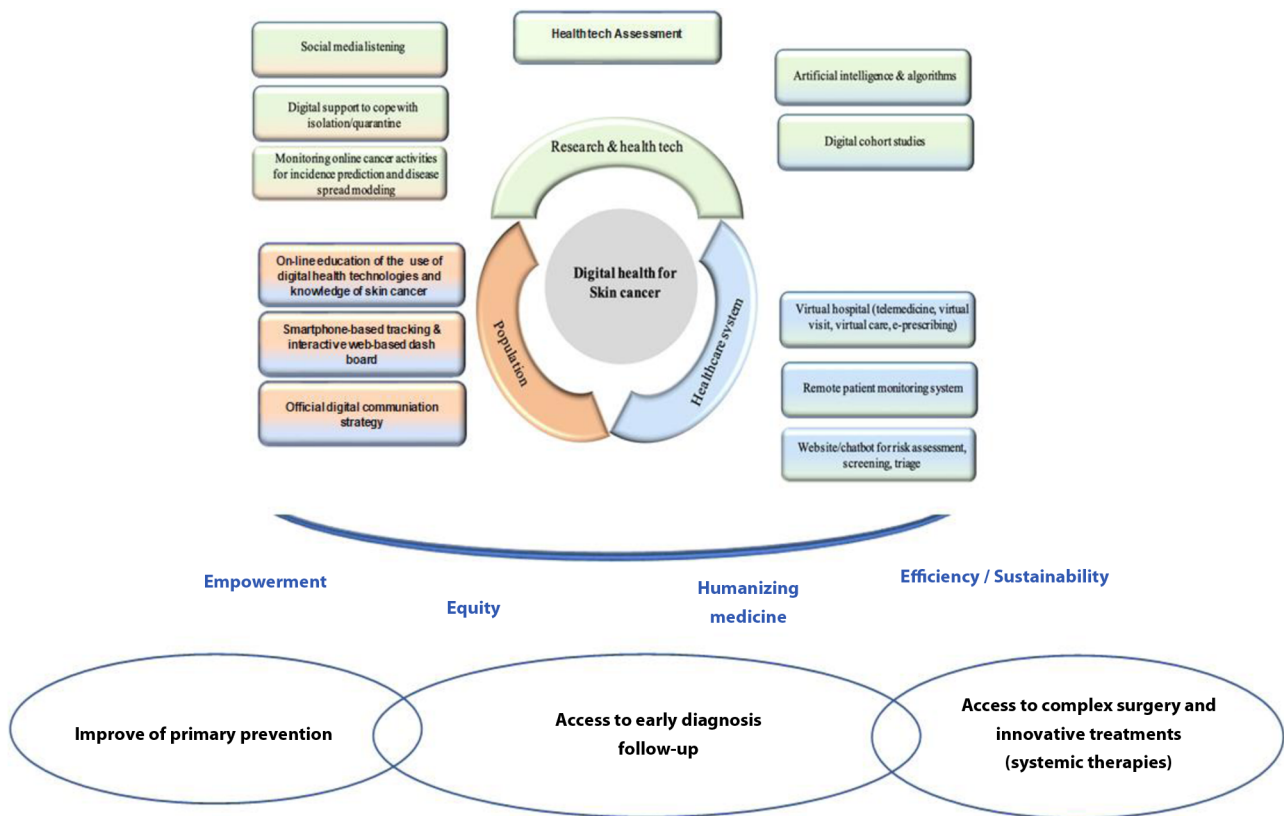
### Statement 6

Validated applications using artificial intelligence for the assessment of skin cancer are requested. Good quality standards metrics (for reporting model performance),

model confidence calibration (to assess the probability of being correct, with every prediction), and model interpretability (to understand the decision-making process) are needed [15]. There is a lack of benefit evidence in most cases, a risk of missing melanoma and a limited specificity with the risk of overdiagnosis [27]. Therefore, prospective studies including large cohorts with different populations and ethnicities in clinical practice are urgently needed to validate them [30,31].

### Statement 7

Confidentiality and data privacy protection should ensure patient/citizen safety [28]. There are important ethical concerns regarding patient confidentiality, informed consent, transparency, and data privacy protection. Although some applications require users to consent to their data policies, the process of how a patient data (including sensitive digital body images) are accessed, used, and externally shared is often not transparent. Adequate definition of data protection policies and guidelines for the consumers, companies, and health professionals to guide the fast implementation of new smart skin cancer technologies is needed.



**Figure 2.** Global components of smart skin cancer care. Global components include Research and Health Technologies, Health Care system and Population (care givers, citizens, and patients). The main areas in skin cancer to be considered in the global model are: primary prevention (e-education, identification of risk factors, behaviors, sun-protection, treatment of pre-cancer,...); access to early diagnosis (access to dermatologists, dermoscopy, advanced diagnostic tools such as RCM) and stratification of risk population for specific follow-up in skin cancer centers using deep phenotyping and other strategies) and access to complex treatment when necessary (surgery–Mohs, complex surgery; innovative systemic therapies).

### Statement 8

Adequate pre- and post-marketing certification is also required. The new regulation of medical devices in the EU implemented since May 2021 includes software programs for diagnosis (Medical Device Directives (MDD): AIMDD 90/385/EEC; MDD 93/42/EEC; IVDMD 98/79/EC). It is expected that a strict evaluation of applications for skin cancer will be implemented for EU certification. Actually, some applications licensed in Europe for risk assessment of tumours (based on photography) for citizens using artificial intelligence are Class I marked certified, which are not intended for diagnostic purposes [29].

A cultural shift is needed in digital health and particularly in the implementation of applications using artificial intelligence by developers, stakeholders, policy-makers, and Dermatology and Oncology scientific societies. Digital technology is complex, and it changes constantly due to fast technical development of the algorithms re-trained with new data provided by the users. By contrast, both clinical validation and regulatory audits are expensive and time consuming. Developers should support trustworthy third-party access to data and codes within the parameters of technical feasibility, while respecting ownership of intellectual

property. Post-marketing quality assurance must be agreed among stakeholders including the society, health policy makers, companies, clinicians, and patients/citizens. This cultural shift will ensure the overall quality of digital solutions.

### Limitations of the Study

Some bias in the selection of the experts may have been as not all European countries were represented.

### Conclusions

In the 4<sup>th</sup> industrial revolution and specially during the post COVID-19 pandemic and in a diverse European environment with significant differences in Skin Cancer Care and difficulty in accessing the dermatologist, a new approach to skin health, prevention and disease management paradigm (focused on integration of new technologies) is needed to minimize the impact of skin cancer and to ensure optimal quality and equity. This new approach must be accompanied by a cultural change in the implementation of new technologies to adequately overcome the crisis and deficiencies in skin cancer management. This implementation needs to go hand-in-hand with education of citizens/patients and health professionals.

The law and policy governing e-Health in Europe has not yet been fully defined. It is important that dermatologists remain involved in policy-making to ensure that these systems are effective, reliable, safe and ethical for citizens/patients.

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