

EADV Policy Roundtable: Towards earlier detection of skin cancer in Europe

REPORT

Key take-aways

- Skin cancer is not well understood amongst the general population, and many misconceptions exist around skin cancer and its seriousness.
- Major disparities in awareness and understanding of skin cancer exist in Europe, with some countries having long-standing prevention campaigns and others lagging behind.
- Patients' organisations have a key role to play in promoting understanding and awareness about skin cancer amongst the general population and must work together with clinicians and policymakers to promote early detection and raise awareness of the importance of prevention and of the seriousness of the disease.
- A multi-faceted strategy, which includes screening at its core, is needed to reduce the burden of skin cancer.
- New melanoma therapies have been introduced in the past 10-15 years, and while mortality is decreasing, it is impossible to determine whether this is as a result of skin cancer screening or treatment.
- While studies have been carried out to assess skin cancer screening programmes in different settings including Australia, the US and Germany, further evidence is needed to inform the design and delivery of cost-effective screening approaches.
- A skin cancer screening study in northern Germany (SCREEN) demonstrated remarkable reductions in mortality in both men and women. While population-based skin cancer screening from age 35 is now offered across the whole of Germany, weaknesses in the data mean than effectiveness of screening cannot be accurately determined.
- Skin cancer screening innovations in the Netherlands include a prediction model to stratify people with actinic keratosis into high or low

risk for follow-up visits, and a Skin Vision app developed in collaboration insurance companies.

- While Australia has the world's highest rates of skin cancer, the country boasts excellent opportunistic screening, in part thanks to the training of a large number of skin cancer specialists.
- Evidence on both cost and effectiveness of skin cancer screening is needed, and current models must be filled with prospective data.
- Screening of high-risk populations may be costeffective, and a European feasibility study for riskadjusted skin cancer screening should be conducted.
- The cost impact of keratinocyte carcinoma is larger than melanoma in many countries, and as such should be included in skin cancer screening studies.
- Consensus is needed between experts on the appropriate trial design and outcome measures, as well as risk factors of relevance.
- New technologies such as 3D full body photography and Artificial Intelligence are changing the way skin cancers are detected, and dermatologists must take a leading role in their development and implementation in the field of skin cancer.
- large network of stakeholders be А must mobilized skin cancer to advance screening and progress may take many years.
- Existing skills, knowledge, resources and shared experiences in Europe and internationally should be harnessed to exchange good practice and to build a national or even European screening programme.
- The European Union's Cancer Mission provides funding via Calls for Proposals for studies in the field of cancer.

Welcome and Introduction



Alexander Stratigos EADV President Professor of Dermatology-Venereology, University of Athens Medical School

Alexander Stratigos opened the session, welcoming participants and explaining the rationale for EADV's series of multi-stakeholder Policy Roundtables on skin cancer.

1 in 3 cancers diagnosed worldwide is a skin cancer, and prevalence of melanoma and keratinocyte carcinomas **continues to increase** in Caucasian populations. While the burden of skin cancer is very high for patients as well as healthcare systems and society, it remains a **severely underestimated public health problem**.

Europe's Beating Cancer Plan, with its major focus on prevention, is an important opportunity to make advances in primary and secondary prevention of skin cancer.

Secondary skin cancer prevention - or screening - can be achieved through a simple and quick skin examination and results in **improved survival and quality of life** through earlier identification and consequently earlier treatment.

In the context of the upcoming revision of the EU Council Recommendation on cancer screening, EADV convened the present Policy Roundtable to stimulate debate between members of the European health community around:

- The optimal approach for skin cancer screening in Europe
- Lessons in skin cancer screening from national settings
- Further research efforts needed in skin cancer screening

Keynote speech: Tackling the skin cancer epidemic through earlier detection



Alan Geller

Senior Lecturer, Department of Social and Behavioral Sciences, Harvard School of Public Health

Alan Geller from Harvard T. H. Chan School of Public Health explained the need for a **multi-faceted strategy** for tackling melanoma.

With nearly **17,000 melanoma deaths in EU-27** in 2020 alone (more than double the US), the highest rates of melanoma mortality can be found in Slovakia, Denmark, Sweden, Croatia, Netherlands and Ireland (in descending order).

Explaining that a **50% reduction** in melanoma deaths could be within reach, Geller stressed that such an achievement should not be expected through treatment alone but would require a **multi-pronged approach** including:

- Initial screening of the 70% of individuals who have never been screened
- Dermatologic surveillance for those who have already been screened
- Training of non-dermatologist physicians who are in daily contact with the skin to make referrals to skin experts
- Ensuring that more eligible advanced melanoma patients are treated
- Behavioural studies to understand the barriers for immunotherapy
- Understanding myriad factors that distinguish treated versus untreated patients

Geller cited data from the US showing a growing rate of **thick**, **invasive melanomas** in the over-70s, a pattern that is likely also occurring elsewhere. Importantly, detection of melanoma **by a physician** rather than by the patient or a third person, is associated with thinner melanoma.

While studies have been carried out to assess skin cancer screening programmes in different settings including Australia, the US and Germany, **further evidence is needed** to inform the design and delivery of cost-effective screening approaches.

The **primary goal** of a screening programme would be to blanket-screen all individuals over a certain age (exact cut-off age to be defined) who have never or rarely been screened. Given the regularity with which older agegroups visit their primary care practitioners, screening could be embedded in these routine visits.

Geller stressed that any screening programme must include a major **training** component, and pointed to the remarkable achievement of Germany's nationwide skin cancer screening trial (2008-2014) which succeeded in training 45,000 physicians in skin cancer examination. Another important aspect is **surveillance**, i.e. how to follow all screened individuals in order to record tumour thickness, determine interval melanoma, track whether treatment takes place in eligible individuals, determine vital status plus age, gender, country etc.

The major **outcome of interest** of a screening study would likely not be mortality, but rather a reduction in the proportion of melanoma greater than 2 mm after the initial screening or a reduction of melanoma with lymph node invasion.

A multi-country study must **respect the approaches used** in the respective settings, including dermatologist-led screening in some countries.

In preparation for a screening study, **pilot tests** would be needed to assess how to attract the at-risk population to be screened, ensure adequate training of screeners and to determine how data will be collected and stored and accessed.

Geller concluded by repeating that we cannot rely on treatment alone to reduce the mortality and morbidity of melanoma and that existing skills, knowledge, resources and shared experiences should be harnessed to build a **national or pan-European screening programme**.

Patient Testimonial



Kacie King Melanoma Survivor

Melanoma survivor Kacie King recounted her personal experience of being diagnosed and treated for the disease.

With **no signs of ill health**, apart from 'an ugly spot' on her arm, King was diagnosed with stage 3 nodular melanoma in 2013. By 2014, her melanoma had progressed to stage 4, and had spread to the liver and bones. She received **immunotherapy** (ipilumumab) and **radiation therapy**, which were unfortunately unsuccessful, then pembrolizumab via a **compassionate use programme**. Since then, she has remained healthy and active.

King described her experience of navigating her way through a **maze of scientific information**, and the difficulties she had finding **clear information tailored to patients** about treatment options.

Her experience was also that melanoma, and skin cancer more broadly, are **not well understood** amongst the general population, with many misconceptions about skin cancer and its seriousness.

Together with other patients, King founded **Melanoompunt**, an organization providing up-to-date information for patients on how to find and participate in clinical trials, as well as what questions to ask. While the focus was initially on treatment of late-stage melanoma, early detection is now included, thanks to collaboration with Dutch patients organization **Stichting Melanoom**, who have their own App to help people identify melanoma early.

King underscored the important role of patients organisations in **promoting understanding and awareness** about skin cancer amongst the general population and concluded with a strong call for patient groups, clinicians and policymakers to **work together** to promote early detection and raise awareness of the seriousness of the disease.

Skin cancer screening in Germany



Eckhard Breitbart Chairman Association of Dermatological Prevention, Germany and Scientific Board member, EUROSKIN

Eckhard Breitbart gave an overview of Germany's experience in skin cancer screening.

From 2003-4, a **feasibility study** (SCREEN) was undertaken in Northern Germany to obtain evidence on the effectiveness of the whole-body skin cancer test. Three years after the end of the SCREEN study, a **remarkable decrease in mortality** of around 45% was seen in both men and women. Consequently, in 2008 Germany's Joint Federal Committee introduced **mass screening** for the whole of Germany, with skin checks offered to men and women over 35 every two years by general practitioners and dermatologists. As part of the screening programme, around **42,000 general practitioners** were trained in the whole-body skin cancer test, as well as the country's **3,000 dermatologists**.

Evidence on the effectiveness of skin cancer screening in Germany is **insufficient** due to weaknesses in the data. Firstly, there is an over-estimation of screening, with patients counted twice if they are referred from the general practitioner to the dermatologist, and secondly it is impossible to determine which biopsies are performed as part of, or as a consequence of the screening programme. As such, impacts of the screening programme on mortality, morbidity, quality of life and harm versus benefit, **cannot be accurately determined**. Furthermore, new treatments were introduced in 2011, so while mortality is decreasing, it is impossible to determine whether this is as a result of skin cancer screening or treatment.

Breitbart explained that screening of high-risk populations may be **cost-effective**, and his vision for the future is for **risk-adjusted skin cancer screening**. This would consist of mass screening with time- and risk-adjusted intervals in a 2-stage procedure, implementation of an evidence-based decision analytic model and improvement of evaluative data through documentation and linkage to cancer registries.

Breitbart concluded that a **European feasibility study** for risk-adjusted skin cancer screening would be needed to compare different screening procedures across Europe for specific cancer and all-cause mortality, morbidity, quality of life, harms versus benefits and cost-effectiveness.

Skin cancer screening: A Dutch perspective



Marlies Wakkee Principal Investigator, Department of Dermatology, Erasmus Medical Center, The Netherlands

Dutch melanoma guidelines include the recommendation for **annual screening** of individuals with **more than 100 nevi or more than 5 atypical nevi**, and for instructions on **self-examination** for these individuals.

Wakkee explained that **targeted screening** was performed and evaluated in one catchment area of the Netherlands over the course of 5 years. Over a thousand patients with multiple or atypical nevi were screened, and followed-up by dermoscopy or total body photography. Melanoma incidence was 3.4%, and the melanomas detected were **fairly thin** (median Breslow thickness 0.67), and a number of them were **in-situ**.

While there is no specific guidance in the Netherlands for keratinocyte carcinoma screening, there is a guideline for **actinic keratosis (AK)** which includes the recommendation for (bi-)annual screening of patients with high-risk

AK, extensive actinic dysplasia or AK among immunocompromised patients. However, given that approximately a quarter of the Dutch population over 50 years old has at least one AK, this recommendation is still **too broad**. As a result, a **prediction model** has been developed which can be used to stratify people into **high or low risk** for follow-up visits.

Regarding the future of skin cancer screening, Wakkee believes that targeted screening, including **polygenic risk scores**, has the greatest potential. **Lesion-directed screening** should be considered, since studies have shown **no difference in detection rate** comparing full body skin examination to lesion-directed screening.

Wakkee highlighted **Artificial Intelligence (AI)** as a tool to support skin cancer screening. Currently, the **sensitivity** of a general practitioner to recognize a skin cancer is around 40%. Al could be considered to **support** self-screening or primary care physicians, without the need for training the latter. While AI has high potential, there is **limited research** on actual implementation.

The Netherlands' **Skin Vision app** has been freely offered to around 2.2 million people in the country by a large health insurance company. Only 1.1% of this group used it, but results show users have a **higher likelihood** of having a **skin cancer diagnosis** based on claims made to the health insurance company. However, this group also has a **2-3 times higher likelihood** of having a diagnosis for a **benign skin lesion**. No data was obtained on the type of skin cancer or staging, but this study should be repeated to evaluate long-term effects. The next step is a **long-term RCT**, also bringing in another insurance company, and offering the Skin Vision app to all insured. Individuals' data could be linked to national pathology records, claims data and further clinical data.

Early detection of melanoma in Australia



H. Peter Soyer Director of the Dermatology Research Centre, The University of Queensland and the Dermatology Department, Princess Alexandra Hospital Brisbane, Australia

Twenty years ago, Prof. Joanne Aitken conducted a **population-based melanoma screening trial** in south-east Queensland. Results of the trial showed initial increased incidence in those screened, and then a decrease after the three-year screening window. This pattern was identical in both genders.

The most interesting outcome was a rise in incidence in thin and in situ melanoma, and a 40% lower likelihood of diagnosis of thick melanoma.

Soyer explained that we can do much better in risk stratification than currently, and that while **targeted screening programmes** are the future, **holistic risk scores** will be needed and integrated into screening programmes. Given the significance of genetic make-up, **polygenic risk scores** are likely to be a key element determining who to screen, although there remain many questions around **mainstreaming** genetics into daily practice.

New technologies such as **3D full body photography** and **AI** are changing the way skin cancers are detected, and also present opportunities for the field of **inflammatory skin diseases**. Much research in AI is ongoing, and Soyer underscored the importance of dermatologists taking a **leading role** in its development in the field.

In this regard, The University of Queensland, The University of Sydney and Monash University have received a 10-million-Austrialan Dollar grant establishing the Australian Centre of Excellence in Melanoma Imaging and Diagnosis (ACEMID) to transform early detection of melanoma using total body surveillance to enhance individual lesion management.

These technologies will be offered also in rural Australia where there are very few dermatologists. Furthermore, Australia's national funding body has just provided a grant for the development of a roadmap for targeted melanoma screening in Australia.

PANEL DISCUSSION: Multi-stakeholder perspectives on skin cancer screening in Europe

MODERATORS



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Matthias Augustin

Institute for Health Services Research in Dermatology and Nursing (IVDP), University Medical Center Hamburg-Eppendorf

Introduction

In the ensuing discussion, panellists were asked to provide their perspectives on how to move to a more systematic approach to skin cancer screening, and the role of research therein. The panel discussion was moderated by Myrto Trakatelli, Chair of EADV's Advocacy Working Group, and Alexander Stratigos, EADV President.

Cost-effectiveness

Matthias Augustin explained the need to obtain **evidence on both cost and effectiveness** of skin cancer screening. Sound economic modelling studies have been published from US, Italy, Australia and Germany, and while such models can indicate where there could be economic benefit, modelling is not measuring, and the models now need to be filled with **prospective data**.



Matthias Augustin

The cost impact of **keratinocyte carcinoma** is larger in many countries than melanoma, and as such Augustin recommended including keratinocyte carcinoma in skin cancer screening studies, not least because any skin cancer screening exam can identify all types of skin cancer.

Risk factors

The risk factors to take into consideration when designing targeted skin cancer screening were discussed. While older age is a clear risk factor, Soyer argued that in Australia, melanoma has the highest incidence and greatest overall mortality in the **19-39 age-group**. As such, he advocated the consideration of **polygenic risk scores** to segment screening efforts.

Geller explained that from a public health perspective, the optimal approach is to try to draw in as many people as

possible to be screened who have **never been screened before**. The disadvantage of using risk factors such as a high number of nevi (moles), or changing nevi, is that people often **do not know** if they have a changing mole or many moles. Furthermore, studies show that most people who are diagnosed with melanoma do not have a lot of moles, meaning they might not even make the cut-off. He reiterated that it is in the **large, unscreened pool** that thin melanomas will be found in people who may otherwise have **died due to late diagnosis**.

Breitbart recalled experience in Germany which points to the optimal approach being a **combination of risk factors**. He recommended creating an expert group to define the risk population for melanoma and for keratinocyte carcinoma in different European countries, and to define phenotypes. Wakkee suggested considering use of **polygenic risk scores**, **total body photography and AI**, with those individuals with a high polygenic risk score having a lower threshold for AI evaluation of lesions or more frequent follow-up, or offer those with low polygenic risk score being offered lesion-directed screening rather than whole body screening.

Trial design

Augustin explained that since mortality is not the biggest problem presented by skin cancer (rather the burden of the disease is characterized by **morbidity**, **loss of quality of life** and **increased treatment burden** if the early intervention point is missed), a **broader set of endpoints** is preferred, rather than simply mortality. A series of different end-points can determine the overall **value** of screening. He added that there may be **different risk criteria** for melanoma and keratinocyte carcinoma. Therefore, it is important to **separately identify patients** at risk of melanoma and those at risk of keratinocyte carcinoma.

Soyer added that, thanks in part to the excellent outcomes of immunotherapy, mortality is in decline, which is another reason **not to use mortality as an endpoint**. More innovative trial designs are needed, with appropriate endpoints. Geller agreed that the issue of endpoints is a crucial one, and one that should be the basis of **further discussion**. Another consideration, provided by Soyer, is to use **lymph node involvement** as an end-point, given that the overall aim is to save lives. Geller recalled the challenges faced by the breast cancer community in determining how many lives are saved by treatment and how many by mammography, and suggested that this might also be an **important question** to answer for skin cancer.

Geller said that in case an RCT is undertaken, people would need to be pre-selected geographically to a clinical exam versus a clinical exam and dermoscopy in countries that have high rates of skin cancer. A **stepped wedge design**, where one part of the population is screened, another is not, and mortality rates are followed over a number of years, could be considered, along with a number of other designs.

Soyer is currently involved in two nationally funded studies. Firstly, the **IMAGE trial** is focused on Melanoma Surveillance Photography, which combines 2D or 3D total body photography with digital dermoscopy to monitor skin lesions. The outcomes will determine whether 2D or 3D total body photography leads to earlier detection of melanoma and reduces unnecessary biopsies.

Soyer underscored the importance of a different approach to screening people who have a different melanoma risk and in this context he mentioned a nationally funded **cohort study** which is ongoing in over 15 sites to collect images, genetic and histo-pathologic data of up to 15,000 people. These people will be followed for 3 years to determine the phenotypic/genotypic correlation. The project involves a **large multi-modal group of experts** including epidemiologists, pathologists, biostatisticians, health economists and dermatologists. Soyer stressed that involvement of **health economists** in screening studies is crucial since no progress will be made in the absence of economic data, even if information on effectiveness is available.

Harry de Koning, Professor and Deputy Head of Public Health at Erasmus University, the Netherlands, and a renowned expert on cancer screening, expressed support for the EADV's initiative to **bring members of the multi-stakeholder skin cancer community together** to discuss the future of skin cancer screening. He commented that as long as the debate around effectiveness of skin cancer screening is still ongoing, it very difficult to ask policymakers to implement screening programmes.

De Koning has been involved in various cancer screening programmes, many of which, he explained, are targeted or risk-based, and which may be an interesting option for skin cancer. He emphasized the importance of **obtaining data on effectiveness**, and of studies using **morbidity** as an endpoint. He explained that there is a lot of debate within the cancer community about use of **intermediate outcome measures**, and these should at least be discussed in skin cancer. He believed it would be possible to devise trials to answer questions that the whole community agrees on. De Koning recalled experience from the breast cancer field, in which information is being sought on the impact of mammography versus treatment. The same information is needed in skin cancer, and data on screening and data on

treatment trials should be brought together to **create a model**. He reiterated the importance of an initiative in this field and was **optimistic** about possibilities to improve early detection of skin cancer.

Awareness-raising, education and training

Veronique del Marmol recommended targeting **as many people as possible** with skin cancer prevention and detection messages, as **regularly as possible** and in **many ways**. Different population groups have **different educational needs**. Furthermore, **increased education** about skin cancer is needed amongst all healthcare professionals who see the skin (general practitioners, pneumologists, cardiologists etc) as they need to be able to recognize skin cancer, recognize those at risk from skin cancer and select patients who need to be screened.

Soyer explained that Australia is the **world leader** in primary prevention of skin cancer, with **sunbeds completely banned** since 2015, excellent **opportunistic screening** and various **prevention programmes** in place. For instance, there are very stringent policies in place for **outdoor workers**, who must be fully dressed and wear suitable headwear, and **school children** are not allowed to play outdoors unless they are wearing a hat, no matter what their skin colour.

Australia has a vast experience in **educating general practitioners**, since it has a very low number of dermatologists (around 700 in the whole country) and has trained up around a thousand so-called **skin cancer specialists** who work exclusively in skin cancer. He suggested that, in Australia at least, the immediate future of early detection may be



opportunistic screening driven by doctors and a population that is very keen on getting screened, rather than a nationwide targeted screening programme which might take decades before formally implemented.

Del Marmol described **major disparities** in primary and secondary prevention between European countries. While some Member States have been conducting prevention campaigns for many years, others have only started more recently, leading to significant differences in diagnosis and prognosis of melanoma across the continent.

Veronique del Marmol

King lamented that there is still a **desire amongst the general population to tan**, and a belief that being tanned is akin to being healthy. She said that if skin cancer prevention messages are restricted to the doctor's office, many people will be missed, and that there is a **role for patient groups** in raising awareness. Similarly, early detection can be improved by educating professionals who come into contact with the skin, such as hairdressers, beauty salon workers, tattoo artists etc. Community awareness can be improved by initiatives such as the provision of sunscreen dispensers throughout cities, or setting up stands at local sports events.

Political and stakeholder support for skin cancer screening

Breitbart recounted his experience of generating political interest in early detection of skin cancer. His first ambitions, through a small Working Group on skin cancer prevention in 1984, were discouraged by his dermatology teachers and it took 24 years to **sensitize the government** about the need for policy initiatives before implementation of nationwide screening. After the introduction of nationwide screening, the stakeholder network had to be constantly maintained and mobilized, which has now been the case for over 37 years. Breitbart suggested creating an **expert group** to exchange experiences on engaging stakeholders on this topic.

Wakkee said that discussions about screening and use of new technologies are ongoing with **health insurance companies** in the Netherlands, who are very enthusiastic. There is also a strong lobby from technology companies to have their innovations implemented.

The European Union's Mission on Cancer



Jan-Willem van de Loo Theme Lead cancer, scientific lead cancer mission, European Commission, DG Research and Innovation

Jan-Willem van de Loo presented **the EU's Mission on Cancer**, which is part of the Horizon Europe research framework programme and developed as part of the overall flagship initiative 'Europe's Beating Cancer Plan' of the Von der Leyen Commission.

One of the hallmarks of the five Missions is the emphasis on **generating synergies** with pre-existing initiatives within as well as outside Europe. Similar to previous framework programmes, the Mission on Cancer includes **calls for proposals** for research projects on high priority topics in cancer. However, topics are defined to bring many stakeholders together, such as scientists, NGOs, citizen representatives, patient representatives, innovators, Member

States, etc., with a strong focus on the **end user** (for example using a 'living lab' approach). Calls for proposals can be found on the funding and tenders portal of the European Commission (https://ec.europa.eu/info/funding-tenders/ opportunities/portal/screen/home). A call for proposals to 'Develop new methods and technologies for cancer screening and early detection' closed last April and is under evaluation and another one on 'Improving and upscaling primary prevention of cancer through implementation research' is open with a deadline of 7 September.

RCTs are still the gold standard for cancer research and a call for proposals has recently opened on 'Pragmatic clinical trials to optimize treatments for patients with refractory cancers' (which covers all cancers and cancer subtypes, including melanoma).

Van de Loo explained the difference in objectives between Missions and the Health cluster part of Horizon Europe is that Missions aim to **bring together all relevant stakeholders** through a 'portfolio of actions' approach, such as clustering projects, implementing policies and legislation (e.g. taxation) and establishing synergies between various cancer policy activities at EU, national, regional and local community level. In 2023, the Commission aims to publish another call for proposals on prevention, focusing entirely on behavioural research. For further information about Calls for Proposals, **National Contact Points** of each Member State can be contacted.

Van de Loo explained that the European Commission is **engaging with citizens**, through citizen engagement events, such as focus groups, to understand what is important to them in the field of cancer.

Wrap-Up

Alexander Stratigos

EADV President and Professor of Dermatology-Venereology, University of Athens Medical School

Stratigos wrapped up the Policy Roundtable, concluding that in order to control the skin cancer epidemic, concerted action is needed in both primary and secondary prevention. Screening is an ongoing debate with multiple perspectives. Stratigos praised colleagues in the Netherlands, Germany and Australia for their efforts in skin cancer screening and for sharing their experiences with the group.

He stressed the importance of designing the right kind of studies with appropriate endpoints. We must look to innovative trial designs and integration of technology and genetics, and an optimal screening approach may be quite different to what was envisaged 10-20 years ago.

EADV remains committed to supporting discussions and initiatives to raise awareness about skin cancer, and through its series of Policy Roundtable discussions, aims to define and promote actions and policy changes needed to bring about progress in the field of skin cancer.

ABOUT EADV

Founded in 1987, the European Academy of Dermatology and Venereology is a global community with the unifying goal of advancing excellence in patient care, promoting knowledge and expertise among healthcare professionals, as well as advocating on behalf of the specialty and patients. It is a non-profit organisation with over 7000 members across more than 100 countries in the world, providing a valuable service for every type of dermato-venereologist professional. Learn more on **eadv.org**

For more information about EADV's advocacy and public affairs activities, please contact **publicaffairs@eadv.org**