ESMO 2014 Congress Scientific Meeting Report – Public Health and Health Economics Extract

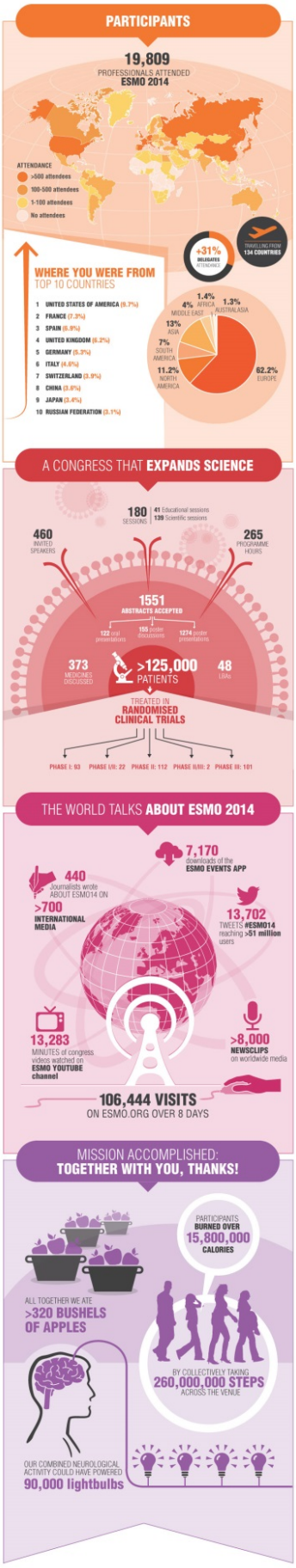
26-30 September 2014

Madrid, Spain

Summary

The European Society for Medical Oncology (ESMO) Congress, held September 26 to 30 in Madrid, Spain, was a record-breaker on nearly all levels. It was resounding success and in a dedicated infographic you can find the congress statistics. A primary emphasis in the scientific programme was placed on precision medicine and how it will change the future treatment landscape in oncology. In addition, a number of scientific presentations were dedicated to cancer immunology and immunotherapy across multiple tumour types. This report is an overview of key scientific presentations made during the congress by leading international investigators. It attempts to represent the diversity and depth of the ESMO 2014 scientific programme, as well as advances in oncology.

Infographic (right): ESMO 2014 record breaking Congress



Contents

Public Health and Health Economics

Risk of incremental toxicities and associated costs of new anticancer drugs

Dr Saroj Niraula of the CancerCare Manitoba MacCharles, Winnipeg, Canada said that newly approved anticancer drugs are associated with increased toxicity and management of toxicity leads to an increase in overall cost of treatment except when agents with a specific molecular target on cancer cells are used. Adopting policy to encourage development of biomarker-driven drugs is encouraged. Frequency of toxicity and associated costs are likely higher in less selected patients treated in general oncologic practice.

The aim of this meta-analysis was to quantify the frequency of serious toxicities caused by new anticancer drugs and incremental costs associated with their management, according to the type of anticancer drugs.

The researchers identified anticancer drugs approved by the US Food and Drug Administration (FDA) during 2000-2011, and pivotal trials supporting their registration. Twelve frequent, grade III-IV adverse events were weighted and pooled in a meta-analysis to obtain both relative and absolute excess risk in experimental groups compared to the control groups of the registration trials. Estimates of incremental drug prices and costs for management of adverse events were calculated according to types of new agents based on target-specificity of the new drugs and activity of comparator groups used in the pivotal trials. Costs were derived from pharmacy "red book" and literature, adjusted for inflation to reflect 2014 dollar value.

The study team identified 41 studies with 27,500 patients involving 19 drugs. Agents directed against a specific molecular target on cancer cells had a lower incidence of grade III-IV toxicities than the controls, median relative risk 0.7, $p = 0.2$; whereas less-specific targeted agents, including angiogenesis inhibitors (median relative risk 3.4, $p < 0.001$), and chemotherapeutic agents (median relative risk 1.6, $p < 0.01$) were more toxic. Risk was increased regardless of whether the control arm contained active treatment (relative risk 2.1, $p < 0.001$) or not (relative risk 3.0, $p < 0.001$).

Median incremental drug-price for experimental agents was 6000 dollars/patient/month. Median cost of managing adverse events was decreased in the experimental arm compared to the control for specifically targeted agents but this was persistently higher than controls across all 12 adverse events for less-specific targeted agents and chemotherapy. Sensitivity analyses performed using broader hypothetical range strengthened the findings.

However, Dr Niraula reported the study limitations: they only used published data and toxicities are underreported in published clinical trials, information on recurring adverse events are usually not clear in clinical trial reports, they did not consider low grade adverse events, sources of cost of toxicity were heterogeneous and such cost is sensitive to local healthcare market. Therefore, the data on toxicity are likely to be underestimates of the true cost.

Dr Josep Borras of the Institut Català d'Oncologia Hospital Duran i Reynals, Barcelona, Spain, who discussed the study results, said that median incremental drug price was higher in the experimental drug than in the control group for less specific target drugs and for chemotherapy. This work allowed analysis of the question of access in a more qualitative way: relevance of safety and risk/benefit ratio of new drugs, as well as impact on health care resources utilisation and cost.

Different drugs showed a higher cost for cancer care. A relevant question is if these differences should be taken into account in the approval process. Drugs are not equal in efficacy but also not in their risk/benefit ratio and in the incremental cost of management of the adverse events associated with new drugs. There is a need for a better alignment between prescribers and regulators in order to assess the quality and contribution of a new drug more consistently.

All authors in this study have declared no conflicts of interest.

Reference

1386O_PR: Risk of incremental toxicities and associated costs of new anticancer drugs: A meta-analysis

Author financial conflicts of interest in clinical practice guidelines for systemic anti-cancer drugs

Dr Ariadna Tibau of the Hospital de la Santa Creu i Sant Pau, Barcelona, Spain said that reporting of financial conflicts of interest (COIs) in clinical practice guidelines (CPGs) and consensus statements has improved in the last decade. However, published expert recommendations may still be influenced by use of medical writers or financial COIs of authors. Author financial COIs are associated with endorsement of specific drugs.

CPGs and consensus statements are used to apply evidence-based medicine or expert recommendations to routine clinical practice. In this study, the researchers explore the prevalence and transparency of self-reporting of financial COIs and their relationship with endorsement of specific drugs.

An electronic search of MEDLINE was conducted to identify CPGs and consensus statements in breast, colorectal, lung and prostate cancer published between January 2003 and October 2013. The search was restricted to English language articles evaluating systemic therapy. When more than one CPG or consensus statement from the same source was identified, the most recent version was evaluated. Particular attention was paid to collecting data on self-reporting of funding sources, author financial COIs and involvement of manuscript writers who were not listed as authors. The association between endorsement of a specific drug in the abstract of the guideline and author financial COIs with the company marketing that drug was evaluated.

In total, 142 articles were evaluated; 64% were CPGs and 36% were consensus statements. In total 41% of articles addressed breast cancer, 20% CRC, 25% lung cancer, 11% prostate cancer and 3% more than one tumour type. Only 45% of articles explicitly reported funding sources and of these, 65% disclosed partial or full industry sponsorship. Use of medical writers was declared in 13%, but among the other articles, only 17% of articles explicitly reported that authors were involved in the writing and final approval of the manuscript.

Author financial COIs were declared in 45% of articles, 23% affirmed no financal COIs and 31% did not include disclosures of financial COIs. The proportion of articles reporting financial COIs increased from 11% in 2003 to 93% in 2013. There was a significant association between financial COIs of any author and endorsement of specific drugs ($p = 0.001$). Similar results were obtained when analysis was limited to first, senior or corresponding author ($p = 0.01$).

Further research is needed to improve published standards for guideline development.

All authors have declared no conflicts of interest.

Reference

1385O: Author financial conflicts of interest (FCOIs) in Clinical Practice Guidelines (CPGs) for systemic anti-cancer drugs

Cross-comparison of cancer drug approvals among international regulatory bodies

Dr Nardin Samuel of the Sunnybrook Odette Cancer Centre, Toronto, Canada reported findings from the first study to systematically compare cancer drug approvals between three major regulatory bodies. The researchers anticipated that the differences in drug approval times can create a dialogue between clinicians and government agencies to understand the current challenges in approval processes and work jointly towards improving them.

The therapeutic care of cancer patients is significantly impacted by timely access to drugs that improve survival and overall patient outcomes. The key objective of this study was to examine the drug approval process and time to approval by three international regulatory bodies – Health Canada, US FDA and European Medicines Agency (EMA).

The publicly available Health Canada Drug Product Database was surveyed for all currently marketed anti-neoplastics approved between 1 January, 2005 and 1 June, 2013. For this set of cancer drugs, data was obtained on submission and approval dates by Health Canada, FDA and EMA and time to approval were calculated from the dates of initial drug submission filing to final approval for marketing.

Using Health Canada as a comparative benchmark, the study team identified 41 antineoplastic agents that met the study criteria. Overall, the time to approval was significantly less for the FDA when compared with the EMA (6.0 months, $p < 0.001$) and Health Canada (7.6 months, $p < 0.001$). There was no overall significant difference in time to approval between Health Canada and the EMA (3.43 months, $p = 0.446$).

Azactidine, approved for haematological malignancies, had the greatest delay (66.1 months) between FDA and Health Canada approval. The EMA approved azactidine 10.3 months earlier than Health Canada but 55.8 months following FDA approval. Among all drugs assessed cabazitaxel, approved for metastatic prostate cancer, was associated with the shortest time to approval by the FDA at only 17 days. In Canada and Europe, the time to approval for cabazitaxel was 11.63 months and 11.03 months, respectively.

Regarding drug approval timelines, on average, cancer drugs are approved by the FDA 20.6 months earlier than Health Canada. The EMA approves cancer drugs an average of 10.0 months earlier than Health Canada, while the FDA approvals are an average of 24.9 months earlier than the EMA.

Dr Samuel stated that the analysis was limited by the consideration of only initial drug approvals in Canada and not supplementary drug approvals, which constitute a large portion of cancer drug approvals. Indeed, the trends observed may be different when considering time to supplementary drug approval once the drug has initially been given regulatory approval. Approval times are not the only dimension to drug access. Cancer drug approval times may not necessarily precede swift regulation of drug costs and coverage, yet early approval times are a salient aspect of drug access.

Dr Josep Borras of the Institut Català d'Oncologia Hospital Duran i Reynals, Barcelona, Spain, who discussed the study results, said that FDA approved drugs an average of 24.9 months earlier than EMA. Also, EMA approves cancer drugs an average of 10.0 months earlier than Health Canada. Benchmark as a method focused in this study on two variables (time to approval and timelines), but in reality there are relevant differences in other key aspects, such as health care services organisation, reimbursement systems, price negotiations between industry and regulators (also, among EU countries), societal values, and we should not forget that we are not comparing similar countries.

Access to cancer therapies is defined as a timely use of personal health services to achieve the best possible health outcomes. Relevant factors associated with access are attributes of health systems (coverage of health care, geographic access, coordination among levels of care, reimbursement), patients (perception of benefit, information available), and physicians (knowledge, expertise). Differences according to socio-economic level, residence of patient, reimbursement systems are widely found. Access to cancer drugs is an essential factor in high quality cancer care, but pressure for cost containment in health care systems runs up against ensuring affordable access to new cancer drugs.

Policy issues not considered in the study, but relevant at country level are after regulatory approval at national or EU level, price negotiation and funding evaluation for reimbursement from national health system, regional and hospital level (approval for local drug formularies) in several countries. Access to cancer drugs is an essential factor in high quality cancer care, but access should be timely to high quality cancer care, not only to cancer drugs. High quality cancer care is a multidisciplinary activity involving diagnosis, surgery, radiotherapy and chemotherapy in many caner patients. In this study access to cancer drugs measured by time to approval showed clear differences related to health care systems.

All authors in this study have declared no conflicts of interest.

Reference

1036O_PR: Cross-comparison of cancer drug approvals among international regulatory bodies

RELATED INFORMATION

Click here to access the Conference abstracts.

Click here to access the meeting webcast page.

Save the date

European Cancer Congress 2015 (ECC 2015), Vienna, Austria, 25-29 September 2015.

Affiliations and Disclosure

Affiliation

Dr Svetlana Jezdic, ESMO Head Office

Disclosure

No conflicts of interest to disclose.

Acknowledgment

ESMO would like to thank Drs Gligorov, von Minckwitz, Zhu, Kang, Lenz, Stintzing, Konecny, Krishnansu, Goss, Robert, McArthur, Weber, and Blay for giving their permission to publish images from the studies presented during the ESMO 2014 Congress in the ESMO Scientific report.