Proceedings Book

3rd ECOP (European Conference of Oncology Pharmacy)

19–21 May 2016, Dubrovnik, Croatia

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European Journal of Oncology Pharmacy (EJOP) is the official Journal of the European Society of Oncology Pharmacy (ESOP).

SCOPE

The *European Journal of Oncology Pharmacy* (EJOP), published quarterly, sets out to offer a professional communication platform to European oncology pharmacy practitioners. As the official journal of ESOP, the scope of EJOP is to satisfy ESOP members' needs in terms of improvement on professional standard, setting guidelines, further education and sharing practice experience. EJOP offers ESOP members an insight into the differences and commonalities of oncology pharmacy standards and training, as well as the opportunities to learn the unique benefits and advantages from the different oncology pharmacy practitioners.

EJOP carries an editorial focus for providing information on current development in oncology treatment, sharing practice-related experiences as well as offering an educational platform via conference/meeting reports. The editorial content includes papers in the area of scientific, clinical, therapeutic, economic and social aspects. Prominent experts and eminent professionals support EJOP by sharing their original and qualitative knowledge and insight via high quality review papers covering drug breakthroughs, developments in oncology treatment along with practice guidelines and educational topics which fall within the scope of oncology pharmacy practice.

EJOP is published quarterly and distributed to more than 3,500 oncology pharmacists, pharmacy technicians, subscribers and key opinion leaders in 33 countries and at major international and national conferences. EJOP is available online (www.ejop.eu).

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Letter of Welcome

On behalf of the European Society of Oncology Pharmacy (ESOP) and the Organizing Committee, we warmly welcome you to the third European Conference of Oncology Pharmacy (ECOP), in the time-honoured city of Dubrovnik, Croatia, 19–21 May 2016.

Close cooperation between oncology physicians and oncology pharmacists is essential for optimal patient care. ECOP 2016 offers a tremendous opportunity for exchange and debate between its 3,000 members, colleagues and partners worldwide.

The primary focus of this unique European conference is to promote the highest standards of pharmaceutical care in the management and support of patients with tumours. The latest advances in research, patient management and practice are being showcased in keynote lectures, scientific symposia and poster sessions in two distinct tracks, clinical and practical.

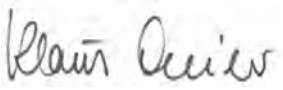
We know that a multi-professional, multidisciplinary approach in oncology will not only ensure economic use of resources, but also significantly improve patient safety.

We would like to take this opportunity to invite you to the Welcome Reception held in the exhibition area of the conference venue on Thursday 19 May 2016 from 18:30, providing you with the opportunity to meet colleagues from around the world, to network in a convivial setting and forge new links for future collaboration.

Lastly, but by no means least, our host city will match the exciting promise of the conference itself. Speakers, participants, guests and friends should make time to discover the wonderful city that is Dubrovnik with its wealth of historical buildings and beautiful coastline.

We trust that you will return from the conference inspired by colleagues from around the world and that you will have made new friends and scientific contacts that will support you in your essential work.

We are delighted to be welcoming you to what promises to be a highly educational, collaborative and successful conference.



Klaus Meier
ECOP Conference Chair

Mikael Daouphars
ECOP Scientific Chair

Welcome from EU Commissioner Vytenis Andriukaitis

I wish to express my best wishes of success to the European Society of Oncology Pharmacy and to all participants in this European Congress on Oncology Pharmacy 2016 in Dubrovnik.

Cancer is not something that only 'happens to other people'. Most people I know have been affected by cancer in one way or another. They have either survived cancer or supported a loved one. Unfortunately, I know myself first-hand what it is like to lose close family members to this terrible disease.

On the top of the fact that cancer makes us go through extremely difficult times and more often than not a lot of pain, it also affects our societies and healthcare systems. In the European Union (EU), in 2012 alone, 2,6 million EU citizens were diagnosed with some form of cancer, and 1,26 million died of cancer. Given today's incidence rates, we expect that in the EU, 1 in 3 men and 1 in 4 women will be directly affected by cancer before reaching 75 years of age.

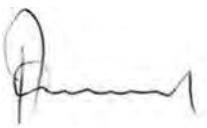
Fighting cancer is, and must remain, a high priority at all levels. As a European Commissioner for Health, contributing to cancer prevention, screening and care is a priority for me. I am committed to keeping high on the agenda our joint efforts to fight cancer, and to help those who suffer from cancer or have survived cancer. Indeed, for over 30 years, the European Commission has contributed towards addressing the cancer challenge.

Just last year, the Commission launched a Joint Action on Comprehensive Cancer Control. This action will identify quality standards for cancer control in Europe; and facilitate co-operation and exchange of best practices among Member States, so as to help improve care and reduce inequalities across the EU. At a national level, a key requirement for successful cancer management is the development of National Cancer Control Plans. The Commission has helped Member States develop and implement such plans.

Clearly, close co-operation between oncology physicians and oncology pharmacists is essential for optimal patient care. Oncology pharmacists have the training and expertise that places them in a position to provide evidence-based care to cancer patients, including initial treatment decisions and subsequent therapeutic management, supportive care, and survivorship.

This 2016 European Congress will focus on promoting the highest standards of pharmaceutical care in the management and support of patients with tumours. These areas also resonate strongly with the cancer research and cancer care communities as they strive to reduce both the incidence and mortality of this disease. These are also the areas where real difference can be made for people who suffer, if only making it just an ounce less unbearable ...

I wish you a productive and successful congress.



Vytenis Andriukaitis
European Commissioner for Health and Food Safety
European Commission
Brussels, Belgium

Conference Committees

Organizing Committee

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Vesna Pavlica (Croatia), Organizing Committee Chair
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Camille Groos (Luxembourg)
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Publication Committee

Ahmet Sami Bosnak (Turkey)
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Bouchra Meddah (Morocco)	

Acknowledgements

The European Society of Oncology Pharmacy wishes to thank the following companies and organizations for their support of the Conference by taking part in the exhibition.

Exhibitor name	Booth number
B Braun Melsungen AG*	14
Bristol-Myers Squibb GmbH & Co KGaA**	1
CIS Healthcare	8
CODAN	5
DuPont de Nemours (Luxembourg) Sàrl	3
EuroBioConcept	2
Equashield Medical Ltd	9
medac GmbH	12
Novartis Hrvatska d.o.o.	10
Paxxo	4
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Teva Pharmaceuticals	7
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** Euros 7,200*
*** Euros 3,600*

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Official Media Partner

On behalf of the ECOP Conference Committees, we would like to acknowledge the collaboration and support of our official media partner:

EJOP www.ejop.eu European Journal of Oncology Pharmacy
Official Journal of the European Society of Oncology Pharmacy (ESOP)

General Information

The third European Conference of Oncology Pharmacy (ECOP) is organized by the European Society of Oncology Pharmacy (ESOP), the Croatian Working Group of Oncology Pharmacists – Croatian Pharmaceutical Society and Croatian Society for Medical Oncology of Croatian Medical Association.

Conference Secretariat

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HR-10000 Zagreb, Croatia
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Fax: +385 1 4813 010
Email: ivana.resetar@otours.hr
www.otours.hr

Conference Venue

Valamar Lacroma Dubrovnik Hotel 4*+
34 Ulica Iva Dulčića
HR-20000 Dubrovnik, Croatia

The lectures will be held at the Valamar Lacroma Dubrovnik Hotel located on the Babin Kuk peninsula. Babin Kuk peninsula is located on the north end of Lapad, about 4 km away from the old town. Valamar Lacroma Dubrovnik Hotel offers the largest conference hall in Dubrovnik – Elafiti hall and spaceous exhibition area.

Croatia

Croatia is a beautiful country at the crossroads of Central Europe, Southeast Europe, and the Mediterranean. Its capital city is Zagreb, the population is around four million, total area is 56,594 km^2. Croatia became a member of NATO on 1 April 2009, and joined the European Union on 1 July 2013.

Croatia is on Central European Time zone.

Dubrovnik

Towards the southern tip of Croatia lies the Old Town of Dubrovnik, the priceless jewel of the Dalmatian Coast and a world famous UNESCO World Heritage Site steeped in history and culture. George Bernard Shaw once wrote, 'Those who seek paradise on Earth should come to Dubrovnik', due to its profound beauty and historic magic.

Dubrovnik is also, without doubt, currently one of Europe's most fashionable conference destinations. A surfeit of modern facilities combined with unique activities for delegates make this a popular choice for event organizers.

Another attraction for the participants in gatherings and congresses in Dubrovnik is certainly the possibility to organize business meetings in the inspiring historic venues, renaissance palaces and medieval forts. The more relaxed part of congresses and gatherings in Dubrovnik includes a selection of special events at the top class restaurants and on terraces with unforgettable views of the Adriatic Sea and sunsets, while the mild climate enables the enjoyment of nature all year round.

In Dubrovnik you can find many city attractions:

City walls

Dubrovnik's most important feature and the most visually dominant symbol of the town; an impressive Middle Age construction where the corner towers of Minčeta, Revelin, Bokar and Sveti Ivan create the city's famous historical shield.

Rector's Palace

'Obliti privatorum publica curate or 'Forget your private business, concern yourself with public affairs'. This remarkable inscription can be found above the entrance of the Rector's Palace, the most important public building in Dubrovnik and a site that was once the government headquarters and the Rector's residence.

Stradun (Placa)

Stradun is the main 'artery' of the city, stretched between the two town gates, the gate of Pile and Ploče. Stradun invites you to walk it and feel its rhythm.

Sponza Palace

The oldest multimedia building in Dubrovnik, built in 1520 in a mixed late gothic and renaissance style. It used to be a storage and customs building [Divon], and is now the State Archive where the most important documents about Dubrovnik's history are kept.

Franciscan Monastery

Franciscan Monastery is a wonderful work of Dubrovnik architecture and one of the most prominent Dubrovnik attractions. Part of the monastery contains a very rich library that has a large number of preserved manuscripts of invaluable cultural and historical value. A pharmacy was founded in the monastery in 1317, the third oldest in the whole world, continuously functioning until present day.

Dominican Monastery

The oldest monastery in Dubrovnik (1225) is an extremely valuable historical building, and also houses an important treasury of ancient Dubrovnik artwork, including 239 incunabula.

Church of St Blaise

The Church of St Blaise (Crkva Sv. Vlaha) is an 18th-century baroque church on Luza Square dedicated to the patron saint and protector of Dubrovnik. This majestic church is located at the intersection of two main thoroughfares, where public gatherings in Dubrovnik are held – 'Placa' and 'Pred dvorom'. It was built by the Venetian architect and sculptor M Gropelli at the beginning of the 18th century.

Old port

Another witness of the times, once the main trading and maritime hub, today a picturesque part of Dubrovnik.

Transportation

Dubrovnik Airport is situated about 20 km from the city of Dubrovnik. Approximate travel time from Dubrovnik Airport to venue hotel is 45 minutes. Please allow extra time during rush hour, inclement weather and special events. The easiest way to

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come from Dubrovnik Airport to the venue hotel is by booking the transfer via technical organizer of the Conference – O Tours.

Travelling by car

Dubrovnik can be easily accessed from Central and West Europe in several ways.

From West Europe:

1. **Via Rijeka** - motorway and continental highway: Rijeka - Senj - Žuta Lokva - Gospić - Dugopolje (motorway) - Vrgorac - Ploče - Dubrovnik.
2. **Combining the Adriatic Highway (along the coast) and the highway**: Rijeka - Senj - Karlobag - Maslenica - Split (motorway) - Makarska - Ploče - Dubrovnik.

From Central Europe:

1. **Via Zagreb**: Zagreb - Karlovac - Žuta Lokva - Gospić - Dugopolje (motorway) - Vrgorac - Ploče - Dubrovnik. This route can also be combined with the Adriatic Highway.
2. **Via Osijek** (through Bosnia and Herzegovina): Osijek - Slavonski Brod (or Brčko) - Sarajevo - Mostar -Metković - Dubrovnik / Sarajevo - Foča - Trebinje - Dubrovnik

Local transportation

Direct bus line from hotels located on Babin Kuk is number 6.

Taxi

Please notify your hotel reception staff to arrange a taxi transfer at any time.

Badge

For security reasons, participants are requested to wear their badges at all time during the Conference.

Participants who lost their badges can obtain a replacement badge at the registration desk.

Replacement fee of Euros 100 will be charged.

Catering

Lunch

Thursday, 19 May 2016 from 13:30 to 14:00

Friday, 20 May 2016 from 13:00 to 14:30

A complementary lunch will be served in the exhibition area – Level 1.

Coffee breaks

Complementary coffee breaks are served in the exhibition area – Level 1.

Thursday, 19 May 2016 from 16:00 to 16:30

Friday, 20 May 2016 from 11:00 to 11:30 and from 16:00 to 16:30

Saturday, 21 May 2016 from 11:30 to 12:00

Certificate of Attendance

Certificates of Attendance will be available at the registration area as of Friday 20 May 2016 from 15:00 onwards. Participants will be requested to complete a Conference evaluation form in exchange for their certificate. The Conference Secretariat will not mail Certificates of Attendance to participants after the Conference.

Currency

The official currency is Croatian kuna (HRK). Currency can be exchanged in banks, hotel or exchange offices. International credit cards are accepted in most hotels, restaurants and shops.

Exhibition

The exhibition is held on the Level 1.

Exhibition opening times

Thursday, 19 May 2016 from 10:00 to 21:00

Friday, 20 May 2016 from 9:00 to 17:00

Saturday, 21 May 2016 from 8:30 to 12:30

For the list of exhibitors, see pages 13–15.

First Aid

The Conference venue is located within a 5 minutes driving distance (3 km) and 30 minutes walking distance to General Hospital Dubrovnik, 2 Dr Roka Mišetića, HR-20 000 Dubrovnik, Croatia

Insurance

The organizers of ECOP 2016 do not accept liability for individual medical, travel or personal insurance. Participants are strongly recommended to obtain their own personal insurance coverage. The organizers disclaim all responsibility for loss due to theft or negligence.

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WiFi and Internet access

Free WiFi is available throughout the Conference venue.

Language

The official language of the Conference is English. No simultaneous translation is offered during the Conference.

Lost and Found

All enquiries should be directed to the registration desk. Participants are advised to mark their Conference bag and materials with their name. The organizers disclaim all responsability for loss due to theft or negligence.

No smoking

There will be a strict non-smoking policy within all areas of the facilities used by the Conference.

Opening Lecture

The Opening Lecture access is free for all registered participants. Please refer to the Scientific Programme for further details.

Poster Sessions

Posters are displayed on the Level 1. Posters will be on display in the dedicated poster area for the entire duration of the Conference and during all poster sessions. On Thursday, 19 May 2016 starting at 11:00, poster presenters will be allowed access to the poster area to mount their poster on the poster board displaying their assigned poster number. For assistance please check with ECOP staff onsite. Posters must be removed on Saturday 21 May 2016 by 13:30. Please note that any posters remaining after this time will be removed by the organizers and cannot be reclaimed. Presenting authors are kindly requested to be present at their poster for poster defence during assigned poster viewing and coffee breaks.

Best Poster Award recognizes outstanding posters presented at ECOP 2016. All posters will be evaluated by a committee and the winner will be notified during the Conference. The award will be presented at the Closing Session. The winner must reconfirm his/her presence at the Conference and at the ceremony.

Registration

The Conference is opened for all registered participants. For security reasons, participants are requested to wear their badges at all times during the Conference.

Registration opening hours:

Wednesday, 18 May 2016 from 15:00 to 19:00

Thursday, 19 May 2016 from 9:00 to 19:00

Friday, 20 May 2016 from 7:00 to 18:30

Saturday, 21 May 2016 from 8:00 to 14:30

The registration package includes: entry to all scientific sessions and exhibition; entry to all Satellite Symposia organized during the Conference; Proceedings Book; lunch and coffee breaks during the Conference; conference bag; attendance to the Welcome Reception on Thursday, 19 May 2016 at 18:30 in the exhibition area.

Speaker preview room

The Speaker Preview Room is located in the Glass room close to the poster session. It will be available during the hours of the Conference, half an hour before the start of the session and half an hour after the end of session. In this room, there will be some desktop computers. Speakers will be able to view and upload their presentation.

Industry-sponsored Symposium

Industry–sponsored Satellite Symposia are taking place during ECOP 2016. For schedules and more information, see the section 'Industry-sponsored Satellite Symposia' on pages 69–71.

Networking Events

Opening Event – a small get-together with drinks and finger food. All delegates are invited to join the Organizing Committee and ESOP Board at the Opening Event in the exhibition area – Level 1 in the Valamar Lacroma Dubrovnik Hotel on Thursday, 19 May 2016 from 18:30 to 21:00. This is your chance to meet colleagues from around the world, to network in a convivial setting and forge new links for future collaboration.

Social event on Friday

Conference dinner on Friday 20 May 2016 starting at 19:00 at the Valamar Lacroma Dubrovnik Hotel. We invite you to join us at the conference dinner – a small cocktail party with drinks and finger food. On a beautiful terrace of the hotel, you will enjoy the view of the beautiful Adriatic Sea and feel the charms of the Mediterranean climate. You can book the Conference dinner with the conference technical organizer for a price of only Euros 15 per person.

European Society of Oncology Pharmacy (ESOP) Profile

The European Society of Oncology Pharmacy (ESOP), founded in 2000 in Prague, Czech Republic, is the largest organization of oncology pharmacists in the world with 3,190 members from 51 countries. ESOP is a full member of the European CanCer Organisation (ECCO) since 2013 a non-commercial consulting society for the European Medical Agency (EMA).

Aim and Objectives

The aim of ESOP is to support optimal treatment for cancer patients. The objectives are to develop and promote clinical and oncology pharmacy practice through:

1. Education and training
2. Safe handling and administration of drugs
3. Quality management
4. Research and development
5. Pharmaceutical care

The Oncology Team – Co-operation

The pharmacy as coordination Center of Cytostatic Therapy implements the quality management of the oncology pharmacy service and takes responsibilities in patient care and personnel protection regarding all areas of cytostatic therapy.

The pharmacy collects and processes all medical and toxicological data relevant to cytostatics, as well as accompanying and supportive measures if possible.

Regarding the fact, that the situation of the oncology patient must be viewed upon as a whole, and that his/her needs and desires play an important factor we are aware that focusing on the cytostatic treatment alone is not enough. We realize, that we also need to focus on a variety of other things, such as the appropriate diet, an adequate analgesic medication and the correct anti-emetic scheme, we understand that we cannot ignore the social and psychological problems that the patient may experience by his or her situation.

In view of the fact that financial resources have become limited, it is necessary to intensify our pharmaceutical services in order to increase cost-effectiveness, to help ensuring adequate medical treatment and to prevent quality loss. Thus, we promote the application of the following instruments:

- Epidemiology
- Chrono-oncology
- Pharmacoeconomy
- Pharmaceutical Care

Ljubljana Declaration 2006

'The close co-operation between oncology physicians and oncology pharmacists is vital for optimal patient care. The multi-professional approach will deliver best practice to patients within a clinical governance framework. Professional, close and timely collaboration will ensure economic use of resources and improve patient safety.'

Our Goals: Quality Standards, Continuous Education and Certification

Since the first publication in 1996 the fifth edition of Quality Standards for the Oncology Pharmacy Service (QuapoS) – translated into 27 languages – presents the considerable changes which have taken place with respect to the positioning of this service. They are in use to promote the standardization of national principles and to speak with one single voice in Europe. The beneficiary of these efforts will always be the patient who will appreciate it.

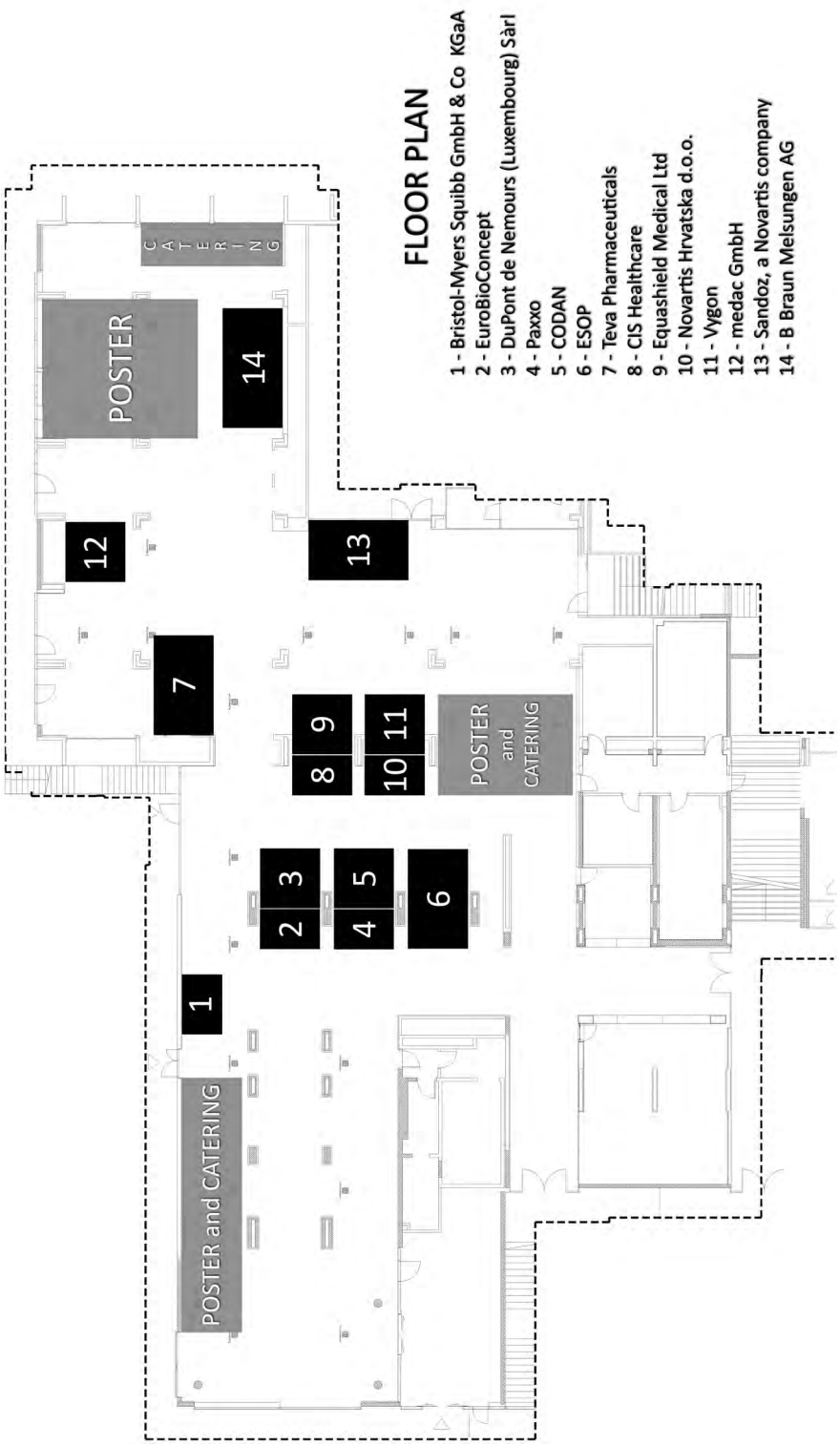
Specific Activities

Since 9 years the ESOP Masterclass in Oncology Pharmacy Practice is a yearly event in order to provide continuing education in oncology for hospital pharmacists, whose duties require them to be experts on cytotoxic drug preparation, handling and administration (including risk management) and for clinical pharmacists, so they can give patients the best possible care and support. The European Journal of Oncology Pharmacy (EJOP) has been launched with its mission to satisfy these desires for better quality and to open new horizons.

www.esop.eu

Floor Plan

Venue and exhibition Floor Plan



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Vygon	11

B Braun Melsungen AG

With over 55,000 employees in 64 countries, B Braun is one of the world's leading manufacturers of medical devices and pharmaceutical products and services.

Through constructive dialogue, B Braun develops high quality product systems and services that are both evolving and progressive - and in turn improves people's health around the world.

Bristol-Myers Squibb GmbH & Co KGaA

Bristol-Myers Squibb is a global BioPharma company firmly focused on its mission to discover, develop and deliver innovative medicines to patients with serious diseases. Around the world, our medicines help millions of people in their fight against such diseases as cancer, cardiovascular disease, hepatitis B and hepatitis C, HIV/AIDS and rheumatoid arthritis. Our R & D organization is considered among the most productive in the industry. As we are leading the transformation of treating cancer through immunotherapies, we have remained equally focused on developing a diverse and robust pipeline of new compounds.

CIS Healthcare

CIS Healthcare is the company behind the number one selling chemotherapy system called **ChemoCare** and the cytostatic production tool called **Cypro**.

We are proud of our track record in developing expert systems for clinical users working in the specialised area of chemotherapy and we believe that our product's success is down to our unique approach to product design and implementation.

Our expert programming team works closely with both healthcare services and experts in the field of oncology to design and test the functionality of our software to ensures that the right solution is delivered to you that makes caring for your patients more consistent, safer, successful and cost-effective than ever before.

We believe in building strong relationships with our customers.

CODAN

CODAN is one of the market leading companies within the field of infusion management. With over 60 years of experience we know what it takes to produce and sell products of high quality. CODAN is a family-owned company with sales companies on all major European markets and production in Europe.

Our product portfolio contains disposables for IV-therapy, transfusion therapy, urology flushing devices, pressure monitoring and infusion pumps. Safety for user and patient is important for CODAN, we therefore have a special focus on safety devices for handling cytotoxic drugs. We were one of the first to develop products for safe preparation and administration of cytotoxic drugs. A method used in the major part of Europe. Welcome to visit us by our booth at ECOP 2016!

DuPont de Nemours (Luxembourg) Sàrl

Cytostatic contamination control solutions from DuPont

DuPont is the world leader in providing protective solutions for diverse working environments including those used by pharmaceutical manufacturers and cleanroom operations. By collaborating with industries and authorities, we can engineer and offer the latest personal protective equipment solutions that can help keep your environments clean and protected.

DuPont comprehensive selection of protective garments and accessories is designed for use in environments that require high standards for particle and microbiological contamination control. Our DuPont™ Tyvek® protective solutions made of continuous strong and pure high-density polyethylene, are tough, yet extremely lightweight and soft thus offer an ideal balance of quality, protection, durability and comfort.

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Equashield Medical Ltd

Equashield is a privately held medical device company with over 200 employees providing a state-of-the-art Closed System Transfer Device (CSTD) for the safe handling of hazardous drugs. Dedicated to providing a simple and elegant design that is also unprecedented in safety and ease of use, Equashield has committed itself to protecting healthcare workers from the risks associated with exposure to hazardous drugs and vapours.

As such, the Equashield team has created a proprietary family of products for the safe handling of hazardous drugs to extend from the compounding in pharmacy to the administration in nursing. Product portfolio includes a wide array of closed syringes and adapters for accessing vials and IV bags in pharmacy as well as a selection of connectors and tubing sets for nursing.

EuroBioConcept

French designer and manufacturer of isolators, EuroBioConcept is specialized in bio containment solutions (RTP and BCS Class III) for the pharmacies, pharmaceuticals industries and research centres.

With more than 15 years in technology of containment, our team provides you customized solution on a very safe way. Based in Paris, EuroBioConcept is to be found all over the world, with distributors and partner companies in sales and service.

EuroBioConcept protects both products and operators.

medac GmbH

medac is specialized in the treatment of malignant diseases since its foundation in 1970. Now, medac is one of the leading manufacturers of oncology products not only in Germany, but in many international markets. medac offers both innovative and well-proven therapeutic options in the fields of Oncology, Haematology, Urology, Autoimmune diseases and Fibrinolysis and is one of a handful of companies which is also specialized in the field of diagnostics.

Novartis Hrvatska d.o.o.

Novartis is a global healthcare company based in Switzerland that provides solutions to address the evolving needs of patients worldwide.

Novartis was created in 1996 through a merger of Ciba-Geigy and Sandoz. Novartis and its predecessor companies trace roots back more than 250 years, with a rich history of developing innovative products.

Mission of Novartis is to provide healthcare solutions that improve and extend people's lives. Novartis uses science-based innovation to address some of society's most challenging healthcare issues with a goal to discover and develop breakthrough treatments and find new ways to deliver them to as many people as possible.

Paxxo

Paxxo is Swedish-based packaging company with a 30-year history. Our business concept is to manufacture the unique endless bag system Longopac that, thanks to innovative, smarter waste management and packaging solutions, creates a better working environment for all industries. Our successes are possible because our products offer rational handling, a better working environment and low environmental impact. Our bag system is based on a strong, 3-layer polyethylene bag material which is folded into compact cassettes that today is sold in more than 30 countries.

Our main product for hazardous waste handling is Pactosafe. It is a waste sealing unit for safe airtight sealing of cytotoxic waste, smelly waste and toxic laboratory waste.

For more information see www.paxxo.com

Sandoz, a Novartis company

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Tevadaptor® is a Closed System Drug Transfer Device for safe compounding and administration of hazardous

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drugs, minimizing risk of exposure to hazardous drug substances and risk of needle-stick injuries, protecting pharmacists, nurses and patients alike.

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Programme Overview: ECOP 2016

Thursday, 19 May 2016

Elafiti 1	Elafiti 2
Industry-sponsored mini Symposia 10:30–12:00 Elafiti 1	Industry-sponsored Symposia 10:30–12:00 Elafiti 2
Industry-sponsored Symposia 12:15–13:45 Elafiti 1	Aseptic Work Training 12:15–13:45 Elafiti 2
Opening 14:00–14:30 Elafiti 3/4	Opening 14:00–14:30 Elafiti 3/4
Keynote - Lecture 14:30–16:00 Elafiti 3/4	Keynote - Lecture 14:30–16:00 Elafiti 3/4
Coffee Break 16:00–16:30	
Clinical Symposium 16:30–18:30	New Horizons Practical 16:30–17:30
	New Horizons Clinical 17:30–18:30
RECEPTION & Poster Presentation 18:30–21:00	

Poster Viewing 10:00–21:00

Exhibition 10:00–21:00

Friday, 20 May 2016

Elafiti 1	Elafiti 2	Elafiti 3/4
PGEU Opening 08:00–08:30 Elafiti 3/4	PGEU Opening 08:00–08:30 Elafiti 3/4	
New Therapies 08:30–09:30 Elafiti 3/4	New Therapies 08:30–09:30 Elafiti 3/4	
Symposium Clinical 09:30–11:00	Proffered Papers - Mixed 09:30–11:00	International Relationships 09:30–11:00
Coffee break 11:00-11:30		
Proffered Papers - Clinical 11:30–13:00	Symposium-Practical 11:30–13:00	ESOP 11:30–12:30
Lunch Break	Lunch Break	Lunch Break
Industry-sponsored Symposia 14:30–16:00 Elafiti 1	Industry-sponsored Symposia 14:30–16:00 Elafiti 2	
Coffee Break 16:00–16:30		
Interactive Clinical 16:30–17:30	Interactive Practical 16:30–18:00	Debate Clinical / Practical 16:30–18:00

Poster Viewing 09:00–17:00

Exhibition 09:00–17:00

Saturday, 21 May 2016

Elafiti 1	Elafiti 2
Keynote - Lecture 08:30–10:00 Elafiti 3/4	Keynote - Lecture 08:30–10:00 Elafiti 3/4
Poster Discussion-Clinical 10:00–11:30	Symposium Clinical 10:00–11:30
Coffee Break 11:30–12:00	
Interactive Clinical 12:00–13:30	Poster Discussion Mixed 12:00–13:30
Closing Session / Awards 13:30–14:00	

Poster Viewing 08:30–12:30

Exhibition 08:30–12:30

ECOP 2016 Scientific Programme

Thursday, 19 May 2016

10:30 – 12:00	Industry-sponsored mini Symposia	Elafiti 1
10:30 – 12:00	Industry-sponsored Symposia	Elafiti 2
12:15 – 13:45	Industry-sponsored Symposia	Elafiti 1
12:15 – 13:45	Workshop for Spill Kit Training, Hand Washing and Disinfection, Usage of Clean Working Kit	Elafiti 2

14:00 – 14:30	**Opening Session**	**Elafiti 3/4**
14:30 – 15:00	**Keynote – Lecture** Team Medicine in Japan Professor Yuichiro Ohe (Japan)	
	EBM or Value-based Healthcare? Chair: Marko Skelin (Croatia)	
15:00 – 15:30	Different Access and Prices of Oncology Treatments in Europe: Why? Professor Jaime Espin (Spain)	
15:30 – 16:00	Value-based Pricing of oncological Drugs: Are we there yet? Professor Rok Hren (Slovenia)	
16:00 – 16:30	Coffee Break	
	Clinical Symposium: Off-label use and Challenges for future Market Access of high-cost Drugs	**Elafiti 1**
	Chair: Dr Mikael Daouphars (France)	
16:30 – 17:00	Safe Off-Label Use in Oncology – which are the main Factors and what are the Challenges for Pharmacists? Dr Tilman Schöning (Germany)	
17:00 – 17:30	Complexity and Challenges for Future Market Access of high-cost Drugs - a Challenge for Health and Pharmaceutical Services Dr Chiara Poggiani (Italy)	
17:30 – 18:00	SROI (Social Return on Investment) - Analysis Dr Jose Ignacio Chacón and Ana Rosa Rubio Salvador (Spain)	
18:00 – 18:30	Cancer Care in developing Countries: Does Africa needs monoclonal Antibodies? At what cost? Sherif Kamal (Egypt)	
	New Horizons Practical: Oncolytic Virus Therapy	**Elafiti 2**
	Chair: Professor Alain Astier (France)	
16:30 – 17:00	Clinical Rationale Dr Karsten Geletneky (Germany)	
17:00 – 17:30	Recommendations for Safe Use Dr Francois Lemare (France)	
	New Horizons Clinical: Drug Safety – Faking of Drugs and Security of manufactured Drugs	**Elafiti 2**
	Chair: Bouchra Meddah (Morocco)	
17:30 – 18:00	Faking of Drugs – Stakeholders´ Collaboration to protect Patients´ Health Dr Jana Mladá (Czech Republic)	
18:00 – 18:30	Falsified Medicines Directive (FMD) – the current Position and Challenges for Hospital Pharmacists Joan Peppard (Belgium)	

Friday, 20 May 2016

	PGEU Opening	**Elafiti 3/4**
08:00	Collaborative Care for the Benefit of Cancer Patients Dr Jan Smits (Belgium)	
	Chair: Marika Saar (Estonia)	
08:30 – 09:30	New Drugs of the Year Jürgen Barth (Germany)	
	Symposium Clinical: Oncology Patient in Community Pharmacy	**Elafiti 1**
	Chair: Ahmet Bosnak (Turkey)	
09:30 – 09:50	Clinical Pharmacist Interventions for oncology Outpatients Fiona MacLean (UK)	
09:50 – 10:10	Medication Reconciliation in Oncology Dr Christophe Bardin (France)	
10:10 – 10:30	Oral Chemotherapy: Are we following up Patients correctly on correct Administration and monitoring Adherence? Dr Fabrizio Festinese (Italy)	
10:30 – 10:50	A Cancer Patient in a Community Pharmacy Dahna Arbanas (Croatia)	
	Proferred Papers – Mixed	**Elafiti 2**
	Chair: Dr Adrian Munilla Das (Spain)	
09:30 – 11:00	**P002 -** EGFR Inhibition +/- Irradiation induce an HIF-2 Addiction in Head and Neck Cancer resistant Tumours Pierre Coliat (France)	
	P006 - Influence of SNP-SNP Combinations in Anthracycline Transporter Genes in the Standard Induction of Acute Myeloid Leukaemia Juan E Megias Vericat (Spain)	
	P010 - *In Vitro* and *Ex Vivo* of Temozolomide Resistance in GBM Dr Bodo Haas (Germany)	
	P029 - New Approaches for online Quality Control of Monoclonal Antibodies in Hospital Pharmacy E Jaccoulet (France)	
	P035 - Identification of Raltitrexed Photodegradation Pathways in Injectable Solution Hassane Sadou Yaye (France)	
	International Relationships	**Elafiti 3/4**
	Chair: Sherif Kamal (Egypt)	
09:30 – 10:00	The New USP 800 Dr Michael Koraleski (USA)	
10:00 – 10:30	Drug Codex from Japan Shinya Suzuki (Japan)	
10:30 – 11:00	Guidelines in Germany Dr Ulrich Warnke (Germany)	
11:00 – 11:30	Coffee Break	

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Proferred Papers – Clinical **Elafiti 1**

Chair: Marta Trojniak (Italy)

11:30 – 13:00 **P011 –** Genetic Variants in ERCC1, ERCC2 and SOD2 are associated with increased Risk of Neurotoxicity in Taxane-treated Breast Cancer Patients
Virginia Boso (Spain)

P055 – Patients´ Satisfaction with Information on oral Anticancer Agents
Christel Boons (The Netherlands)

P074 – Supporting Adherence to oral Anticancer Agents: Clinical Practice and Clues to improve Care
Lonneke Timmers (The Netherlands)

P098 – The Oncology Pharmacist as Part of the Palliative Treatment Team
Mirjam Crul (The Netherlands)

P110 – Surrogate Endpoints in metastatic Breast Cancer in First or Second Line Trials
Sandra Flores Moreno (Spain)

Symposium Practical **Elafiti 2**

Chair: Dr Tilman Schöning (Germany)

11:30 – 12:15 Session on CAM
Professor Hans-Peter Lipp (Germany)

12:15 – 12:35 Nanotechnologies: Vectorization of Drugs
Dr Tanguy Boissenot (France)

12:35 – 12:55 Nanomaterials as Destructive Sorbents for Surface Decontamination after Cytostatics Exposure
Dr Václav Štengl (Czech Republic)

ESOP Session **Elafiti 3/4**

Chair: Klaus Meier (Germany)

11:30 – 12:00 Establishment of a European best-practice Model for Improvement of Health Care for oral Chemotherapy Patients – EPIC project
Andreja Eberl (Slovenia)

12:00 – 12:30 Results of MASHA Project (Research about Environmental Contamination by Cytotoxics and **Ma**nagement of **S**afe **Ha**ndling Procedures)
Ewelina Korczowska (Poland)

12:30 – 13:00 Meet the ESOP Board Members

13:00 – 14:30 Lunch Break

14:30 – 16:00 Industry-sponsored Symposia Elafiti 1

14:30 – 16:00 Industry-sponsored Symposia Elafiti 2

16:00 – 16:30 Coffee Break

Interactive Clinical: Risk Management/ Medication Errors **Elafiti 1**

Chair: Roman Goněc (Czech Republic)

16:30 – 17:00 Risk Management – Overview
Michael Heymann (Germany)

17:00 – 17:30 Screening for Safety Signals of Tyrosine Kinase Inhibitors using Spontaneous Reporting Systems
Marin Banovac (UK)

Interactive Practical: How to interpret? **Elafiti 2**

Chair: Shinya Suzuki (Japan)

16:30 – 17:15 Pharmacoeconomic Studies Assessing the Cost-Effectiveness of Treatments for Metastatic Melanoma
Professor John Cairns (UK)

17:15 – 18:30 Clinical Trials Critical Reading and Basic Terms of Clinical Trials in Oncology (metastatic setting)
Dr Robert Šeparović and Marko Skelin (Croatia)

Debate: This House believes in Centralized Compounding versus One-Stop-Shop for Patients which requires just-in-time Compounding on Site **Elafiti 3/4**

Chair: Klaus Meier (Germany)

16:30 – 18:00 Pro – Robert Duncombe (UK) and Shaun O'Connor (Australia)
Contra – Teresa Aqueveque (Chile) and Stavroula Theophanus-Kitiri (Cyprus)

Saturday, 21 May 2016

Keynote – Lecture **Elafiti 3/4**

Chair: Klaus Meier (Germany)

08:30 – 09:00 Demands Patients have to Oncology Pharmacists
Professor Louis Denis (Belgium)

What Doctors have to tell us?

Chair: Marika Saar (Estonia)

09:00 – 09:20 Medical Treatment for advanced Prostate Cancer
Professor Hendrik van Poppel (Belgium)

09:20 – 09:40 Breast Cancer
Professor Georgia Demetriou (South Africa)

09:40 – 10:00 Cardiovascular Effects and Cardiovascular Toxicity of Cancer Treatments
Dr Ana Barac (USA)

Poster Discussion – Clinical **Elafiti 1**

Chair: Andreja Eberl (Slovenia)

10:00 – 11:30 **P008** – Relation between prostate-specific Antigen Levels and progression-free Survival in Patients with Prostate Cancer treated with Abiraterone Acetate
Lucia Jiménez Pichardo (Spain)

P041 – Mobilization of haematopoietic Stem Cells with Plerixafor on Patients with CD34 <10 cells/mcL pre-Apheresis
Aitziber Lizardi (Spain)

P042 – Follow-up Study: Drug Interactions in Chemotherapy Patients
HC van den Berg-Brouwer (The Netherlands)

P044 – Contribution of Cetuximab in the Treatment of Nasopharyngeal Cancer: Experience of Algeria
Réda Kessal (Algeria)

P045 – Improving Chemotherapy Relative Dose Intensity in localized Breast Cancer
Raul Diez Ferández (Spain)

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P085 – Evaluation of appropriate Glucarpidase Prescription to prevent iatrogenic Incident and reduce Medical Cost
C Chauvin (France)

P113 – Fatal Interaction Between Brivudine and Capecitabine: A Case Report
C Garcia Yubero (Spain)

Symposium Clinical: Immunotherapy **Elafiti 2**

Chair: Professor Vesna Pavlica (Croatia)

10:00 – 10:30 **Recent Developments and Research Topics in Immune Oncology**
Professor Damir Vrbanec (Croatia)

10:30 – 11:00 **Immunotherapy in Oncology – Side Effects and their Treatment**
Professor Zlatko Dembic (Norway)

11:00 – 11:30 **Immunotherapy in Oncology - interdisciplinary Cooperation among Immunologist, Oncologist and Pharmacist**
Dr Irena Netiková and Dr Eva Závadová (Czech Republic)

11:30 – 12:00 Coffee Break

Interactive Clinical **Elafiti 1**

Chair: Dr Mirjam Crul (The Netherlands)

12:00 – 13:30 **Multi-professional Case Report Discussion**
Dr Robert Šeparović and Marko Skelin (Croatia)
Fiona MacLean (UK)
Anita Margulis (Switzerland)

Poster Discussion – Mixed **Elafiti 2**

Chair: Dr Tilman Schöning (Germany)

12:00 – 13:30 **P012** – A Strategy to screen and subsequently identify therapeutically valuable microRNAs that target a clinically established KITENIN Oncogene in Colorectal Cancer
So-Yeon Park (South Korea)

P021 – Toxicity Comparison between two commercial Presentations of Gemcitabine in recurrent superficial Bladder Cancer
Rocio Gazquez Perez (Spain)

P028 – Comparative Evaluation of a Drug Website for Incompatibility: Stabilis, Trissel's Handbook and the currently available Tool in Japan
Shinya Suzuki (Japan)

P037 – Safety of antineoplasitic Agents: the Main Issue in which E-Health Technologies could help to Pharmacotherapy Follow-up
Roberto Collado-Borrell (Spain)

P040 – Preventing Medication Errors in Cancer Chemotherapy: Technology Contribution
Talens Amparo (Spain)

P051 – Educational Programme for Patients on oral Chemotherapy: Challenge for Treatment Adherence and Quality of Life
Nelly Etienne-Selloum (France)

P096 – Nivolumab: the Concept of Dose Banding
Charlotte Ablard (France)

13:30 – 14:00 **Closing Session/Awards** **Elafiti 3/4**

Thursday, 19 May 2016

L1 Workshop for Spill Kit Training, Hand Washing & Disinfection, Usage of Clean Working Kit

K Kongi[1]

[1]*Pharmacy Department, North Estonia Regional Hospital, Tallinn, Estonia*

Dear all ESOP Aseptic working e-training programme participants!

The last part of Your Training in ESOP certified training programme – Aseptic Work Training – will take place in Dubrovnik on 19 May 2016. For more details, please see the official ECOP3 programme.

Please note: The training is only for trainees, who have attended all ESOP Aseptic Working e-training lectures!

Keynote – Lecture

L2 Team Medicine in Japan

Y Ohe[1]

[1]*National Cancer Center Hospital, Tokyo, Japan*

In Japan, palliative care team, infection control team and nutrition support team are commonly established in the hospitals which are treating cancer patients. These teams consist of physicians, pharmacists, nurses and other medical professionals such as medical social workers, dietitians, physical therapists. Palliative care team consisting of, for example, palliative care physicians, psycho-oncologists, medical oncologists, pharmacists, nurses and medical social workers is one of most important activity in cancer hospitals. In addition to these common activities, hot lines between patients who received chemotherapy in outpatient clinic and pharmacists or nurses, outpatient clinic by pharmacists, follow-up system using telephone for high risk outpatients by pharmacists and nurses, and skin care support of patients who received target-based medicine such as ant-EGFR therapies are successfully performed in the National Cancer Center Hospital East. In the National Cancer Center Hospital, appearance support centre has been established to provide supports regarding appearance of cancer patients such as alopecia, pigmentation and acne. These team medicine are very important to improve quality of life of cancer patients and quality of cancer patient care.

EBM or Value-based Healthcare?

L3 Different Access and Prices of Oncology Treatments in Europe: Why?

J Espin[1]

[1]*Andalusian School of Public Health, Granada, Spain*

The equal access to medicines in Europe has always been a challenge difficult to tackle. In the European Union we have 28 different healthcare systems and 28 ways to deal with pricing and reimbursement of medicines. The result is predictable: delay in access to medicines, problems of affordability, shortages in small countries ... The problem increases with high-cost medicines, especially oncology treatments and orphan medicines.

During this conference I will present the main challenges related to access to oncology treatments in Europe and what can be some proposals to increase access to innovative products. Value-based pricing, differential pricing, parallel trade, international reference pricing will be some of the topics that will be exposed jointly with some data about pricing and delay in introducing oncology treatments in Europe. The last trend, payment by results/outcomes-based agreement, will also be explained with some examples for cancer treatments.

L4 Value-based Pricing of oncological Drugs: Are we there yet?

R Hren[1]

[1]*University of Ljubljana, Ljubljana, Slovenia*

Oncological drugs are among the pinnacles of breakthrough technological evolution within the health care that has fundamentally changed treatment options during the past two decades. It is encouraging that the effective cancer therapies are developed at the unprecedented rates, however, it is also notable that the average price of oncological drugs has substantially increased over the last 15 years. It is thus understandable that the authorities/payers are searching for options that will continuously make new oncological drugs accessible to the patients, while also ensuring the sustainability of the reimbursement systems.

One of the tools, which have been applied in assessing the innovativeness of new drugs, is value-based pricing (VBP). In this paper, we will first introduce VBP against the backdrop of diminishing rates of return of research and development among top pharmaceutical companies. Next, we will critically evaluate VBP as pertaining to the oncological drugs by reviewing some recent approaches within European jurisdictions. Special care will be given to the design of clinical studies that is potentially leading to challenges in estimating overall survival of patients and cost-effectiveness of new technologies. Finally, we will assess other policies – besides VBP – that are employed by the authorities/payers to reimburse the innovative oncological drugs.

Clinical Symposium: Off-label use and Challenges for future Market Access of high-cost Drugs

L5 Safe Off-Label Use in Oncology – which are the main Factors and what are the Challenges for Pharmacists?

T Schöning[1]

[1]*Pharmacy Department, University Hospital Heidelberg, Germany*

Antineoplastic drugs are widely used beyond their approved indications in first-line-therapy as well as in refractory state despite many existing issues associated with Off-Label-Use (OLU). OLU is sometimes necessary from a medical point of view, but will always be associated with a higher risk of causing harm to the patient, for reasons of lack of experience with these drugs. Standardized regimes which are implemented in a computerized physician order entry (CPOE) software might be able to promote safe prescribing; nevertheless the indication is generally not object to plausibility checks. An approach to identify OLU prescriptions in oncology and an algorithm for action according to feasible criteria which verify the proper reason for OLU will be presented and might also be prospectively implemented in a CPOE at our place.

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L6 Complexity and Challenges for Future Market Access of high-cost Drugs - a Challenge for Health and Pharmaceutical Services

C Poggiani[1], Silvia Adami[2], Sara Nocera[1], PierFranco Conte[3], Giovanna Scroccaro[2]

[1]*Coordinamento Regionale Unico sul Farmaco – Veneto Region*

[2]*Settore Farmaceutico-Protesica-Dispositivi Medici Regione Veneto – Veneto Region*

[3]*Veneto Oncology Institute (Istituto Oncologico Veneto IRCCS)*

The rapid development and approval of oncologic drugs considered to be innovative foster a high pressure on Health Systems. Many of these new agents carry a very high price tag, especially considering the relatively modest gain in overall survival offered [1]. In this context, a value-based pricing system is necessary, in order to guarantee a sustainable and fair access to drugs.

In Italy, at the national level, drug reimbursement is defined together with policy actions aimed at promoting appropriateness and sustainability, such as: (i) registries, defining patient eligibility and follow-up; (ii) managed entry agreements (MEAs) between the National Health System (NHS) and pharmaceutical companies (e.g. risk sharing or financial agreements).

Locally, the Veneto Region has promoted policy actions based on the Health Technology Assessment (HTA). Evidence-based recommendations on new drugs are produced considering drug benefit-risk profile, quality of evidence and the presence of therapeutic alternatives. Since 2014, 19 recommendations have been produced concerning solid tumours and one in haematology setting [2].

A rigorous value-based pricing system in addition to HTA-based policies could guarantee NHS sustainability.

References

1. Sobrero A, Bruzzi P. Incremental advance or seismic shift? The need to raise the bar of efficacy for drug approval. J Clin Oncol. 2009;27:5868-73.
2. Regione del Veneto. Raccomandazioni evidence-based [homepage on the Internet]. [cited 2016 Apr 13]. Available from: http://www.regione.veneto.it/web/sanita/raccomandazioni-evidence-based

L7 SROI (Social Return on Investment) – Analysis

JI Chacón[1], AR Rubio Salvador[2]

[1]*Hospital Virgen de la Salud, Medical Oncology Service, Toledo, Spain*

[2]*Pharmacy Department of Complejo Hospitalario de Toledo, Spain*

Social Return on Investment (SROI) is a process for understanding, measuring, and reporting the social, economic and environmental value created by an intervention, programme, policy or organization.

SROI is based on the principles of cost-benefit analysis, as costs and benefits are quantified and compared to evaluate the desirability of a given intervention expressed in monetary units. But, in addition, it incorporates socio-economic and environmental outcomes to measure the value of social benefits created by an organization in relation to the relative cost of achieving those benefits. The result is known as the SROI ratio, capturing the effectiveness of the organization in turning its resources into positive outcomes.

This methodology can be conducted retrospectively (based on actual outcomes that have already taken place) or prospectively (predicting how much social value will be created if the activities meet their intended outcomes).

An SROI assessment is considered as an internal tool for strategic decisions and an external tool for communicating results, and has been applied across different public health sectors, including social impact assessment of home care services, social impact of drug treatments or the social impact of biomedical research.

'SROI is about value, rather than money.' (A guide to Social Return on Investment, The SROI Framework, 2012).

L8 Cancer Care in developing Countries: Does Africa needs monoclonal Antibodies? At what cost?

S Kamal[1]

[1]*Children Cancer Hospital, Cairo, Egypt*

In this presentation we will discuss the cancer care in developing countries with special focus on Africa. The World Health Organization (WHO) said that in 2010, cancer would overtake ischaemic heart disease as the leading cause of death in the world. Approximately 50% of cancer in developing countries occurs in individuals less than 65 years of age.

The WHO states that there are four key components to cancer control: cancer prevention, early detection, diagnosis and treatment and palliation. Developing countries face major challenges in each of these four areas.

Another significant problem in combating cancer in developing countries is that even if cancers are caught early, the treatment options are both limited and expensive. Cost is a major factor in influencing access to drugs since most of the spending is 'out-of-pocket' by patients.

In this presentation we will go through:

1. The cancer care in developing countries with focus in Africa
2. Role of monoclonal antibodies in cancer cure
3. Pharmacoeconomics and Health Technology Assessment
4. Cancer burden in Africa
5. Cost-effectiveness of monoclonal antibody

New Horizons Practical: Oncolytic Virus Therapy

L9 Clinical Rationale

K Geletneky[1]

[1]*General Hospital Darmstadt, Department of Neurosurgery, Darmstadt, Germany*

The idea to use viruses for cancer treatment was triggered by observations of tumour remission after spontaneous virus infection of patients with mostly haematological malignancies. However, first clinical applications of viruses in the 1950s to 1970s failed to show clear effects, and only after advances in molecular engineering of viruses was the field revived in the 1990s.

The initial goal of OV-therapy was to achieve direct destruction of tumour cells by virus infection, known as viral oncolysis. Over the years, numerous and very divers, mostly early-phase clinical trials targeting different types of cancer were unable to demonstrate major oncolytic effects as they were known from preclinical models. However, these trials were primarily suited to demonstrate safety of the OV-strategy, which is now well established.

In more recent clinical trials promising signs of clinical efficacy could be demonstrated, and, in October 2015, an engineered herpes virus, IMLYGIC™ (Talimogene Laherparepvec, Amgen), has been approved by the US Food and Drug Administration (FDA) for the local treatment of unresectable melanoma recurrent after initial surgery. Parallel to this important clinical success the understanding of OV therapy has undergone a paradigm shift away from direct tumour lysis to a distinct form of cancer immune therapy, a field experiencing a striking and promising renaissance.

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New Horizons Clinical: Drug Safety – Faking of Drugs and Security of manufactured Drugs

L10 Faking of Drugs – Stakeholders´ Collaboration to protect Patients´ Health

J Mladá[1]

[1]*SÚKL - State Institute for Drug Control, Prague, Czech Republic*

Falsified medicines are fake medicines that are designed to mimic real medicines. Both branded and generic products can be falsified. The content of active or any other substance in the fake medicines, as well as efficacy and safety is always uncertain. The aim of the EU Directive on falsified medicines from July 2011 is to prevent falsified medicines entering the legal supply chain and reaching patients in the EU. The two safety features (a unique identifier and an anti-tampering device) were introduced by the Delegate Regulation (EU) 2016/161 on 9 February 2016. Marketing authorization holders must place these safety features on the packaging of medicinal products in EU no later than 9 February 2017. The supply chain (wholesalers and pharmacist) also must be ready to control the medicinal product during the distribution. European Medicines Verification System (Pan-European system to verify the authenticity of medicinal products) is currently under development. The system will be set up and governed by stakeholders under supervision of regulatory authorities. The new legal frameworks and the collaborative effort from all key stakeholders across the EU is the best way to successfully deal with falsified medicines and protect patients´ health.

L11 Falsified Medicines Directive (FMD) – the current Position and Challenges for Hospital Pharmacists

J Peppard[1]

[1]*President, European Association of Hospital Pharmacists (EAHP), Brussels, Belgium*

The presentation will outline the development of the Falsified Medicines Directive (FMD) through the auspices of the European Commission. The timeframes for development and implementation of the structures to support implementation of the FMD requirements will be described.

The potential involvement of hospital pharmacists with national medicines verification organizations will be described as well as known developments in the 34 member countries of European Association of Hospital Pharmacists (EAHP).

The obligations on hospital pharmacists, to act on behalf of their institutions and the options for managing compliance with the legislation will be explained.

The obligation on institutions and hospital owners to support hospital pharmacists in this task will be considered.

The needs assessment and the resulting staffing and equipment requirements for pharmacy departments to successfully meet the legislative requirements will be outlined for one hospital pharmacy department.

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L12 Collaborative Care for the Benefit of Cancer Patients

J Smits[1]

[1]*President, Pharmaceutical Group of the European Union (PGEU), Brussels, Belgium*

Considerable efforts have been made to improve the treatment and care of cancer patients. The results of all these efforts are remarkable. In general patients live substantially longer. Some patients perceive this as getting a second life. There are even people who characterize cancer as a chronic disease. Whereas decades ago this would have been unthinkable. Furthermore, more (oral) cancer therapies have become available in primary care. These changes do have implications for physicians, pharmacists, nurses and other healthcare professionals. The emphasis on hospital treatment will decrease and treatment in primary care will become more common practice. The practical consequence is that the hospital-based team of professionals (specialist, hospital pharmacist, nurse) treating a patient is extended with professionals in primary care (general practitioner, community pharmacist, home care nurse). Although it is not possible to draw a precise line in this matter one could say that there will be considerably more interaction between professionals in primary and secondary care. The diagnosis and the initiation of cancer treatment will still be specialized and performed in a hospital setting. However dispensing medicines, medication management, dealing with drug-drug interactions and side effects will increasingly be managed by primary healthcare professionals who will interact with patients and professionals in secondary and tertiary care to help and advise these patients. This will be more prominent when the palliative phase becomes a major part in the treatment of cancer. More will be asked from professionals outside the hospital to acquire the necessary profesional competences to provide care to cancer patients, and to collaborate in the best interest of patients, including the exchange of medical and pharmaceutical data. Or in other words collaborative care follows the cancer patient.

L13 New Drugs of the Year

J Barth[1]

[1]*Justus-Liebig-University Gießen, University Hospital, Gießen, Germany*

In this lecture the new oncology drugs approved in 2015 will be presented and particularities in mechanism of action, side effects, their management and/or administration and schedules are highlighted, based on a subjective selection.

Symposium Clinical: Oncology Patient in Community Pharmacy

L14 Clinical Pharmacist Interventions for oncology Outpatients

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Introduction: Pharmaceutical verification of chemotherapy prescribing is a vital step to assure the quality and safety of chemotherapy. Cancer care clinical pharmacists are an integral part of the outpatient oncology team.

Clinical interventions: The cancer care clinical pharmacist makes many interventions every day from prescription legality and prescribing errors, choice of regimen and supportive medications to drug interactions and influencing patient concordance. Clinical pharmacists ensure that chemotherapy protocols are followed and advise prescribers on dose modifications based on critical test results and concomitant illness and drug therapy. With the new oral anticancer therapies, there is an increasing need to cross-check for interacting medicines and provide patients with additional support to improve concordance. Often the cancer care pharmacist will contact a patient's primary care team to provide specialist advice to general practitioners (GPs), community pharmacists and community nurses.

Conclusion: Clinical pharmacists are experts in medicines and make multiple interventions whilst working in outpatient oncology services. The cancer care pharmacist is key to the safe use of chemotherapy.

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L15 Medication Reconciliation in Oncology

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Clinical pharmacists are contributing to safe medication use by providing comprehensive management to patients and medical staff. Oncologic patients may be at particular risk due to narrow therapeutic index of drugs, frequent comorbidities, polymedication and frequent transfers between home and hospital. Medication errors are a leading cause of patient harm. Many of these errors result from an incomplete overview of medication either at a patient's referral to or at discharge from the hospital. The transition between different care levels has been identified as one of the major critical points in hospital patient management.

Reconciliation is a process of identifying the most accurate list of all medications a patient is taking - including name, dosage, frequency and route - and using this list to provide correct medications for patients anywhere within the healthcare system. Reconciliation involves comparing the patient's current list of medications against the physician's admission, transfer, and/or discharge orders, and all interfaces of care. Results of different studies highlight weakness at patient transition care levels.

Thus, clinical pharmacy services comprise discharge counselling, medication review, and medication reconciliation. This activity is a useful tool to find and correct discrepancies, minimizing the risk of adverse drug events and improving patient safety.

L16 Oral Chemotherapy: Are we following up Patients correctly on correct Administration and monitoring Adherence?

F Festinese[1]

[1]*IRCCS Foundation, National Cancer Institute of Milan, Italy*

What is the first thought, when we are talking about therapeutic adherence? If we try to do a search we will find different definitions.

According to the World Health Organization (WHO) 'Adherence to therapies is a primary determinant of treatment success. Poor adherence attenuates optimum clinical benefits and therefore reduces the overall effectiveness of health systems'. It is crucial to make the right counselling on an oral chemotherapy from the first cycle. During dispensing it is important to focus on a few crucial aspects, such as how to take the therapy, pay attention to warnings, how to include the new cancer therapy with any already taken therapies checking possible interactions. These steps need to be adapted to all types of patients (young and old, single or multiple therapy in place, for example), with the goal to find for each patient the best possible solution. For all these types of patients is fundamental the importance of communication, avoiding complicated terms but using comprehensible words and finding clear examples. It is important to support the patient cycle after cycle understanding together what are the possible troubles. Make the patient aware of the importance of their own care is the first step for the success of his/her treatment.

L17 A Cancer Patient in a Community Pharmacy

D Arbanas[1]

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Cancer patients use lots of drugs. In addition to chemotherapy (applied in a hospital, in Croatia), they use antiemetics, opioid drugs for pain relief, over-the-counter drugs and drugs for the treatment of co-morbid conditions. In Croatia, these drugs are dispensed in a community pharmacy. It is necessary for a community pharmacist to be familiar with all the drugs a cancer patient is using, to be able to counsel the patient about the doses, time intervals, side effects and possible interactions. To improve the care it is useful for a community pharmacist to work in cooperation with a general practitioner.

International Relationships

L18 The New USP 800

MJ Koraleski[1]

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Personnel in healthcare settings who may come in contact with hazardous drugs are at risk for unintentional exposures and their related adverse health effects. Agencies such as the Environmental Protection Agency and Occupational Safety and Health Administration have been established for decades to ensure the protection and safety of the US workforce and the environment. The purpose of the new USP Chapter <800> is to set forth the standard policies and procedures required to safely handle antineoplastic and hazardous drugs in healthcare settings across the US. The National Institute for Occupational Safety and Health maintains the list of agents that have been defined as hazardous due to their potential to cause carcinogenic/teratogenic effects, reproductive toxicity, or organ toxicity. Chapter <800> was published on 1 February 2016; however, federal regulation will not begin until 1 July 2018 to allow entities the necessary preparation for such regulatory standards.

L19 Drug Codex from Japan

S Suzuki[1]

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The first guideline for handling hazardous cancer agents, 'JSCN/JSMO/JASPO Joint Guidelines for Safe Handling of Cancer Chemotherapy Drugs 2015' has been established in Japan (JSCN: Japanese Society of Cancer Nursing, JSMO: Japanese Society of Medical Oncology, JASPO: Japanese Society of Pharmaceutical Oncology). We used the existing evidence, such as OSHA, NIOSH, ASHP, ISOPP and ONS guidelines. The main databases used were PubMed, CINAHL and Japan Medical Abstracts Society. The searches retrieved articles up to 23 July 2015. JASPO had an important role in making the guideline, and the National Cancer Center Hospital East (NCCHE) is one of the leaders, that will conduct projects to prevent exposure of the hazardous medicines. When we made the guideline, we realized many real world discrepancies between ideal managements and daily practice managements in a hospital. In the session, I would like to share ideas and tips on how to implement the guideline and make better environment for every healthcare professional.

L20 Guidelines in Germany

U Warnke[1]

[1]*Pharmacy Department, Havelland Kliniken GmbH, Nauen, Germany*

The lecture will give an introduction on the relevant guidelines for good practice of aseptic preparation of medicinal products in healthcare establishments applying to Germany. Main topics of the guidelines of German pharmacists (BAK, 2012), of the German hospital pharmacists (ADKA, 2013) and of the Apothekenbetriebsordnung, the legal regulation for the administration of pharmacies in Germany, which was considerably revised in 2012, are pointed out. Similarities and differences will be presented and deductions for the daily practice will be drawn.

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Symposium Practical

L21 Nanotechnologies: Vectorization of Drugs

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Nanoparticles have been known since the early 1960s with the discovery of the first liposome by Bangham et al.. Their small size and ability to encapsulate drugs have made them good candidates for drug formulation. They allow improving solubility of hydrophobic drugs, improving drugs stability *in vitro* and *in vivo*, and may enable prolonged circulation time and tumour accumulation by enhanced permeation and retention effect. However since then, only few nanoparticles based formulations have reached the market, the most known being Doxil® and Abraxane®. A closer look at their formulations, pharmacokinetics and efficacies during clinical trials help to understand the main advantages and limitations of nanoparticles yet available. New development in preclinical and clinical trials will also be addressed to understand why nanoparticles for drug delivery in cancer treatment are believed to be one of the future breakthroughs in the support of patients with cancer.

L22 Nanomaterials as Destructive Sorbents for Surface Decontamination after Cytostatics Exposure

V Štengl[1], I Netíková[1], M Št'astný[1]

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Nanostructured oxides of selected metals, e.g. Ti, Al, Zn, Mn, have high ability to degrade on its surface hazardous substances, such as warfare agents or organophosphorous pesticides. These materials contain hazardous substances on their surface not only absorb, such as active carbon, but also decompose. Therefore, they are also called destructive sorbents. Environmental contamination with cytostatic drugs can occur in an accident during production, storage, transport and distribution of cytostatics. Other situation of inadvertent release of cytostatic drugs is during preparation ready-to-use parenteral solution in pharmacies and by administration to the patients on the ward. Currently, a sufficiently effective decontamination method is not available. Degradation by sodium hypochlorite or sodium hydroxide is not effective for all used cytostatics and its degradation products. The possibility of cytostatics degradation with destructive sorbents has a very high commercial potential. It allows decontamination of large areas, whether by normal use when handling cytostatics or during accidents connected with their handling.

ESOP-Session

L23 Establishment of a European best-practice Model for Improvement of Health Care for oral Chemotherapy Patients – EPIC project

A Eberl[1]

[1]*Institute of Oncology Ljubljana, Ljubljana, Slovenia*

Oncology is currently the fastest developing area of healthcare. Many of the new drugs are formulations for oral administration. This means that the complex treatment of often co-morbid oncology patients is moving from a supervised hospital setting to the patient's home and dispensing of potent oral anticancer drugs to general community pharmacies.

Our purpose is to empower pharmacists to improve therapy-related outcomes and patient safety by lending support for the pharmaceutical counselling related to the dispensing of oral anticancer drugs. By doing so in selected member countries, we will create a best-practice model for the European Union (EU).

I will present the results of the survey about the current situation and problems at dispensing of oral anticancer drugs in the EU at the conference. Based on the results, we will design an education programme for pharmacists about oncology topics and develop IT-tools that assist the pharmaceutical counselling process. This will allow the pharmacist quick access to essential information on oral oncology drugs including important advice for patients as well as useful service options like the preparation of treatment plans for the patient.

This system will be put to effect in the participating member countries and later made available for implementation in other EU-countries. These measures will improve patients' self-efficacy regarding his or her disease and therapy, and will consequently enhance the adherence.

L24 Results of MASHA Project (Research about Environmental Contamination by Cytotoxics and **Ma**nagement of **S**afe **Ha**ndling Procedures)

Ewelina Korczowska[1]

[1]*Clinical Hospital of Lord's Transfiguration, University of Medical Sciences in Poznan, Poland*

Evaluating environmental contamination with cytotoxic drugs in hospitals is one of the fundamental requirements to ensure the safety of all healthcare professionals. Safe handling procedures should be closely monitored in all areas where antineoplastic drugs are delivered, stored, prepared, administered and disposed of. Over the last few years, environmental contamination with cytotoxic drugs in hospitals units has been reported in several publications. However, detailed information on surface contamination with antineoplastic drugs in European hospitals in areas where these drugs are handled is still limited. Therefore, the European Society of Oncology Pharmacy (ESOP) undertook the first independent, multicentre, pan-European study, involving over a dozen hospitals, to measure the current state of cytotoxic contamination in the workplace. This project is called MASHA – *Research about Environmental Contamination by Cytotoxics and **Ma**nagement of **S**afe **Ha**ndling Procedures*.

The study was designed to investigate any possible weak points during drug preparation, transportation and application and during the disposal of medical devices after treatment. Lessons learned would be used to create international guidelines for the handling of antineoplastic drugs. The study was carried out at 15 hospitals in Europe in order to observe a broad variety of procedures and cases. The results of the MASHA project will be presented during the European Conference of Oncology Pharmacy (ECOP) in Dubrovnik, 20 May 2016.

Interactive Clinical: Risk Management/ Medication Errors

L25 Risk Management – Overview

M Heymann[1]

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Human errors are inevitable and may occur anywhere. Accidents demonstrate substantial matching with regard to causes, regardless of industry.

Common causes of human error are lack of attention, inadequate communication, team disturbances, unclear instructions and/or wrong assessment of the situation.

Further, organizational processes and interfaces have been identified as cause of error. Latent potential for error occurs due to incorrect conditions or inadequate management decisions. The people involved are located at the blunt end.

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The person on site is at the sharp end and must compensate for any previous shortcomings. Even minor changes can trigger accidents. Iceberg principle according to Heinrich's law:

For 10,000 insignificant deviations, there are 1,000 deviations with minor consequences, 100 deviations with noticeable consequences, 10 critical situations and 1 catastrophic event. Thus, systematic analysis of even insignificant deviations is suitable to capture more severe incidents.

A risk management process allows systematic checking of all activities of a company. According to ISO 31,000, standard specifications can be integrated into an existing management system without great effort. Various methods are available for risk assessment.

A significant approach in risk management is the establishment of a positive error management culture. This includes a communicative, friendly, flexible and learning culture.

L26 Screening for Safety Signals of Tyrosine Kinase Inhibitors using Spontaneous Reporting Systems

M Banovac[1]

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After the pivotal clinical trials have been completed and a medicinal product was granted a market authorization, the exposure to the medicine often exponentially increases. The adverse drug reactions which are rare and very rare, i.e. 1/1,000 or 1/10,000, respectively; cannot be captured due to the limited exposure in clinical trials. Furthermore, clinical trials do not reflect the real life setting of medicinal products' use. Spontaneous reporting systems complement clinical trial data as a fundamental source of information for detecting safety concerns after placing a medicinal product on the market, especially detecting rare adverse events. As the large pharmacovigilance databases contain millions of reports, statistical algorithms have been developed to prioritize and flag the drug-event pairs which are reported more frequently than our statistical expectations. The presentation will focus on the detecting of safety signals with tyrosine kinase inhibitors in large spontaneous reports databases as well as on the European Union (EU) network's drug safety signals detection and management system.

Interactive Practical: How to interpret?

L27 - Pharmacoeconomic Studies

Assessing the Cost-Effectiveness of Treatments for Metastatic Melanoma

J Cairns[1]

[1]*Department of Health Services Research and Policy, London School of Hygiene & Tropical Medicine, London, UK*

In this presentation I distinguish the key challenges in interpreting pharmacoeconomic studies: appropriateness of comparators, economic model, survival analysis, health state valuation, costs of treatment, and interpretation of incremental cost-effectiveness ratios. Each of these will be illustrated with recent examples from economic evaluations of the treatment of metastatic melanoma. The European Medicines Agency (EMA) has issued marketing authorizations for eight products between July 2011 and December 2015 (ipilimumab, vemurafenib, dabrafenib, trametinib, pembrolizumab, nivolumab, cobimetinib and talimogene laherparepvec). Decisions by third-party payers regarding which of these should be approved for routine use requires robust assessment of their cost-effectiveness.

L28 - Clinical Trials

Critical Reading and Basic Terms of Clinical Trials in Oncology (metastatic setting)

R Šeparović[2], M Skelin[1]

[1]*General Hospital Šibenik, Croatia*

[2]*University Hospital Sisters of Mercy, University Hospital for Tumors, Zagreb, Croatia*

Introduction: Clinical trials are scientific and medical tests carried out on healthy or diseased subjects who voluntarily consented to participate. Their purpose is to discover or verify the pharmacokinetic and pharmacodynamic properties of the drug; detection of adverse drug reactions; detecting drug interactions; testing the safety profile of the drug as well as its efficiency. Clinical trials are an important and indispensable part of the progress of modern medicine and health care. They are the base of evidence-based medicine. Results of clinical trials are used for drug registration in different countries of the world and for scientific purposes in order to improve the guidelines for the treatment of diseases. Because of these reasons it is important that oncology pharmacist know the results of clinical studies to well interpret and implement in daily work.

Aim: The aim of the workshop is to introduce participants to the concepts of the clinical studies. It will be shown in clinical studies, according to which the participants will be able to get a good overview of terms related to clinical trials as well as the correct interpretation of their results. At the end of the workshop a few short lessons would be held in which participants will once again be able to determine the knowledge of the terms used for the interpretation of the results of clinical studies.

Learning outcomes: After the workshop, participants will gain a clearer insight into critical reading of clinical trials, which would enable them better understanding of pharmacotherapy treatment in their daily work.

Saturday, 21 May 2016

Keynote – Lecture

L29 Demands Patients have to Oncology Pharmacists

L Denis[1], N Einer-Jensen[2]

[1]*Europa Uomo Belgium & US TOO Belgium*

[2]*Europa Uomo Denmark & PROPA*

Clinical management, holistic care and research interest in prostate cancer changed considerably since our respective organizations incorporated the results of the Luxembourg Conference for Standardization in Oncology Pharmacy in 2008. What has not changed is the part of the Ljubljana Declaration 2006 that 'The multidisciplinary approach will deliver best practice to patients within a clinical governance framework'.

Trained as an academic onco-urologist I learned to respect oncology pharmacy the hard way and all my major publications have been conceived and edited with expert pharmacologists and nationally with community pharmacists. The subjects ranging from 'Medicine around Rubens' in 1977 to 'anti-androgens in Prostate Cancer – A key to tailored endocrine treatment' in 1996.

In this tradition I was lucky to have the support of Professor Niels Einer-Jensen as co-author and fellow member of Europa Uomo for this honorific address.

Limiting our presentation to the dramatic changes in all aspects of the patient's journey through the different phases of prostate cancer from early diagnosis to palliative care we focused on the main changes in basic understanding of the disease, personalized targeted management and some practical applications in our social healthcare systems.

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Specific topics include early diagnosis, active surveillance, prostate cancer units, pharmacovigilance, individualized management and personalized care, technical developments, genomics, molecular diagnostics, Castration-Resistant Prostate Cancer (CRPC) treatment, trial endpoints and last but not least pharmacist-patient dialogue on these topics.

What Doctors have to tell us?

L30 Medical Treatment for advanced Prostate Cancer

H van Poppel[1]

[1]*University Hospitals Leuven, Belgium*

Prostate cancer is the second most detected malignancy in men. Despite all efforts to diagnose the disease in an early stage, amenable for curative treatment, many patients will be confronted with metastatic disease.

Typically androgen deprivation therapy or hormonal treatment is the mainstay for metastatic prostate cancer. Years ago, orchiectomy and estrogens were used. Since 1985, LHRH agonists (leuprolide, goserelin, triptorelin, buserelin, histrelin), anti-androgens and the concept of maximal androgen blockade were introduced.

In 2000, the LHRH antagonists (Abarelix, Degarelix) were introduced while also pure anti-androgen hormone-therapy was used in well-defined indications. Because of the toxicity of androgen deprivation therapy intermittent androgen deprivation was used more and more often. Once hormonal treatment has been installed, one can expect that the disease becomes castration resistant. A couple of secondary hormonal manipulations can be proposed (anti-androgen withdrawal, estramustine phosphate, corticosteroids ...). None of these have shown survival benefit. Therefore, Taxotere was introduced after a European and US trial showed a significantly improved 3-year survival.

Around the same time, new second-line hormonal therapies were developed, abiraterone (CYP-17 selective inhibitor), with similarities to the old ketoconazole, and enzalutamide, an androgen receptor antagonist. The two latter were first used in patients previously treated with taxanes but are today administered in the newly diagnosed castrate resistant metastatic prostate cancer. The challenge is to optimize sequence or to combine these different new treatment modalities.

Equally after Taxotere failure patients can get cabazitaxel, a new taxane with also improved survival.

Since prostate cancer mostly metastasizes to the bone, specific bone targeted treatments came along with Zoledronic acid and later Denosumab. Older radiopharmaceuticals (beta-emitters like strontium, samarium and rhenium) have been abandoned while an alfa-emitting agent Radium-223 also demonstrated a survival advantage.

Other agents are promising: cabozantinib, a c-MET and VEGFR-2 inhibitor; sipuleucel-T, an autologous vaccine based on dendritic cells; Tasquinimod, an immunomodulating and antiangiogenetic compound; ARN-509, the newest androgen receptor antagonist; PROSTVAC, another vaccine that expresses the human PSA gene and ipilimumab, a human monoclonal antibody to boost the antitumoral T-cell response.

Many other new agents are currently evaluated in clinical trials.

L31 Cardiovascular Effects and Cardiovascular Toxicity of Cancer Treatments

A Barac[1]

[1]*MedStar Heart and Vascular Institute, MedStar Washington Hospital Center, Washington, USA*

Recent advances in cancer treatments have led to remarkable survival benefits with significant prolongation of life expectancy in the paediatric and adult cancer patient population. A number of anticancer agents including chemotherapeutic drugs and molecularly-targeted agents may cause cardiac and vascular damage and significantly increase the short- and long-term risk of cardiovascular disease, including hypertension, venous and arterial thromboembolism, myocardial and cerebrovascular ischaemic events, cardiomyopathy, and heart failure. This presentation will summarize recent advancements in understanding of the mechanisms of cardiovascular injury of the most common oncology treatments, as well as the strategies for cardiovascular monitoring and prevention.

Symposium Clinical: Immunotherapy

L32 Recent Developments and Research Topics in Immune Oncology

D Vrbanec[1]

[1]*University Hospital Zagreb, Department Medical Oncology, Zagreb, Croatia*

Great progress has been made in the last few years at the molecular level with regard to understanding the role of the immune system in regulating the growth of malignant cells. The identification of molecules that regulate immune processes has lead to the development of new immunotherapeutic approaches in oncology. The goal of cancer immunotherapy is to restore the ability of the immune system to detect and destroy cancer cells by overcoming the mechanisms by which tumours evade and suppress the immune response. In general there are two types of immunotherapy in oncology: passive immunotherapy (tumour-directed monoclonal antibodies and cell therapies) and active immunotherapy (cytokines, mediators of T-cell activation and therapeutic cancer vaccines). The major breakthrough in cancer immunotherapy resulting in successful clinical phase III clinical trials followed the development of mAbs against immune checkpoints.

Clinical trials with checkpoint blocking mAbs to CTLA-4 (ipilimumab), PD-1 and PD-L1 (nivolumab, pembrolizumab) have shown impressive response rates in patients, particularly for melanoma, non-small-cell lung cancer (NSCLC), renal cell carcinoma (RCC), and bladder cancer. Further clinical studies are needed for better understanding the mechanisms of variable response rate, to identify biomarkers for clinical response, and to combine these treatments with other therapies.

L33 Immunotherapy in Oncology – Side Effects and their Treatment

Z Dembic[1]

[1]*Department of Oral Biology, Dental Faculty, University of Oslo, Norway*

Recent immunotherapies of immunogenic cancer like melanoma in stages III or IV use checkpoint (PD1, CTLA4) inhibitors (pembrolizumab, ipilimumab, respectively) as the first choice therapy with remarkable prolongation of survival. Similarly, transfer of personalized T cells able to kill cancer cells is also being used as targeted treatment of some cancers (prostate). These treatments target cancer's avoidance of destruction by the immune system. However, such therapies can have a variety of side effects because they break immune tolerance to self tissues. In rare cases, patients may develop autoimmune phenomena ranging from mild to severe adverse effects that include vitiligo (discoloration of skin), lichenoid reactions, arthritis, tenosynovitis, collagenous inflammation of the gastrointestinal tract, hypothyroidism or rhabdomyolysis. The list is being widened with recent success of checkpoint immunotherapies. The support and treatment of such adverse effect has always been conservative with discontinuation of the primary regimen. However, a latest report described the reinstatement of the checkpoint inhibitor (pembrolizumab) after symptomatic treatment with selected corticoids in a melanoma patient. These results provide hope, in such cases, for continuation of treatment with immune checkpoint inhibitors, as there is a strong benefit to overall survival.

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L34 Immunotherapy in Oncology - interdisciplinary Cooperation among Immunologist, Oncologist and Pharmacist

I Netíková[1,2], E Závadová[1], B Konopásek[1], L Petruželka[1]

[1]*Department of Oncology, General University Hospital and First Faculty of Medicine Charles University, Prague, Czech Republic*

[2]*Department of Clinical Pharmacology and Pharmacy, General University Hospital Prague*

Immune status and immune response becomes an important factor for decision about patient treatment, particularly in time of growing immunotherapy in oncology.

Results from Immunoscore programme in our department show, that patients with stage II colorectal cancer have predominantly a depression in cellular immunity. Plasma levels of immunoglobulins were also reduced. Most patients showed some clinical symptoms of immunodeficiency, such as frequent respiratory tract infections and/or herpetic infections. The correlation of neoangiogenic and immunosuppressive factors, as well as the state of anticancer immunity, could help in the future as a prognostic marker and contribute to the selection of targeted immune therapy in patients with colorectal cancer.

From this reason was established 'Ambulace' of Immuno-oncology in our department, where medical oncologist, immunologist and clinical pharmacist cooperate. The aim is to select immunocompromised patients, not only with colorectal cancer, and help to stratify them for the most suitable therapy.

Poster Sessions (Thursday 19 May – Saturday 21 May 2016)

Poster Session	Abstract Number
Basic research in oncology	P001 – P013
Cytotoxic drug preparation	P014 – P025
Automation/robotics in oncology pharmacy	P026 – P027
Quality assurance/microbiology/analytics/stability in oncology pharmacy	P028 – P035
Computer and software in oncology pharmacy	P036 – P040
Clinical pharmacy/pharmaceutical care in oncology pharmacy	P041 – P075
Managing side effects in oncology pharmacy/ oncology pharmacist intervention	P076 – P091
Organization and management	P092 – P097
Palliative care in oncology pharmacy	P098
Treatment/regimen	P099 – P108
Other	P109 – P117

Poster Presentations

Poster Session: Basic research in oncology

P002 EGFR inhibition +/- irradiation induce an HIF-2 addiction in head and neck cancer resistant tumours

P Coliat[1], L Ramolu[1], A Jung[1], E Pencreach[1]

[1]*Centre Paul Strauss, Laboratoire de biologie tumorale, Strasbourg, France*

Introduction: Therapeutic management of head and neck squamous cell carcinoma (HNSCC) are mainly based on surgery and chemo/radiotherapy. Treatments that target the epidermal growth factor receptor (EGFR) using the cetuximab monoclonal antibody are the only targeted therapies approved for management of locally advanced HNSCC. However, the prognosis has not improved in the last decades, with less than 50% of the patients being alive 5 years after treatment. The resistance of these tumours to treatment might involve tumour hypoxia. Indeed, it has been shown that the stabilization of hypoxia inducible factor (HIF), that are key regulators of the cell adaptation to hypoxia, correlates with tumour resistance to ionizing radiations and adverse prognosis. HIF-1α± expression can be induced independently from oxygen concentration by oncogenic signalling pathways, like the EGFR/mTOR pathway. Pharmacological approaches using targeted agents that inhibit the EGFR/mTOR pathway with specific inhibitors have shown efficacy in some solid tumours, such as non-small lung cells cancer. Moreover, some studies suggest that cancer cells can be sensitized to ionizing radiation and anti-EGFR therapies by using mTOR inhibitors.

Material and method: The cetuximab-sensitive (CAL27) and cetuximab-resistant (SQ20B) cell lines were xenografted to nude mice, and the impact of cetuximab and rapamycin, alone or in combination with radiation therapy, on HIF-1 expression, as well as on tumour growth and time to relapse was evaluated. DNA double-strand breaks generation, clonogenic survival, and EGFR/mTOR axis signalling activation were measured *in vitro*.

Results and discussion: The rapamycin/cetuximab combination showed a remarkable efficacy on tumour growth control *in vivo* and improved sensitivity of the resistant SQ20B cells lines to radiation therapy *in vitro*. Despite the fact that the drug combination and irradiation increased DNA double-strand breaks, radiotherapy combined to either cetuximab, or cetuximab + rapamycin resulted in a shorter time to regrowth and an increased relapse frequency. In addition, efficient HIF-1 inhibition by the combination of rapamycin and cetuximab, resulted in a reduction of SQ20B clonogenic survival to about, 50% suggesting the induction of a resistance mechanism. We investigated if HIF-2 could take a part in this adaptation. We observed that HIF-2 expression was induced with EGFR treatment and/or irradiation.

HIF-2 silencing using SiRNA alone had no impact on clonogenic survival. Silencing HIF-1 or HIF-1 and HIF-2 induced a 50% reduction of clonogenic survival. However HIF-2 silencing combined with treatment resulted in a dramatic drop of clonogenic survival (< 1% clonogenic survival).

Conclusion: HIF-2 oncogenic addiction is induced by EGFR treatments +/– irradiation in resistant HNSCC cell lines (SQ20B). HIF-2 expression is induced with treatments and does not result from HIF-1 inhibition. HIF-2 induction could be implicated in tumour resistance and recurrence in head and neck cancer patients.

P003 Places to check medicines brought to hospital by inpatients: which is better central pharmacy or hospital wards

S Suzuki[1], K Ikegawa[1], N Yoshino[1], S Saito[1]

[1]*Division of Pharmacy, National Cancer Center Hospital East, Kashiwa Chiba, Japan*

Introduction: Managing medicines brought to hospital by inpatients, medication reconciliation is one of the core services in pharmacy division. At the National Cancer Center Hospital East, pharmacists performed the service in a central pharmacy, however, it has changed the working place, from central pharmacy to hospital wards, since it was criticized that patients had long waiting time for checking brought in medicine. According to the change of working place, ward pharmacists check the medicines in a nurse station from 5 February 2015, compared that pharmacists in a dispensing division checked the medicine in a dispensing room in the past.

Aim: We evaluated benefits of change locations from central pharmacy to hospital wards to check medicines brought to hospital by inpatients.

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Material and method: We conducted retrospective analysis of pharmacists' records of medicines brought to hospital from 7 January to March 2015. We made two groups, central pharmacy group (CPG) which pharmacists who worked in dispensing room worked for the service in the central pharmacy from 7 January 2015 to 4 February 2015 (total 20 business days); and ward pharmacy group (WPG) which ward pharmacists worked for the service on a ward from 5 February 2015 to 5 March 2015 (total 20 business days).

Results and discussion: There were 836 cases in WPG and 836 cases in CPG, respectively. The rate of medicine check of brought to hospital was higher in WPG [87% (724/836)] than in CPG [72% (606/836)] (p <0.001). Average (±SD) time of the service, from start to double check, was shorter in WPG [53 minutes (±38)] than in CPG [126 minutes (±60)] (p <0.001). Pharmacists interventions according to the check was higher in WPG [32% (264/836)] than in CPG [14% (121/836)] (p <0.001). Check for narcotic medicines was 15% (127/836) in WPG and 0% in CPG.

Conclusion: The change of service location does not only reduce patients' waiting time but also enhances clinical pharmacy service in inpatient.

P004 Analysis of the use and effectiveness of Trastuzumab emtansine in metastatic breast cancer in a tertiary hospital

M Ruiz de Villegas[1], B Mora Rodríguez[1], I Munoz Castillo[1]

[1]*Malaga, Spain*

Introduction: Trastuzumab-emtansine (TDM-1) is indicated for the treatment of adult patients with HER2-positive, unresectable locally advanced or metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination.

Aim: To describe the use and progression-free survival (PFS) in patients with metastatic breast cancer treated with TDM-1.

Material and method: We performed a retrospective observational study. All patients who received TDM-1 between 1 February 2014 and 30 September 2015 were included. The data collected using the clinical records were: sex, age, line of treatment and number of cycles. The effectiveness variable was PFS.

Results and discussion: TDM-1 was administered to 16 patients (100% female) with a median age of 51.5 years (28–78). All received prior taxane and trastuzumab-based therapy or lapatinib plus capecitabina or lapatinib plus trastuzumab in first-line treatment of metastases. In 11 of them trastuzumab-emtansine was used in second- line treatment while in the rest it was used in third, fourth and fifth line. The median cycles was 7 (3–17). Regarding PFS, 9 of the 16 patients progressed, obtaining a median PFS of 5.6 months. The other 7 patients have a median follow-up of 5.7 months to the time of writing.

Conclusion: When TDM-1 started to be used in our centre, 5 of our patients had already had several lines treatment but in 11 patients, TDM-1 was used as second-line treatment. In our study, the median PFS (5.6 months) was lower than that obtained in clinical studies but 7 of 16 patients continue with the treatment, thus, the median PFS is expected to increase. TDM-1 has demonstrated a good profile among our patients and has shown clinical activity as second-line treatment in patients with HER2-positive metastatic breast cancer.

P005 Aflibercept: effectiveness, safety and utilization analysis

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Introduction: Pharmacy and Therapeutic Committee (PTC) included aflibercept in our hospital in March 2014 under the following conditions: combination with FOLFIRI in metastatic colorectal cancer(mCRC), ECOG 0-1, second line after FOLFOX-containing regimen with/without monoclonal antibodies (mAbs) and no rapid progression(< 6 months) to first line.

The aim of this study is to evaluate the suitability of aflibercept use, as well as its effectiveness and safety.

Material and method: Retrospective observational study including mCRC patients who received aflibercept in combination with FOLFIRI (March 2014–October 2015).

Variables included: demographics (sex and age), clinical data (diagnosis, time from diagnosis, KRAS status, ECOG before second line, progression to first line, free-progression survival (FPS), overall survival (OS)) and pharmacologics (first-line mAb, second-line cycles, dose adjustment, discontinuation), and adverse drugs reactions (ADRs).

Response was evaluated by positron emission tomography-computed tomography (PET-CT) according to RECIST criteria, and classified as disease stabilization (DS), complete response (CR), partial metabolic response (PR) or tumoural progression (TP).

Results and discussion: We collected 25 patients (mean age: 60.4 ± 10.7 years old; 13/25(52%) women. KRAS was mutated in 12 patients (48%) and wild type in 8 (32%). Median time from diagnosis was 29 months (min. 9–max. 222).

Referring to restrictions: 21 patients had received previous FOLFOX-containing regimen (4 received XELOX). 100% had ECOG 0-1. 16 (64%) patients received mAbs (9 cetuximab, 6 bevacizumab, 1 panitumumab). 4 progressed to first line before 6 months.

Median cycles in second line was 7 (1–18) with FOLFIRI and 4 with FOLFIRI-aflibercept. FOLFIRI and aflibercept dosage reductions were needed in 12 and 5 patients, respectively. Aflibercept was discontinued in 11 patients (6 toxicity, 5 not reported).

The most frequent ADRs were: 10 asthenia (5 grade(G) 3–4), 9 diarrhoea (1 G4), 8 mucositis (1 G4), 7 nausea (1 G4), 6 hypertension (3 not previously present), 4 proteinuria, 3 hand-foot syndrome (1 G4), 7 others. 11 G 3–4 ADRs were notified (6 in the same patient).

Response rate was 44% (8/18): 1CR, 7 PR. 6 patients presented DS and 4 TP. The remaining 7 were not evaluable (NE) due to short time of treatment or absent data. Median PFS was 7 months (1–16). 8 patients had died when data were compiled. OS among them was 5 months (1–22).

Conclusion: A proportion of patients did not fulfill the PTC criteria established. A more strict follow-up should be carried out.

Among our patients, safety profile is consistent with the expected.

Aflibercept constitutes an alternative with an acceptable response, although effectiveness cannot only be attributed to aflibercept, but also to FOLFIRI.

PFS is consistent with trial results. Our OS data are limited due to small sample size dead when data compilation.

P006 Influence of SNP-SNP combinations in anthracycline transporter genes in the standard induction of acute myeloid leukaemia

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Introduction: Anthracycline uptake by blast cells could be affected by influx transporters (SLC22A16 and SLCO1B1) and efflux pumps, such as ABCB1. Previous studies suggested that single nucleotide polymorphisms (SNPs) of these transporters may influence their effectiveness or toxicity in acute myeloid leukaemia (AML) induction therapy. However, the impact of the combinations of these SNPs remains undetermined.

Material and method: Combinations between wild-type genotypes of influx transporters (SLCO1B1: rs4149056; SLC22A16: rs12210538) and variant genotypes of ABCB1 (rs1128503, rs1045642, rs2032582 and haplotype) were evaluated in 225 adult patients at initial diagnosis from AML using a Sequenom (iPLEX) mass spectrometry - based multiplex genotyping assay (Sequenom, San Diego, CA). All patients received induction chemotherapy consisting of idarubicin plus cytarabine (PETHEMA-LMA 99, 2007 and 2010 trials).

Efficacy of first induction cycle was evaluated comparing complete remission (CR) vs partial remission or resistance. Patients dying during induction were considered as no evaluable for efficacy. Based on the World Health Organization (WHO) grading scale, toxicities were grouped as binary variables (grade 0–1 vs grade 2–4). The grade of toxicity assigned to an organ group was the maximum grade of all the specific toxicities within that group. Association between variables was assessed using linear and logistic regression adjusting for age, gender, ECOG, leukocyte and platelet count at diagnosis (R® version 3.1.2).

Results and discussion: The median age of patients was 51.1 years (16–78 years). There were no statistically significant differences in CR. The combination between wild-type genotypes of influx transporters (TT for SLC22A16 and AA for SLCO1B1) and triple variant genotype of ABCB1 (TT/TT/TT) was associated to renal (OR: 5.86; 95%CI: 1.29–24.64; p = 0.015), cardiac (OR: 4.15; 95%CI: 1.10–14.87; p = 0.029) and lung (OR: 5.69; 95%CI: 1.46–21.57; p = 0.010) toxicities compared to other genotypes. These combinations of SNPs ensure the uptake of idarubicin in cells and inhibit its expulsion by ABCB1 pump, increasing the toxicity in these tissues.

Conclusion: This study shows a prognostic impact of combinations of transporter genes polymorphisms in adult AML patients regarding induction chemotherapy toxicity. Further studies with larger population are needed to validate these associations, which could be useful biomarkers in clinical practice.

P007 Evaluation of chemical contamination of waste containers within a centralized cytotoxic reconstitution unit

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Introduction: As part of an assessment policy and risk management, centralized cytotoxic reconstitution unit (CCRU) of our hospital has evaluated environmental contamination. The objective of the study was to determine the contamination of waste containers hermetically sealed by anticancer agents from production area. The platinum is considered as a tracer because platinum derivative drugs represent more than 20% of preparations realized in our hospital. Furthermore, electrothermal atomic absorption spectrometry is a reliable technique for platinum trace assay surfaces.

Material and method: The surface samples at the gripping area (2 samples of 200 cm^2 per container) were performed on 3 types of containers: small containers used and sealed under isolators (J), large yellow and blue containers used in a controlled atmosphere area (GJ and GB). The analysis was performed according to the validated method of Chappuy et al. [1]. The method includes a linear calibration curve from 6 to 150 ng platinum per sample. The limit of detection and the limit of quantification were 2 and 6 ng of platinum per sample, respectively.

1. Chappuy M, Caudron E, Bellanger A, Pradeau D. Determination of platinum traces contamination by graphite furnace atomic absorption spectrometry after preconcentration by cloud point extraction. J Hazard Mater. 2010;176(1-3):207-12.

Results and discussion: A total of 19 J (n = 38 samples), 2 GJ (n = 4 samples) and 3 GB (n = 6 samples) were analysed. 4 of the 48 samples showed a contamination beyond the limit of detection: 2 in a J (6 and 9 ng/sample) and 2 in a GB (8 ng/sample). Despite the low level of contamination, workers in charge of waste disposal are potentially exposed. These results allowed raising awareness of assistant pharmacist and hospital agents to individual protection. Wearing gloves is the only protective barrier between the manipulator and cytotoxic molecules. Gloves should guarantee optimal protection and their characteristic is of paramount importance. The use of powder-free gloves, latex or nitrile is recommended, and vinyl gloves should be avoided according to the literature [2].

2. Easty AC, Coakley N, Cheng R, et al. Safe handling of cytotoxics: guideline recommendations. Curr Oncol. 2015;22(1):e27-37.

Conclusion: Handling of waste containers may expose to risk as well as the transfer to the garbage of hazardous drugs and contaminated supplies. The management of anticancer drug waste containers must be carried out by qualified workers. Disposable gloves and gowns should be worn to preserve personnel from risk exposure and to prevent spread of environmental contamination.

P008 Relation between prostate-specific antigen levels and progression-free survival in patients with prostate cancer treated with abiraterone acetate

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Introduction: Recent hypothesis about prostate-specific antigen (PSA) levels indicate that a reduction in PSA ≥ 30–50% within the first treatment month with abiraterone acetate (AA), as well as a basal level in PSA < 114 ng/mL, could be considered positive predictors in a largest progression-free survival (PFS). The aim of the study was to confirm this hypothesis in patients who were treated with AA in a single hospital experience.

Material and method: Retrospective observational study which included patients with castration-resistant metastatic prostate cancer (CRPCm) who started treatment with AA between August 2011–November 2015. Patients who had not finished the treatment at the end of period were excluded. Data were obtained with the oncology electronic prescription program (Farmis®) and the clinical history. Primary endpoint was mean PFS, whose variation was measured in relation to two independent categorical variables: basal level in PSA (< 114 ng/mL or ≥ 114 ng/mL) and the percentage of basal PSA reduction (% reduction at first PSA determination ≥ 30% or < 30%). Other independent variables were: age, line treatment AA, treatment duration and time to first PSA determination after starting treatment with AA.

Results and discussion: A total of 62 patients started AA during the period study. 22 of these were excluded from the analysis due to having not finished the treatment and other three were excluded due to having no available data. Patients mean age was 73 years old (62–87). All of them had been treated with a complete androgen blockade before being treated with AA. Mean PFS was 9.2 months (CI:95%, 7.1–11.4). 70% of the patients were prescribed AA in first-line treatment, 22% (n = 8) were in

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second-line treatment and the other 8% (n = 3) in third-line treatment. There was not any statistically significant difference between the mean PFS and the considerated independent variables. Mean PFS in groups of basal PSA < 114 ≥ 114 ng/mL was 9.5 vs 8.5 (difference: 1 month, CI:95% –4.7–6.7). Mean PFS in groups which PSA reduction ≥ 30% or < 30% was 8.5 vs 9.6 (difference: –1.1 months, CI:95% –5.6 to 3.4). Mean time to first PSA determination after starting treatment with AA was 48 days.

Conclusion: According to outcomes obtained in our clinical practice, basal level in PSA and the percentage of PSA reduction achieved after starting treatment with AA were not related to the PFS. To confirm these results it would be appropriate to conduct studies including a larger number of patients.

P010 *In vitro* and *ex vivo* analyses of temozolomide resistance in GBM

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Introduction: Glioblastoma multiforme (GBM) treatment consists of radiotherapy after neuro-surgery. Adjuvant chemotherapy is carried out with the alkylating agent temozolomide (TMZ; Temodal®). The extreme aggressiveness of GBM is based mainly on intrinsic resistance to radio- and chemotherapy. In order to understand the underlying molecular mechanisms of resistance we analysed the response of the intrinsic resistant GBM cell line U251 to TMZ. Following *in vitro* experiments we used tumour samples derived from eight GBM patients and performed a systematic phospho-proteome profiling approach

Material and method: GBM cell line U251 was treated with increasing concentrations of TMZ (1–5,000 µM) and IC50 was determined in cell viability assays. Cells were subsequently treated with 1,000 µM TMZ (IC50) for 72 hours and apoptosis was determined by Annexin V/PI FACS analysis. Proteome profiler arrays™ were performed to detected dysregulated MAP-kinases and apoptotic pathways. Tumour samples of secondary GBM were derived from neuro-surgery and protein was isolated and subjected to Proteome profiler arrays™.

Results and discussion: TMZ induced cell death in U251 cells with an IC50 of 1,000 µM. This was paralleled by an increase in apoptosis as measured by Annexin V/PI FACS analysis. Subsequent proteome profiling after TMZ treatment revealed that expression of a wide range of pro-apoptotic proteins (e.g. p53, CD95, Pro-Caspase-3) were strongly induced. These findings were in-line with phosphorylation/activation of several kinases (e.g. AKT, GSK-3, JNK) after TMZ treatment, which are involved in in cell cycle regulation and/or drug resistance. To link the *in vitro* results with the clinical situation we isolated protein from four secondary GBM before and after TMZ treatment. (Phospho-) proteome analysis of these samples showed that from a total of 61 (phospho-)proteins 5 were significantly regulated in TMZ-resistant recurrent tumours as compared to untreated samples. In contrast to the findings observed after short term TMZ treatment of U251 cells, in the *in vivo* situation after various cycles of TMZ over longer period of time, apoptotic proteins tended to be down-regulated (e.g. pro-caspase-3, RAD17) and kinases, such as AKT and CREB involved in cell cycle progression were less phosphorylated/activated.

Conclusion: Taken together our investigations revealed that short term TMZ treatment (72 hours) of U251 GBM cell line induced apoptotic cell death only at high concentrations (IC50: 1,000 µM) what can be attributed to the intrinsic resistance of U251 cells. Interestingly, in the *in vivo* situation after long-term treatment using TMZ in recurrent (resistant) GBM apoptosis and cell cycle progression appeared to be reduced resembling the resistant state of the tumour. It is remarkable that despite the heterogeneity of the tumour material, from 61 (phospho)proteins analysed, 5 were significantly regulated. These pathways (e.g. AKT, CREB) appear to play a major role in GBM resistance towards TMZ.

P011 Genetic variants in ERCC1, ERCC2 and SOD2 are associated with increased risk of neurotoxicity in taxane-treated breast cancer patients

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Introduction: Neurotoxicity is one of the most severe toxicities of taxanes. It affects patients' quality of life and limits the treatment. Besides the action on tubulin, oxidative stress has been proposed as a mechanism involved in chemotherapy-induced neuropathy. The aim of this study is to assess the association between single nucleotide polymorphisms (SNPs) in genes coding for proteins involved in the generation of reactive oxygen species (ROS), DNA repair mechanisms and antioxidant response with neurotoxicity in breast cancer (BC) patients treated with taxanes.

Material and method: Adult women with histologically confirmed BC treated with taxanes were included. Neurotoxicity was evaluated in each cycle and classified according to NCI CTCAE v4.0. SNPs in ERCC1 (rs11615, rs3212986), ERCC2 (rs13181, rs1799793), GSTM3 (rs1799735), NOS3 (rs1799983, rs1800779, rs2070744), RRM1 (rs1042858, rs9937) and SOD2 (rs4880) were analysed by mass spectroscopy (MassARRAY SEQUENOM®).

Neurotoxicity was grouped as a binary variable (grade 0–1 vs grade 2–4). Association between variables was assesed by logistic regression, adjusting for age, performance status, chemotherapy squeme and metastatic disease, and also by Elastic Net regression, including the same covariates (IBM® SPSS® Statistics v.19; R® v. 3.1.2 (glmnet v. 2-2.1).

Results and discussion: 101 docetaxel-treated patients were included [mean age 51.0 years (95%CI=48.9; 53.1)]. 48.5% received docetaxel 100 mg/m² every 21 days and 51.5% received docetaxel 75 mg/m² plus doxorubicin and cyclophosphamide every 21 days.

58 paclitaxel-treated patients were included [mean age 58.3 years (95%CI=54.8; 61.1)]. 81.0% received paclitaxel 80 mg/m² every 7 days and 18.9% received paclitaxel 80 mg/m² every 7 days plus doxorubicin.

ERCC2 rs13181 was found in association with neurotoxicity in docetaxel-treated patients (2.2% TT/GT vs 22.2% GG) with an OR = 12.7 (95%CI=1.6–104.4; p = 0.028) for GG carriers (associated with reduced DNA repair capacity).

Two SNPs were associated with neurotoxicity in paclitaxel-treated patients: ERCC1 rs3212986 (14.7% GG vs 41.7% GT/TT; OR = 4.2 (95%CI=1.2–14.7; p = 0.022), where T allele is associated with reduced DNA repair capacity; and SOD2 rs4880 (33.3% TT/TC vs 0.0% CC; p = 0.002) where T allele is associated with lower enzyme activity.

Elastic Net analysis including both treatment groups (n = 159) selected as predictors of neurotoxicity in taxane-treated patients: ERCC1 rs3212986 GT genotype, NOS3 rs1799983 GT, SOD2 rs4880 TT and paclitaxel scheme as risk factors; and carrying ERCC2 rs13181 TT as protective factor.

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Conclusion: Genetic variants associated with reduced DNA repair capacity and detoxification are associated with an increased risk of neurotoxicity. These could be useful biomarkers in clinical practice, but further studies with larger populations are needed to validate these associations.

P012 A strategy to screen and subsequently identify therapeutically valuable microRNAs that target a clinically established KITENIN oncogene in colorectal cancer

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Introduction: Deregulation of microRNAs (miRNAs, miRs) in colorectal cancer (CRC) can contribute to cancer development and altered expression of miRNAs is causally associated with the initiation and progression of CRC. However, the regulation of CRC cell motility by miRNAs and the consequent modulation of CRC progression are not fully understood.

Material and method: We previously observed that KITENIN (KAI1 C-terminal interacting tetraspanin) is highly expressed in sporadic human CRC tissues and that the functional KITENIN complex acts to promote progression of CRC. However, it remains unknown whether KITENIN-targeting microRNAs modulate CRC cell motility and colorectal tumourigenesis. We here developed a strategy to initially screen for miRNAs that effectively target a clinically established oncogene in colorectal tumourigenesis, such as KITENIN and to subsequently identify therapeutically valuable anti-oncomirs among them.

Results and discussion: We identified KITENIN-targeting miRNAs by miRNA library screening and bioinformatic analyses, and selected three miRNAs, namely, miR-27a, miR-30b, and miR-124, for further analysis. These miRNAs suppressed the invasion of several CRC cell lines, as shown by functional studies with synthetic miRNA precursors and inhibitors. We also screened for a final candidate via conditional expression of mature miRNAs in a mouse xenograft tumour model using a tetracycline-inducible system, and selected miR-124 as a potential anti-oncomir. Using a constitutive precursor miRNA overexpression system, which ensures biologically relevant interactions with regulatory partners, we confirmed that miR-124 functions as an effective suppressor of colorectal tumourigenesis. To identify other targets of miR-124, we subsequently performed mRNA microarray analysis on isolated tumour tissues from a xenograft tumour model in which precursor miR-124 was overexpressed and found that expression levels of MYH9 and SOX9 were significantly lower in the pre-miR-124-delivered tumour tissues. We also found that MYH9 and SOX9 are real targets of miR-124 in CRC cells using expression analyses.

Conclusion: Our results demonstrated that miR-124 suppresses *in vivo* colorectal tumourigenesis by targeting MYH9 and SOX9 as well as KITENIN. We suggest that miR-124 among the KITENIN-targeting microRNAs is a therapeutically valuable anti-oncomir for CRC.

P013 Excretion and long-term retention of cytotoxic drugs

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Introduction: There is a vast number of scientific literature that describe that cytotoxic drug molecules retain on external packaging of the drugs, and on the surfaces inside and outside of the cytotoxic drugs preparation units. What about the excretion of cytotoxic drugs and their long-term retention in an organism?

Material and method: Searching through scientific and professional literature that describes elimination and retention of cytotoxic drugs in an organism we come across very useful information.

Results and discussion: It is proven that platinum compounds retain in the body for a long time.

Cisplatin highly concentrates in the liver, kidneys and prostate, while something less in bladder, testicles, muscles, pancreas and spleen. In patients who received the last dose of cisplatin 8 years ago, there has been noted 500 times higher concentrations of platinum than those allowed in urine and serum [1]. Gietema and colleagues state that cisplatin can be detected in plasma even 20 years after the last cisplatin chemotherapy application [2]. During the period of time from 8 to 23 months after the last oxaliplatin dose application, patients had 30 times higher plasma concentrations of platinum than the control group [3]. Seven patients had ratio of cyclophosphamide concentrations in plasma and saliva of 0.77 +/- 0.24 after intravenous and oral application [4]. Doxorubicin excretes in saliva 2–4 hours after intravenous application, but high concentrations of doxorubicin (in few patients almost equivalent to the one in plasma) have been found in saliva 48 hours after application of the drug [5]. It is important to mention that this data was taken from a study that lasted only 48 hours and it cannot be certainly concluded that there are no high concentrations of doxorubicin in saliva even after 48 hours. Liposomal doxorubicin excretes via sweat glands. It was noted that 3 hours after intravenous application there was excretion of liposomal doxorubicin on the skin surface. In this case stratum corneum serves as a container of doxorubicin which results with higher dermatologic toxicity [6].

Conclusion: So far there is not enough information about how long cytotoxic drugs retain in the body fluids, and we cannot make a precise conclusion on how to advise patients regarding handling these drugs in an outpatient setting.

According to everything mentioned above, we can conclude that cytotoxic medicines excrete via body fluids, and it is an obligation of oncology pharmacist to warn and counsel patients and their family members about handling these drugs.

References

1. Hohnloser JH, Schierl R, Hasford B, Emmerich B. Cisplatin based chemotherapy in testicular cancer patients: long term platinum excretion and clinical effects. Eur J Med Res. 1996;1(11):509-14.
2. Gietema JA, Meinardi MT, Messerschmidt J, et al. Circulating plasma platinum more than 10 years after cisplatin treatment for testicular cancer. Lancet. 2000;355(9209):1075-6.
3. Brouwers EE, Huitema AD, Beijnen JH, Schellens JH. Long-term platinum retention after treatment with cisplatin and oxaliplatin. BMC Clin Pharmacol. 2008;8:7.
4. Juma FD, Rogers HJ, Trounce JR. The kinetics of salivary elimination of cyclophosphamide in man. Br J Clin Pharmacol. 1979;8(5):455-8.
5. Bressolle F, Jacquet JM, Galtier M, Jourdan J, Donadio D, Rossi JF. Doxorubicin and doxorubicinol plasma concentrations and excretion in parotid saliva. Cancer Chemother Pharmacol. 1992;30(3):215-8.
6. Jacobi U, Waibler E, Schulze P, et al. Release of doxorubicin in sweat: first step to induce the palmar-plantar erythrodysesthesia syndrome? Ann Oncol. 2005;16(7):1210-1.

This work is the result of collaboration of the Working Group for Oncology Pharmacy, employees of Hospital Pharmacy and Department of Medical Oncology in Clinic for Tumors of Clinical Hospital Centre Sisters of Mercy, Zagreb, Croatia.

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Poster Session: Cytotoxic drug preparation

P014 Microbial agents in our cleanroom!

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Introduction: For our daily validation shows microbiological contamination in our cleanroom, we had to act quickly and in the right way to stop the dangerous situation. To provide the patients of our hospital without interruption, we had to integrate the decontamination in everyday work.

Material and method: The manner of action was like a circle of quality management: plan-do-check-act.

In reality we had to contaminate all cleanroom areas and each particle with gas to get the result of successful decontamination.

Results and discussion: Everybody - being a part of the oncological team, occupied with drug preparation - has to check microbiological agents and/or pathogen agents every day. It is definitely fixed by law to work in a validation system, with checking finger prints, monitoring surroundings every day.

Every pharmacist is doing this in the right way, bit when there happens a contamination it is not really easy to know what it is about.

It is important that the pharmacist is accompanied by competent technical persons to do it in the right way.

Conclusion: In our hospital we made the experience of decontaminate our cleanroom with gas successfully. With our poster we will inform you.

P015 Cytostatic drug preparation in an isolator

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Introduction: In conformity with the German Pharmacy Operating Standards the preparation of Ready-to-Use antineoplastic parenterals is allowed under A-in-D™ conditions. The prerequisite is that an isolator is used as a central work area. However, due to the lack of experience many potential users as well as approving authorities are unable to assess the risks associated with the use of such a device. As knowledge of the protection potential is limited, a simulation study was carried out to identify the conditions required to ensure safe aseptic preparations in an isolator.

Material and method: The aseptic production of cytostatic preparations was simulated under A-in-D™ conditions using an isolator set-up, consisting of a cytotoxic isolator, a safety cabinet, and two ventilated airlocks. The experimental scheme was based on an established microbiological validation-procedure for controlling aseptic production routines in pharmacies. During the simulation 120 infusion bags were filled with sterile culture media. In addition to the control of microbial growth inside the transferred media integrity of the workspace was examined using settle and contact plates.

Results and discussion: All samples except for one settle plate from the exit airlock were found to be free of microorganisms. By inoculating sterile nutrient solution with non-sterile water the proper functioning of the detection system could be verified. The study showed that even under A-in-D™ conditions aseptic cytostatic preparations can be carried out without hygienic problems. However, work routines, which up to now have been proven successful for use with safety cabinets, have to be adjusted to the requirements of an isolator.

Conclusion: Although working in an isolator is not as comfortable and fast as in a safety cabinet the aseptic preparation of cytotoxic parenterals is possible under A-in-D™ conditions. The prerequisite, however, is that especially disinfection and transfer processes are carried out in an appropriate mini-environment, such as a safety cabinet, which serves as an airlock addition.

P016 DIN 12980 - the NEW state-of-the art for cytotoxic isolators and safety cabinets

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Introduction: In Germany, safety cabinets for the handling of cytotoxic substances must comply with DIN 12980. The standard describes minimum performance criteria with a focus on personnel protection requirements. Following the modifications of the German Pharmacy Operating Standards towards more stringent demands for the preparation of antineoplastic drug solutions it was necessary to expand the standard with new developments and technologies. After several years of planning and discussion a new version of DIN 12980 will be published in 2016. A first official draft (E DIN 12980) shows what changes can be expected.

Material and method: The main amendments are:

Safety and protection objectives: In contrast to the current version, general safety and protection objectives are explicitly defined in a specific chapter. Personnel and product protection are of equal importance. Nevertheless, some technical requirements illustrate the priority of occupational safety.

Safety cabinets: The new standard raises the requirements for safety cabinets with respect to microbiological tests which are used to examine retention efficiency as well as product and cross contamination protection ability. In addition to the examinations performed at the set point for in- and downflow velocities, protection performance has to be tested at three so-called provocation points. These points represent unbalanced or too low combinations of in- and downflow velocities that can occur as a result of external disturbances. Additional testing is intended to guarantee that the safety margins of a cabinet are sufficient even under unfavourable operating conditions.

Isolators: For nearly 4 years German pharmacists have had to use an isolator for the aseptic preparation of (cytotoxic) parenterals in GMP class D cleanrooms. Since then, interest has grown in this technology, because isolators can be a cost-effective alternative to complex cleanroom solutions. Despite this trend, no performance criteria were specified. The new standard puts an end to this problem. It now defines basic requirements and test procedures for these devices, too.

Conclusion: Even though the current draft is still immature in some points, it offers a very interesting insight into future changes of DIN 12980. Many changes are an overdue clarification of important questions relating to increased security demands and new technical developments. Manufacturers and users should be prepared for the answers in order to develop and buy future-proof products.

P017 Preparation of chemotherapy under isolator: audit of practices

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Introduction: In a quality approach, an audit of practices for preparation of antineoplastic agents under isolator was conducted in the Pharmaceutical Oncology Unit (UPO) of the Hospital. Moreover, following the construction of a new pharmaceutical technology unit within the institution, the audit will lead to a reflection on the practice's organization in the new premises. The main objective of this audit is to

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study the probable differences between the standard procedures and the applied ones.

Material and method: The audit was conducted by an intern in pharmacy and a member of the hospital quality direction and risk management. The assessment of chemotherapy's preparation was followed in two steps. A personal interview which led to assess the knowledge about the isolator and the daily activity in UPO and as the second step; an observational phase based on different steps of chemotherapy's preparation. The audit grid contains 248 items divided into 10 themes: the verification of nominative trays before preparation, the preparation of work plan, the withdrawal and reconstitution of the antineoplastic agents, preparation of chemotherapy bags, syringes and cassettes of 5-fluorouracil (5FU), the management of (un)open vial under isolator, the quality control of finished product and waste management.

Results and discussion: For two weeks, eight hospital pharmacy technicians (PPH) affected by UPO were audited. 6 out of 10 themes had satisfying results and 4 of them were moderately satisfying. Still, some enhancement could be done: as the verification of nominative trays before preparation, the withdrawal and also reconstitution of the antineoplastic agents and the preparation of chemotherapy bags and cassettes of 5FU. Finally, the synthesis of internal audit includes 32 non-conformities, 12 remarks and results generated 6 corrective action requests.

Conclusion: Overall, results of the audit are satisfying (82% correct items). The following corrective actions have been implemented: the addition of checklist on the record sheet which gives instructions for quality control before release, a revision of some protocols, a theoretical continuous formation for some protocol and interest of dual control, and a continuous training session with practical reminder of the Good Practice Manufacturing production. It was also decided to expand the use of 'spikes' and bags with injection system lockable in order to minimize the risk with needles. The implementation of these corrective measures will ensure also harmonization of practices.

P018 Impact of two transfer devices on cytotoxic contamination in workplace surface

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Introduction: The aim of this study was to compare the impact of a closed system drug transfer device (CSTD) (Phaseal®) and an usual system (Codan Spike Swan®) on cytotoxic contamination of workplace surfaces during the cytotoxic drug manufacturing process.

Material and method: This controlled study was conducted in a French Hospital pharmacy. Two devices were evaluated: the CSTD PhaSeal® (phase 1) and the Codan Spike Swan® (phase 2). After isolator cleaning and verification free of contamination, cytotoxic contamination was weekly evaluated during two periods of six weeks. Each week, 14 samples were collected inside isolator (gloves, surfaces, garbage, button). The quantity of platinum was evaluated by graphite furnace atomic absorption after pre-concentration by the cloud point extraction method according validated method. The low limit of detection and quantification were 2 ng and 6 ng of platinum element per sample, respectively. To complete this evaluation, a satisfaction survey was proposed to pharmacy technicians (13 questions divided into 4 items).

Results and discussion: Over the entire period of evaluation, 168 samples were collected. Results show significant contamination over the two period with 10.7% (n = 84) of contaminated samples during the phase 1 using PhaSeal® (contaminations from 6 to 17 ng) vs 2.4% (n = 84) during the second phase using Codan Spike Swan® (contaminations of 4 ng). The maximal contamination was found on neoprene gloves at the end of the first week of the phase 1. In addition, results of the survey highlighted an intermediate satisfaction of use and safety of Phaseal®. During the first phase, some vials leakages were observed due to incompatibility with PhaSeal®.

Conclusion: Despite closed transfer and security offered by Phaseal®, some precautions such as sufficient training period and compatibility with raw materials have to be taken into account to implement new devices.

P019 Dose banding of intravenous chemotherapy preparations: a gain for all stakeholders in cancer care

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Introduction: The number of intravenous chemotherapy preparations at the Ghent University hospital is increasing each year (approx. 10%) but the compounding capacity and the pharmacy staff remain unchanged.

Dose banding was introduced to reduce the peaks in work load, the time pressure in the compounding facility and the patient waiting time at day clinic. By using dose banding patient specific doses are, through agreement between prescribers and pharmacists, rounded up or down to predefined standard doses. The use of standard doses allows batch preparations.

Material and method: The choice of dose banding methodology (linear versus logarithmic) was discussed between pharmacists and prescribers. Selection of the candidate molecules to be used for dose banding was based on criteria like physicochemical stability (data used from literature and manufacturer), the frequency of prescribing specific doses and the infusion volume used. The number of intravenous chemotherapy prescriptions and the processing and preparation times of the intravenous infusions for day clinic were counted and measured during one week in 2013 and 2015 (before and after implementation of dose banding).

Results and discussion: Logarithmic dose banding was chosen for further implementation because of the consistent variance between all of the bands (max. 6%) and because one list of predefined dose bands can be applied for all molecules. Of the 53 molecules studied 22 (18 cytotoxics and 4 monoclonal antibodies) were retained. For example, over a 6-month period, 43% of 661 5-fluorouracil (5FU) infusions prepared could be reduced to 5 standard doses and 89% of 255 Rituximab infusions was covered by 4 dose bands. Since March 2015 the pharmacy has introduced dose banding for 5FU, paclitaxel, gemcitabine, oxaliplatin and rituximab. As the rush hours in the compounding facility are mainly situated in the morning the batch preparations of the standard doses are planned in the afternoon. Preparation times in the pharmacy were reduced from 19 minutes 52 seconds to 7 minutes 10 seconds and the chemotherapy infusions were delivered more often within 30 minutes to the day clinic.

Conclusion: The introduction of dose banding of intravenous chemotherapy optimized the workload in our compounding facility. Batch preparations reduced the time pressure for pharmacy and nursing staff and allowed the implementation of in-process controls, like photo recognition of the compounds and gravimetric control.

P020 Implementation of dose banding cancer chemotherapy to increase the anticipation of cytotoxics preparations and to reduce waste

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Introduction: Our activity of cytotoxic preparations has increased by 60% in 5 years from 20,882 in 2010 to 33,680 in 2014. In the meantime, the staff number has not increased due to budget constraints.

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Pharmacists had to find issues to improve productivity while keeping the optimal quality of the drugs. The interest of the implementation of dose banding (DB) has been evaluated. The preparation of DB were forecasted and attributed to the patient the date of his hospitalization. The dosage was automatically rounded to +/−5% compared to the prescribed dose.

Material and method: Nowadays, 4 circuits of preparation are available: (i) the urgent preparation made the day of the patient's visit, and the anticipated preparations made; (ii) the day before; (iii) 7 days before (FabAct®); or (iv) 90 days before.

The '7 days before' preparation of molecules FabAct® (selected for their low cost and their physico-chemical stability) allows a more constant workflow but increasing loss of preparations.

Reduction of the waste and the stock of compounded drugs have been assessed from 3 very representative drugs to determine if the switch of the circuit of the preparation from FabAct® to BD was efficient.

Results and discussion: In our hospital, 78% of prescriptions and 64% of preparations are made at least the day before the patient's visit with an average waste of 6.1%. The setting up of DB on the 3 FabAct® molecules yielded to reducing the loss of 5FU from 7% to 2%, gemcitabine from 7.6% to 2.8% and Irinotecan from 7.2% to 0.4%. The average reduction loss decreased from 7.1% to 1.9% and the saving was estimated to Euros 16,848 a year. DB represented 20% of our production; the number of drug compounded before patient's visit preparations and stored grew from 76 to 174.

Conclusion: FabAct® preparations allowed us to regulate our activity by anticipating the compounding of cheap preparations. However, compounding 7 days before for a definite patient leads to much waste when doses or treatment change between two cures. The maximum capacity of our production unit being reached, we had to set-up the circuit of the preparation which should not increase the loss. The implementation of DB has achieved this aim by attributing the preparations only when the patient is present and by increasing the number of ready to use doses in stock

P021 Toxicity comparison between two commercial presentations of gemcitabine in recurrent superficial bladder cancer

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Introduction: Patients with a recurrent superficial bladder cancer without response to previous intravescical Bacille Calmette-Guerin (BCG) are treated with gemcitabine intravescical infusion. In June 2013, the commercial presentation of gemcitabine was changed in our hospital due to an increase of the incidence of adverse effects. The aim of the study was to compare the gemcitabine intravescical treatment tolerance before and after changing the commercial presentation

Material and method: Descriptive, observational and retrospective study (May 2012–November 2015). Variables collected were: age, commercial presentation of gemcitabine used and incidence of adverse effects after administration. The dosing regimen used was a dose of 2,000 mg for 60 minutes previous full emptying bladder through the catheter. Two commercial presentations of gemcitabine were used: Gemcitabine Actavis 1 g/25 mL, without further dilution with normal saline (19.75 g ethanol/dose); or Gemcitabine Accord 2,000 mg/ 20 mL with further dilution with normal saline (8.8 g ethanol/dose). Tolerance was assessed according to incidence of adverse effects after instillation

Results and discussion: 16 patients were included. Mean age was 69 years (53–85). Seven patients (44%) were treated with Gemcitabine Actavis. 5 of them (71.4%) had some adverse effects after drug administration; gemcitabine was suspended in 4 patients (80%). Gemcitabine Accord was used in 9 patients (56%), two of them showed any adverse efeccts (22.2%). No Gemcitabine Accord treatments were suspended due to adverse effects. The difference in adverse effects incidence between the two commercial presentations of gemcitabine was 49.2%. Adverse effects in patients under Gemcitabine Actavis treatment were: bad general state, pain, itch, fatigue, increase in urinary frequency, dysuria and haematuria. Adverse effects in patients under Gemcitabine Accord treatment were: haematuria and pain; but these were not forced to stop the treatment.

Conclusion: There were almost 50% more adverse effects with Gemcitabine Actavis. Increased toxicity may be due to more ethanol content per dose (19.75 g ethanol/dose in Actavis commercial presentation versus 8.8 g ethanol/dose in Accord commercial presentation).

P022 Antineoplastic drug contamination on the outside of prepared infusion bags

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Introduction: Antineoplastic drug contamination is found on various work surfaces situated throughout the hospital medication system. Exposure to antineoplastic drugs can cause toxic effects and therefore is a matter of concern to hospital workers. One route of contamination could be the outside of prepared infusion bags. In The Netherlands, cytostatic drugs are prepared in safety cabinets (air classification A) situated in clean rooms with air classification D. For compounding, spikes are used. Prepared infusion bags are not cleansed or disinfected before transport to the wards.

Material and method: Eight Dutch hospital pharmacies took swipe samples of prepared infusion bags with 5-fluorouracil (5FU) just before distribution to the wards. The samples were tested with a validated assay using high performance liquid chromatography and triple quadrupole mass spectroscopy. The limit of detection was 10 ng per swipe.

Results and discussion: From July till November 2014, 146 samples from eight different hospitals were analysed. The volume of the tested infusion bags ranged from 100 mL to 1,000 mL, with surfaces that were swiped ranging from 139.5 to 600 cm^2. None of the swipe samples had a detectable amount of contamination with 5FU and so all results were well below the threshold of 10 ng per swipe.

Conclusion: The outside of infusion bags with antineoplastic drugs prepared in Dutch hospital pharmacies are not contaminated and therefore are not a risk factor with regard to exposure to antineoplastic drugs of hospital workers.

P023 The incidents report of cytotoxic preparation unit on National Institute of Oncology of Rabat

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Introduction: Over the years, the National Institute of Oncology of Rabat, Morocco, is experiencing a considerable increase in patients staff greeted. Consequently a significant increase in cytotoxic preparation unit activity (UPC), this reflects a panel of obstacles that hinders the fluidity of preparation circuit and thus driving a delay of patient's hospitalization and an increase in management costs. The present work is intended to Highlight the critical failures of the circuit of preparations anticancer to prioritize measures implemented to fluidity this circuit.

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Material and method: This is a prospective, descriptive study, in a period of 10 months 'from October 2014 to July 2015' divided in 2 periods of 5 months each. According to method failure modes, effects and criticality analysis (FMECA), failure modes (incidents) detected during the first period were quantified by a criticality index (CI) calculated on the basis of the frequency, severity and the detection probability of incident.

A reassessment of the incident's CI is performed at the end of the second period, after the establishment of an improvement in quality measures.

Results and discussion: For 27 identified incidents, we have established a criticality matrix to 3 parameters, whose criticality threshold is set at 12: 27.14% of the incidents are unacceptable ($16 \leq CI \leq 64$), 15.72% of the incidents are undesirable ($CI = 2$) and 57.14% of the incidents are acceptable ($CI \leq 9$).

Among the critical incident: pocket transfer error, delay in sending preparation, preparation's return, labelling error, prescribing error, double preparation of the same cure ... The improvement measures: training of pharmacy technicians on intrathecal preparation, automatic labelling of pockets, display in the clean room a stability referential for available specialties, a shuttle's register between the pharmacy and nursing services ... The establishment of improvement actions shows amelioration in the preparation circuit: only 5.71% of incidents remain unacceptable and 4.29% of incidents are undesirable.

Conclusion: To ensuring continuity and the safety of care administered to patient with cancer, a continuous improvement of the preparation circuit; based mainly on multidisciplinary meetings and ongoing training of all UPC staff; must be required.

P024 Implementation a therapeutic booklet of medical device of chemotherapy

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Introduction: The manipulation of cytotoxic drugs requires the utmost care by the health personnel. The good use of medical device chemotherapy provides secure preparation of cytotoxic and optimize the cost. The aim is to have a single support on the establishment and dissemination of information relating only to the devices listed in the establishment.

Material and method: The oncology pharmacist of the National Institute of Oncology who developed the booklet considered the technical characteristics of each article. The drug and medical devices committee of our centre will validate the booklet.

Results and discussion: The booklet is split into five parts: pharmaceutical regulation, responsibility and role of hospital pharmacist, general definitions, materiovigilance, sterilization and monography of medical device of chemotherapy.

The realization of the booklet provides a reference of the hospital, orients users to the cost of the materials that they manipulate, and to a better practices improved preparations.

Conclusion: This project aims to establish a quality approach whose purpose to diffuse the necessary information of the good use of this medical device and allow a practice and quick search.

P025 Lichen secondary metabolite, isolated from Pseudocyphellaria coriacea, inhibits lung cancer cell motility

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Introduction: Lung cancer is the most common cancer in humans worldwide, and metastasis is the leading cause of death in lung cancer. Therefore, development of new chemical agents that inhibit cancer cell migration and invasion is required in treatment of advanced cancers.

Material and method: The current study examined the inhibitory activity of 13 Chilean lichen species against migration and invasion ability of human lung cancer cells and further investigated the possible molecular mechanisms underlying their anti-metastatic activity to identify potential novel anti-metastasis agents.

Results and discussion: Physciosporin, isolated from Pseudocyphellaria coriacea (Hook F & Taylor) DJ Galloway & P James, was identified as an effective compound and showed significant inhibitory activity in migration and invasion assays against human lung cancer cells. Physciosporin treatment reduced both protein and mRNA levels of N-cadherin with concomitant decreases in the levels of epithelial-mesenchymal transition markers such as snail and twist. Physciosporin also suppressed KITENIN (KAI1 C-terminal interacting tetraspanin)-mediated AP-1 activityin both the absence and presence of epidermal growth factor stimulation. Quantitative realtime PCR analysis showed that the expression of the metastasis suppressor gene, KAI1, was increased while that of the metastasis enhancer gene, KITENIN, was dramatically decreased by physciosporin. Particularly, the activity of 3'-untranslated region of KITENIN was decreased by physciosporin. Moreover, Cdc42 and Rac1 activities were decreased by physciosporin.

Conclusion: Physciosporin has anti-metastatic activity with molecular mechanisms of action, and further study is required to evaluate the potential anticancer activity of physiosporin in various *in vivo* cancer models.

Poster Session: Automation/robotics in oncology pharmacy

P026 Is the mechanical hand always better than the human one?

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Introduction: One of the most developing fields in the hospital pharmacy is drug preparation and management through the use of robotic systems. Especially preparations of cytotoxic drugs, due to their properties, are one of the highest candidates for this technology.

Material and method: Statistical and subjective evaluation of using the robotic device CytoCare® during the five years use. Statistical data were obtained from the software and are sorted by year, department and generic name of the drug. Subjective evaluation comes from personal experience as well as daily working with CytoCare®.

Results and discussion: During the last years participation of CytoCare® robotic system in comparison to one (2010) or two (2011–2015) isolators was unsteady. At the beginning, 51% from all preparations were done by CytoCare®. During year 2011 only 22% preparations were done in Cytocare®. In following years the ratio continually decreased from 33% in 2012 to 21% in 2015.

Preparations done by CytoCare® were mostly prepared for the Department of Oncology. Due to specific cytostatics and final containers almost all preparations were done by hand for another department.

Most often used cytostatic drug by CytoCare® was fluorouracil (6,584 in total; 39% of all fluorouracil preparations, respectively) followed by Oxaliplatin (1,283; 55%) and Irinotecan (731; 50%). Drug as Calcium Folinate was prepared in CytoCare® as well (7,785, 71%).

The most frequently failed preparations were fluorouracil (5FU) (276 in total; 4% of all 5FU preparations in the device, respectively), Calcium Folinate (253; 3%) and Oxaliplatin (60; 5%). The CytoCare® hardly worked with drugs of high viscosity: Paclitaxel (31, 21%) and Etoposide (71, 17%). From all failed preparations only 52% of all noted faults led to both material and drug loss.

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Based on our experience, there were a lot of options that excluded particular preparation from the list of CytoCare® preparations (e.g. shape of vial, type of final container, drug viscosity). In addition to this, manipulation must be very precise (insertion of all needed material) and be done by qualified person which is employed by CytoCare® on full time.

Conclusion: Although the robotic preparation of cytostatic drugs is going to be preferred in the future it is important to make a critical evaluation of real benefits. From our objective and subjective experience we favour to some types of preparations, to be done by CytoCare® device (suitable containers, vials, used volumes or drug properties). Thus, the biggest usage is expected at workplaces, where many preparations are similar and suitable for this robotic technology.

P027 Performance analysis of a totally automated oncology pharmacy production: the value of data

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Introduction: In order to have a centralized control of the whole production activity, in 2014 the Oncology Pharmacy (OPh) of the Ancona University Hospital completed the single automated production platform. It is composed of a robotic system for automated admixture (APOTECAchemo), a guided preparation system to support manual admixture (APOTECAps) and a workflow management software that controls the activity (APOTECAmanager). The OPh works Monday to Friday from 8:00 a.m. to 4:00 p.m. with 4 technicians and 2 pharmacists. The production is mainly just-in-time (80% outpatient and 20% inpatient) and the rush hours go from 9:00 a.m. to 1:00 p.m. In this study, we present some considerations that can be drawn from the data collected by the unified platform.

Material and method: By means of the statistical tool of the APOTECA platform, we analysed a 7-month OPh activity (January–July 2015), in terms of productivity, dosage accuracy, turnaround time and single operator activity.

Results and discussion: The compounded doses were 13,266 and 2,232 for APOTECAchemo and APOTECAps, respectively with 79 active ingredients: an average of 1 manual preparation every 6 with robot. Regarding dosage accuracy, APOTECAchemo shows better performances with 95.4% of preparations within a deviation of ±5% vs 90.6% of the guided manual compounding. The data analysis demonstrates that only 4% of the production is performed by pharmacists, while 96% is equally distributed between the 4 operators. The turnaround time is very similar for the two procedures: 51 minutes for the robotic and 52 minutes for the manual compounding. In particular, APOTECAchemo preparation takes an average of 4 minutes 50 seconds, while the queue time and the delivery time takes respectively 26 minutes 33 seconds and 19 minutes 47 seconds. On the other side, APOTECAps preparation takes an average of 3 minutes 40 seconds, 40 minutes 13 seconds represent the queue time and 8 minutes 35 seconds the delivery time.

Conclusion: The added value of a single platform to manage the pharmacy activity is the possibility to measure and control every single step of the whole production process, in terms of performances, quality and safety. The real time monitoring allows to prompt take corrective actions in case of deviations, while a deeper remote analysis supports the decision-maker to improve the efficiency of workflow and processes. For example, our next goal is to drastically reduce the queue time by reviewing the procedures.

Poster Session: Quality assurance/microbiology/analytics/stability in oncology pharmacy

P028 Comparative evaluation of a drug website for incompatibility: Stabilis, Trissel's Handbook and the currently available tool in Japan

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Introduction: Stabilis, an online drug compatibility search website organized by Infostab, was recently translated into Japanese and introduced to Japan.

Objective: To evaluate the benefit of Stabilis through a survey of the listings of incompatibility data.

Material and method: By literature review. The review was performed in December 2014 to compare the number of incompatible drugs cited by the Stabilis website, 'Injectable Drug Audit Manual, 4th ed.' (AM) and 'Handbook on Injectable Drugs, 17th ed.' (ID). We used the data on incompatible drugs to compare each database. We selected 10 frequently used anticancer medicines to compare the drugs cited in Stabilis, AM and ID. In addition, we compared Stabilis and AM in 23 frequently used antibiotics as an additional evaluation.

Main Outcome Measure: Endpoints were: 1) the number of incompatible drugs; and 2) rates of duplicate data between Stabilis and AM or ID.

Results and discussion: Stabilis had 678 drugs including 456 injectable drugs, AM had 496 injectable drugs and ID had 332 injectable drugs, as of December 2014. Compared with the fact that most references in AM were unofficial data from manufacturers, Stabilis cited 1,722 references and ID cited 2,830 references. For the 10 selected anticancer drugs, the total number of listed drugs was 118 in Stabilis, compared to 51 in AM and 82 in ID. Overall, mean and median duplication rates were 4.5% and 0% in AM and 60.7% and 59.0% in ID, respectively. For the 23 selected antibiotics, the total number of listed drugs was 462 in Stabilis, compared to 238 in AM. Overall, mean and median duplication rates were 20.1% and 16.0% in Stabilis and 10.3% and 8.0% in AM, respectively.

Conclusion: The study found that AM, one of the most commonly used textbooks in Japan, is inadequate in terms of evaluating drug incompatibilities due to the small number of listed drugs. Stabilis offers a beneficial database for checking drug incompatibilities in a manner similar to ID, which is one of the most well-known textbooks for this purpose worldwide.

P029 New approaches for online quality control of monoclonal antibodies in hospital pharmacy

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Introduction: Compounding activity of monoclonal antibodies (mAbs) constantly grows in hospital pharmacy. Quality Control (QC) for mAbs preparations just before patient administration is becoming of paramount importance. The challenge is therefore to develop fast and simple QC methods allowing identification and dosage of mAbs in the infusion bags. Two approaches were developed and compared: (i) capillary zone electrophoresis (CZE) combined to a cationic capillary coating and; (ii) flow injection analysis (FIA) - UV spectroscopy combined to multivariate analysis (MA) to discriminate four mAbs widely used for anticancer therapy.

Material and method: Commercially available mAbs bevacizumab, cetuximab, rituximab, and trastuzumab were diluted with sterile NaCl 0.9% in a concentration range of 0.5–4.5 mg/mL. For the CZE analysis, a silica-based capillary was coated with a cationic polymer (polybrene). Optimization of the background electrolyte has been performed to reach sufficient resolution between mAb's peaks. An internal standard has been used to perform identification through relative migration time (RmT). For the FIA-UV spectroscopy, an HPLC hardware coupled to a DAD was used to obtain mAbs spectra (190–400 nm). The Savitzky-Golay algorithm provided second derivative spectra. Multivariate analysis has been used to explore relevant spectral regions. A Partial least square-Discriminant Analysis (PLS-DA) on the second derivative data was performed to build models for the prediction of the mAb identity. The optimal models were determined with k-fold cross validation. The best model built on the relevant region was validate d from an external set of mAbs through a matrix of confusion.

Results and discussion: CZE: to achieve a good resolution between the 4 mAbs, perchloric acid and polysorbate 80 were added to the acidic background electrolytes (BGE). The RSD of the RmTs of the 4 mAbs was very satisfactory (< 0.76%) and the inter-day precision less than 1.3%. Significant difference between the RmT of each mAb allowed their identification. PLS-DA demonstrated that regions of the second derivative UV spectra with aromatic amino acids presented high ability to predict the mAbs with 89% of proper classification. Standard normal variate pre-processing (SNV) of tyrosine/tryptophan regions allowed an excellent classification (100%) of the 4 mAbs external set.

Conclusion: Both of these approaches offered routine identification of commercially available monoclonal antibodies after compounding. FIA-UV spectroscopy yields high throughput analysis based on structural difference of the mAbs irrespective of the excipients while CZE brings the possibility of performing a quite fast allows analysis even of a complex mAbs mixture.

P030 Compatibility of QimoHarpoon® device with cytotoxic drug solutions

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Introduction: The QimoHarpoon® system is a novel closed-system drug transfer device (CSDT) for cytotoxic compounding. Prior to clinical use, evidence was required that contact with cytotoxic drug solutions did not affect device integrity or the physical/chemical stability of drug solutions. Six drugs (cisplatin, docetaxel, epirubicin, etoposide, 5-fluorouracil (5FU) and paclitaxel) were studied, representing high and low-pH formulations, hydrophilic and lipophilic molecules, and the presence of various solubilisers and co-solvents. The fluid-path and expansion balloon of the device were exposed to drug concentrates for different time intervals and then drug stability and device integrity were assessed.

Material and method: QimoHarpoon® CSDT's (Vygon, France) were connected to manufacturers vials of cisplatin, docetaxel, epirubicin, etoposide, (5FU) and paclitaxel solutions of 1, 20, 2, 20, 25 and 6 mg/mL, respectively, so the device and solution were in contact. Triplicate vials of each drug were stored at 5°C and at 25°C. Samples taken at 0, 1, 3, 4 and 7 days were subjected to visual and sub-visual particle counts, pH, drug assay (stability-indicating LC) and assay for Fe and Cr metal by ICP-MS. Control vials with no device attached were treated identically. In a second study device balloons filled with 50 mL of each drug solution were immersed in recipient solutions at 25°C for 24 hours which were analysed for drug permeation.

Results and discussion: There was no difference in visible appearance, sub-visual particle counts and solution pH between control vials and vials fitted with the QimoHarpoon® device. Drug assay remained between 95–105% of initial value for test and control vials at all sample times. Iron and chromium levels in the drug solutions increased after prolonged contact (7 days) with the device, but these were well below European Medicines Agency (EMA) limits. In each case the visual appearance and integrity of the CSDT was unchanged after 7 days cytotoxic contact. No drug was detected in any of the recipient solutions so the device expansion balloons were not degraded or permeated by the drug solutions tested (power to detect < 0.00009% permeation).

Conclusion: The cytotoxic solutions tested were physically and chemically stable over extended contact (7 days) with the QimoHarpoon® system. There was no sorption of the test drugs onto the device surface, and device appearance and function were not affected. No drug permeation of the expansion balloon was detected, even when challenged with volumes of drug solutions 500 times greater than contamination volumes expected in practice. This study demonstrates the device maintained a 'closed-system' and effective cytotoxic containment even under extreme testing. The QimoHarpoon CSTD can be safely introduced into clinical use.

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P031 Oncology Competence Pharmacy: update of a German approach to improve quality in oncology pharmacy

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Introduction: The growing percentage of oral chemotherapy in the oncologic patient care demands a lot of expert knowledge by the community pharmacy staff and claims for special education in order to counsel and patronize patients as well as for the communication with other healthcare professionals. To ensure this standard the German Society of Oncology Pharmacy (DGOP) together with Medac developed and keep up the project 'Oncology Competence Pharmacy' (OCP) since 2012.

Material and method: Every participating staff member gets his individual access to an e-learning platform where he has to pass through different trainings provided as online presentations and prove his educational success by a multiple choice test. To become a certified OCP, every member has to pass the starting training and the pharmacy needs to be self-examined. Once certified, each participating member has to educate himself regularly every four months in issues concerning chemotherapy. Furthermore, once monthly each pharmacy has to fill in an online questionnaire about the project and patient affairs.

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Results and discussion: Currently 58 pharmacies with 565 members are certified and carry on the quarterly self-studies. 868 questionnaires were evaluated. The most important questions of oncology patients deal with self-medication (71.4 %) and possible adverse drug events (71.1 %).

Conclusion: The OCP project with its corresponding online tool enables every staff member to study whenever it is possible for the individual and prove his learning success by a multiple choice test. The concept of OCP helps to get insight into oncology patients' problems, improves the quality in oncology pharmacy and grants an offer of specialized pharmacies for the patients.

P032 Use of handheld Raman spectrometer for qualitative and quantitative control of two isomeric cytotoxic drugs

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Introduction: As a rapid, non-destructive and non-invasive method, Raman spectroscopy constitutes a promising tool for real-time analytical control of drug. This study evaluated a handheld Raman device to discriminate and quantify two cytotoxic drugs which are positional isomers with similar UV spectra.

Material and method: Doxorubicin (DOXO) and epirubicin (EPIR) samples were analysed with a portable Raman spectrometer by non-invasive measurements at therapeutic concentrations. Doxorubicin (DOXO) and epirubicin (EPIR) samples were analysed with therapeutic concentrations. The discrimination of these two molecules was objectivized by qualitative analysis using Partial least square-Discriminant Analysis (PLS-DA) for therapeutic concentrations from 0.1 to 2 mg/mL for DOXO and 0.08 to 2 mg/mL for EPIR.

Results and discussion: In order to use Raman spectra for quantitative evaluation, predictive models were developed using PLS regression. The validity of the model was evaluated by the Root Mean Square Error of Cross Validation (RMSECV) and Prediction (RMSEP) that gave respectively 0.0544 and 0.0216 mg/mL for DOXO and 0.1677 and 0.1552 mg/mL for EPIR. Based on accuracy profile, the linearity range was from 1,256 to 2,000 mg/mL for DOXO ($R^2 = 0.999$) and from 0.553 to 2,000 mg/mL for EPIR ($R^2 = 0.999$) with acceptable repeatability (CV% max. of 1.8% for DOXO and 3.2% for EPIR) and intermediate precision (CV% max. of 2.8% for DOXO and 4.5% for EPIR).

Conclusion: Despite limited validated range of concentration for quantitative analysis, this study demonstrated the potential of a handheld Raman spectrometer coupled to chemometric approaches for in real-time quantification of cytotoxic drugs, as well to discriminate two drugs with similar UV properties. Finally, the use of handheld spectrometer with possibility of a direct measurement through container presents an interesting tool to combine patient safety to healthcare workers security.

P034 Survey about the procedure of the temporary authorization of use for anticancer drugs

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Introduction: The Temporary Use Authorization (TUA) is measure permitting a specific land use for a limited period, a medicinal product that has not yet been granted a marketing authorization.

The aim of TUAs is to provide early access to new treatments where a genuine public health need in the treatment of patients suffering from serious disease. In Morocco, we do not possess a procedure for obtaining the TUA.

Material and method: The objective of our study is to make state of play with hospital pharmacists in oncology centres and industrial pharmacists assessing their knowledge relative to the conduct of the procedure for obtaining TUA and establishment of a process procedure for TUA in Morocco.

This is a survey based on a questionnaire sent to 21 hospital pharmacists in different oncology centres which exists in Morocco, and industrial pharmacists. The shipment was made once. It was not because of recall.

Results and discussion: We obtained 18 responses, therefore an 85% response rate. 13 hospital pharmacists in oncology centres and 4 industrial pharmacists responded to the questionnaire. 100% of the responders know the definition of the TUA, 64% (11) ignore types of TUA, and 41% (7) responded that they know how to obtain TUA 41% (7) vs 59% (10). For the question is that you know the time required to obtain TUA, and only 35% (6) answered yes.

According to our results, we find that the majority of pharmacists do not know the procedure for obtaining the TUA cancer drugs, for the delay the answer was between two weeks and one month, a time, which is not fixed.

Conclusion: In many instances, the TUA responds to a public health need by accelerating the availability of new drugs, however, this study suggests the improvement of the administrative path by health authorities.

P035 Identification of Raltitrexed photodegradation pathways in injectable solution

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Introduction: Raltitrexed is a thymidylate synthase inhibitor used for the treatment of advanced colorectal cancer for intravenous delivery. As the active pharmaceutical ingredient can be subjected to environmental stress, especially to photolysis during storage and/or delivery, there is a need to acquire an extensive knowledge of its photochemical degradation pathways. Thus, photochemical-degradation of raltitrexed under simulated light irradiation in aqueous solution has been investigated in terms of mechanisms using liquid chromatography multistage mass spectrometry studies in combination with accurate mass measurements.

Material and method: Raltitrexed monohydrate (purity > 98%) was purchased from Sigma Aldrich (St Quentin Fallavier, France). Stock standard solutions were prepared by dissolving raltitrexed in ultrapure water to obtain 50 µg/mL and then allocated in triplicate in hermetically sealed glass vials. The samples were exposed to light using a xenon test chamber Q-SUN Xe-1 operating in window mode and studied at 30, 60, 70, 80, 90, 100, 110, 120, 150, 180, 210 and 240 minutes. The light intensity delivered was at 1.50 W m^2. An RP-HPLC-UV stability indicating method suitable for drug quantitation was developed and validated according to ICH Q2 (R1) and used for substrate decay analysis. The photochemical products were identified using performance liquid chromatography-multistage high-resolution mass spectrometry.

Results and discussion: Raltitrexed revealed to be extremely fragile towards photolysis conditions. Up to seventeen photochemical products were highlighted suggesting that the photo-transformation of raltitrexed occur via multiple reaction pathways among which, photo-oxidation of the alpha-carbonyl amine, N-oxidation of the tertiary amine along with Meisenheimer rearrangement, N-dealkylation and radical combinations can be cited. Subsequently, the main degradation pathways of raltitrexed were proposed.

Conclusion: The mechanistic approach provided relevant information on the multiple reaction pathways of raltitrexed, when subjected to simulated solar irradiation. Understanding the main photodegradation routes is a good basis to implement appropriate measures to mitigate or avoid instability. Such knowledge can also help assess and manage risks for adverse consequences of the drug photodegradation for ensuring safety and efficacy.

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Poster Session: Computer and software in oncology pharmacy

P040 Preventing medication errors in cancer chemotherapy: technology contribution

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Introduction: Technological resources allow an increase in patient safety. The aim of this paper is to analyse the errors detected and avoided by implementing a total technology-assisted system to improve safety and quality in all processes involved in parenteral chemotherapy within an interdisdisciplinary team.

Material and method: Retrospective observational study where errors found in the different phases of the therapeutic process (prescription, preparation and administration of medication) after the implementation of a comprehensive expert system were analysed.

The sample size calculation was performed assuming a maximum error of ±1%, a confidence of 95% and taking into account the prevalence of 5% error in the preparations, estimated in previous analysis, obtaining a minimum of 1,825 preparations.

A descriptive analysis of the errors was performed with STATA 2013 (R), including data from computer-assisted prescribing/validation module safe and effective assisted preparation module PASE (R) and Safety in nurse administration and validation module SAVE (R) of the Farmis-Oncofarm (R) program. Data refining focused on extreme values, which were analysed to confirm their accuracy. The frequencies of each of the variables along with 95%CI were calculated.

Results and discussion: 2,185 chemotherapy admixtures produced from April to June 2015 were included. The integral system intercepted 151 errors (14 prescription errors, 61 preparation errors and 45 administration errors), representing 6.9% of the preparations. None reached the patient during the study period.

50.0% of prescribing errors were due to incorrect dose, followed by wrong drug in 21.4% of the cases, with memory lapses and forgetfulness identified as the main cause (21.4%). PASE allowed to detect 16 (0.7%) wrong component readings (all fluids), 21 (1.0%) dosages above 5% tolerance set (mean 8.5% 95%CI 6.3–10.6) and 40 (1.8%) underdosing (mean 10.3% CI95% 7.6–12.9).

Six mixtures deviated over 20% and the average deviation of the remaining non-compliant preparations was 9.6% (95%CI 7.8–11.5) Thanks to the assisted administration module SAVE, 45 errors in 36 patients were prevented, mainly due to errors in the sequence 14 (0.6%) and admixtures with ongoing administration 19 (0.9%). Three mixtures (0.1%) reached the wrong patient, which would have caused a serious error.

Conclusion: In the study period the implemented system succeded in intercepting all incidents that could have resulted in errors in 6.9% of the prescribed admixture.

Poster Session: Clinical pharmacy/ pharmaceutical care in oncology pharmacy

P041 Mobilization of haematopoietic stem cells with plerixafor on patients with CD34<10 cells/mcL pre-apheresis

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Introduction: Plerixafor is indicated in combination with granulocyte colony-stimulating factor (G-CSF) to enhance mobilization of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in adult patients with lymphoma and multiple myeloma whose cells mobilize poorly. Age over 60 and/or prior myelosuppressive chemotherapy and/or extensive prior chemotherapy and/or a peak circulating stem cell count of less than 20 stem cells (CD34)/mcL, have been identified as predictors of poor mobilization. In our Hospital we have choosed a cut off of CD34 <10 cells/mcL as trigger to use plerixafor prior to the first apheresis (day 0).

We wanted to evaluate the efficacy of this cut off and the patients whose mobilization failed.

Material and method: Retrospective review of medical records of patients who recieved plerixafor between June 2010 and September 2015.

Results and discussion: Plerixafor has been used is 32 mobilizations on 31 patients (median age 58 [21–69], 52% women). Only 2 mobilizations used QT plus GCSF and all but one patients needed 1 mobilization.

On day 0, plerixafor was used on 21 mobilizations, 16 patients (76%) with CD34 <10 cells/mcL, 4 patients (19%) with CD34 between 10–20 cells/mcL and 1 patient above 20 cells/mcL (27, POEMS Syndrome). Median quantity of cells obtained was 3.09 x 106/kg (0.77–7.12) with a median of 1.89 apheresis.

On day 1, plerixafor was used on 11 mobilizations, 7 patients (64%) with CD34 between 10–20 cells/mcL on day 0. Median quantity of cells obtained was 3.55 x 106/kg (2.29–5.7) with a median of 2.3 apheresis

Mobilization failed on 4 occasions (13%, 3 patients). All of them used plerixafor from day 0 and were multitreated non-Hodgkin lymphoma patients between 32 and 59 years old.

Conclusion: CD34 <10 cells/mcL on day 0 as a cut off for using plerixafor is effective with an acceptable failure rate of 13% on our cohort.

Mobilization failures have occurred despite the use of plerixafor from day 0. In all cases failure affected non-Hodgkin lymphoma multitreated patients.

P042 Follow-up study: drug interactions in chemotherapy patients

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Introduction: Drug interactions are a problem in oncology practice. In our hospital the pharmacist manually checks for potential drug interactions amongst the oncology patients. The purpose of this study is to guarantee medication safety in oncology patients with the introduction of a Computerized Pharmacy Pharmacovigilance System (CPPS) which is: 1) as good as a manual check for drug interactions; 2) efficient; and 3) guarantees the exchange of medical data. We will also investigate if the numbers of drug interactions vary with time.

Material and method: We compared the number and type of drug interactions in the outpatient group (CPPS) with the pulmonology group (manual check for potential drug interactions) in a six-month period in 2015 with the same period in 2014.

In the outpatient group the patient's current medication was synchronized with LSP (a system that allows professionals to access medication records). In the pulmonology group the patient's current medication was verified via pharmacy technicians.

Results and discussion: 111 patients were included in 2014 in the outpatient group where 8 relevant drug interactions were observed (7.2%). 158 patients were included in 2015 where 4 relevant drug interactions were observed (2.5%).

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81 patients were included in 2014 in the pulmonology group where 8 relevant drug interactions were observed (9.8%). 76 patients were included in 2015 where 5 relevant drug interactions were observed (6.6%). Both groups were comparable with the number of medicines and other demographic features.

The number of observed drug interactions in 2015 was significantly lower compared to 2014. This might be explained by an increased awareness of drug interactions and corrective actions while prescribing.

Both the computerized check and the manual check took approximately 10 minutes per patient.

Conclusion: There is no difference between the computerized check and the manual check with regards to drug interactions and time-investment. However, the computerized check had the advantage that it was based on a standardized database and the exchange of medical data was guaranteed for the patients that were registered in LSP.

The exchange of knowledge between pharmacist and prescriber can account for the lower incidence of observed drug interactions.

P043 Subcutaneous or intravenous delivery of trastuzumab: patients satisfaction survey

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Introduction: A subcutaneous formulation of trastuzumab has been developed, offering potential improvements in patient convenience compared with the standard IV infusion of the drug.

Material and method: A-six month cross-sectional study was conducted (March to September 2015) to analyse patient's satisfaction and preference of intravenous (IV) versus subcutaneous (SC) trastuzumab.

Eligible patients were aged 18 years or older, had HER2-positive, newly diagnosed, non-metastatic adenocarcinoma of the breast who were receiving at least three dosages of IV trastuzumab (with dosage adjusted according to body weight) and switched to SC trastuzumab (fixed dose of 600 mg). Both tolerance and patient preferences were assessed by an anonymous questionnaire. Three questions referred to the tolerance assessment after administration IV/SC, evaluating at the same time the incidence of adverse effects. In another three questions, using a five-point Likert scale, patients showed their satisfaction level with each route of administration and with the information received by medical staff at the time of the change. The four remaining questions referred to patient preferences in relation to the route of administration, reduced waiting time at the hospital, the patient's readiness to return to the IV administration and their ability to be autonomous for administrating the drug in the future.

Results and discussion: 14 patients completed the survey. 9 were very satisfied with SC trastuzumab, while the remaining five were only satisfied. Regarding IV trastuzumab, 2 patients were very satisfied, 6 satisfied, 3 unsatisfied and 3 indifferent. 13 of the patients were satisfied or very satisfied with the information received by the nursing staff about the change. Only one patient showed disagreement. With regard to tolerance, 10 patients claimed to have fewer side effects after SC trastuzumab. The remaining 4 patients observed no change in the profile of adverse effects. The adverse reaction most found with SC trastuzumab was pain (n = 6) and haematoma through IV trastuzumab (n = 7). Only one patient preferred IV against SC trastuzumab, although 11 patients said they were disposed to SC or IV delivery of trastuzumab if there was a good and justified reason. In relation to the waiting time, all the patients answered that was less though SC administration. Finally, 9 patients would agree to administer the treatment at home.

Conclusion: Despite being a small sample, in general the changing from SC to IV trastuzumab has been satisfactory for patients with a different toxicity profile derived from the change in the route of administration. The shortened duration of administration with SC trastuzumab compared with IV delivery suggests the potential for substantial time-saving for patients, physicians, pharmacists and nursing staff.

P044 Contribution of cetuximab in the treatment of nasopharyngeal cancer: experience of Algeria

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Introduction: The Naso-Pharyngeal Cancer (NPC) is a highly invasive cancer, and metastatic, it is different from other cancers of the head and neck by its multifactorial etiology.

Indeed, it is unfrequent in most countries of Europe and North America; it is however predominant in South Asia and moderately common in the Maghreb countries (Morocco, Algeria and Tunisia).

Targeted therapies are now little used in NPC, early studies were conducted in patients with relapsed or after metastasis, used alone, targeted therapies showed little interest; and the median time to progression was 3 to 4 months.

However, most studies have shown to be well tolerated.

The combination with conventional chemotherapy has resulted in an overall survival of about 8 to 12 months.

Preliminary studies of the use of an anti-vascular endothelial growth factor (VEGF) and anti-epidermal growth factor receptor (EGFR) in combination with chemotherapy and radiation has led to encouraging results.

The aim of our study was to work on a particular population of Algerian patients in order to observe the contribution of Cetuximab in nasopharnyx cancer in this population and to assess the cost of this therapy.

Material and method: Patients: an open study with a single arm in patients with recurrent or metastatic NPC, expressing the receptor for EGFR, and having progressed within 12 months after completion of platinum-based chemotherapy.

A set of 35 patients were included (2011 to 2013), only 30 cases were evaluated (median 42 years) and sex ratio M/F is 4/1, the other five were dismissed because they had a single cycle of cetuximab.

Treatment: cetuximab was administered at an initial dose of 400 mg/m², followed by doses of 500 mg/m² every 15 days until disease progression.

Platinum salts were administered every 3 weeks up to a maximum of 04 cycles.

Results and discussion: The response to treatment using Response Evaluation Criteria In Solid Tumour (RECIST) criteria is represented as follows:

An overall response (complete, partial, stabilization) of 73.33% and an increase of 26.66%.

The median time to progression varies between 3 and 16 months with a median of 7.5 months two patients had grade 3 skin toxicity (acneiform rash).

Conclusion: Our single-arm study demonstrates in an Algerian population effectiveness of cetuximab over 73% of patients following a failure by conventional therapies.

These results are even more interesting than the targeted therapies which are better tolerated than traditional chemotherapy; remains the issue of cost and the duration of treatment remains undefined.

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P046 Potential savings of risk-sharing agreement with trastuzumab emtansine (T-DM1) in a tertiary care hospital

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Introduction: There are increasing number of new drugs that have been developed in recent years and their high cost there often remains uncertainty about its outcomes outside the strict controls of a clinical trial.The aim of this study was to estimate the possible savings in the use of trastuzumab emtansine (T-DM1) in our hospital if there were risk-shared agreements according to the effectiveness results obtained in patients (pts) with recurrent or metastatic breast cancer treated with T-DM1 agree to efficacy results of the TH3RESA study for pts with progressive disease after two or more HER2-directed regimens.

Material and method: Retrospective observational study of all pts treated with T-DM1 in a Spanish hospital from February 2013 to November 2015. Data collected: age, weight, ECOG Performance Status (PS), previous treatments in the advanced setting, previous HER2 directed regimens, median number of cycles administered, progression and death dates. Disease status was assessed by the Response Evaluation Criteria In Solid Tumors (RECIST).

Results and discussion: 11 women, median age 49.8 years (42–59), median weight 66.2kg (53.5–78), ECOG PS 0 (27.27%) and 1 (72.73%). Number of previous regimens: 2 (45.4%), 3 (27.3%), > 5 (27.3%). All pts received 2 (63.6%) or 3 (36.4%) HER2 directed regimens including trastuzumab (100%), pertuzumab (36.3%) and lapatinib (90.9 %). Pts were treated with T-DM1 3.6 mg/kg every 3 weeks. Median number of cycles was 13.7 (1–29), median treatment duration was 10.5 months (1–28).7 pts (63.6%) had stable disease, 2 (18.2%) disease progression and 2 died (18.2%). Of the 11 pts, 6 (54.5%) achieved a longer progression-free survival (PFS) than in the TH3RESA study (median 16 months versus 6.2 months) and 5 (45.5%) had not reached the PFS of the study (median PFS 4 months). Considering the cost of T-DM1 in this 5 pts who did not get benefit with treatment and making vial sharing the possible savings were Euros 75,301.76.

Conclusion: Risk-sharing agreements implementation is necessary in order to eliminate the uncertainty about the effectiveness of new drugs and to contribute to greater efficiency, avoiding wasting resources without creating value, freeing them for other alternatives.

P047 Nutritional complications associated to the use of total parenteral nutrition in onco-haematologic patients

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Introduction: Onco-haematologic patients are candidates to Total Parenteral Nutrition (TPN) due to chemotherapy adverse effects. TPN objective is to maintain or improve the nutritional state of these patients, which also means to improve their quality of life.

Objectives: Evaluation of all the nutritional complications associated to the use of TPN in onco-haematologic patients.

Material and method: Retrospective observational study of the nutritional complications of all patients (125) that received TPN between 1 July and 30 October 2015.

The evaluated parameters were: indication, route of administration, and number of days of TNP; electrolyte complications associated to TPN use and antitumoural treatment; and patient evolution.

Information has been obtained from the electronical clinic history (SELENE), the Pharmacy Service managing software (FARMATOOLS) and Medical One Parenteral.

Results and discussion: 125 patients with nutritional complications associated to TPN, 6.4% were onco-haematologic patients.

TPN indications were: 50% secondary denutrition, 37.5% oral mucositis and 12.5% upper digestive haemorrhage. Average time length of TPN was 15.8 days. 100% of patients had central route.

Electrolyte complications ordered by incidence were: hypophosphatemia 31.25%, hypertriglyceridemia 18.75%, hyponatremia 18.75%, cholestasis 18.75% and hypophosphatemia 12.5%.

The onco-haematologic patients evolution were: 62.5% changed to oral diet, 12.5% paliative care, 12.5% enteral nutrition and 12.5% were exitus.

Conclusion: All onco-haematologic patients prescribed with TPN showed nutritional complications so close monitoring of the nutritional therapy becomes necessary.

The hospital pharmacist considers all those physicochemical and microbiological aspects related to TPN and antitumoural treatment to adjust nutritional support to the clinical conditions of onco-haematologic patients.

P048 Trastuzumab in HER2-positive metastatic parotid adenocarcinoma: a case report

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Introduction: Parotid adenocarcinoma is an uncommon malignant neoplasm of the salivary glands. The loco-regional management remains primarily surgical but post-operative radiotherapy is indicated in patients with advanced-stage tumour, inadequate margins, or poor prognostic. Systemic therapy is generally reserved for locoregional recurrence and/or metastatic disease. HER2 overexpression incidence in salivary gland range 7–56% depends on histological subtype. In breast and gastric neoplasm, overexpression of HER2 is correlated with poor prognosis and resistance to chemotherapy. Trastuzumab is a targeted therapy approved for the treatment of metastatic HER2-postive breast cancer and gastric neoplasm. Trastuzumab improves overall survival and/or progression-free survival in these tumours, whereas salivary gland adenocarcinoma shows a widely variable response to this therapy. Therefore, there is a need to better understand the role of trastuzumab in these patients. We aim to assess the role of trastuzumab in a patient with metastatic parotid gland adenocarcinoma that overexpresses HER2.

Material and method: A patient diagnosed with parotid acinar cells carcinoma overexpressing HER2, with loco-regional recurrence and metastatic disease who underwent treatment in the Oncology Department. Systemic therapy and medical records were reviewed, and tumour response was evaluated according to Response Evaluation Criteria In Solid Tumors (RECIST) criteria.

Results and discussion: A 46-year-old female patient underwent total parotidectomy. Four months later she developed left cervical loco-regional recurrence and bilateral lung metastatic disease. She received six cycles of cisplatin 50 mg/m² ciclofosfamide 500 mg/m² doxorrubicin 50 mg/m² as first line, which resulted in a 3-month progression-free interval and 80 mg/m² weekly taxol as a second line. This regimen achieved stable disease as best response, however subsequent nodal and pulmonary progressions were confirmed, during which HER2 overexpresion was confirmed. At the time trastuzumab regimen was chosen as third line, the status performance (SP) measured at 1 and increased up to 3 within two months. The computed tomography (CT) scan revealed a disease progression after the third cycle.

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Conclusion: Despite an initial control of the disease, response was not maintained over time resulting in a very aggressive progression disease. These results suggest that HER2 overexpression may not necessarily have a role in clinical activity tumour. More studies are needed to elucidate the subgroups of patients susceptible to benefit from this agent.

P049 Analysis of pharmacist interventions about dose adjustment of chemotherapy prescriptions

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Introduction: The pharmacist, through the validation of chemotherapy prescriptions, can provide improvements to the patient treatment. However, pharmacists are not integrated in the same way in all hospitals. The objective of this study is to analyse the interventions about dose adjustment made in our hospital.

Material and method: Pharmacist interventions were studied over a period of 8.5 months (March–November 2015). Prescriptions were made through the computer program Oncofar® for treatments to be administered in the Oncology Day Unit, through Farmatools® for inpatients and in a paper sheet for clinical trials and Haematology. When a dose error was detected the pharmacist used to call the physician to propose a change in the treatment. We wrote down if the recommendation was accepted or not. Interventions were classified according to the drug, department, reason of recommendation, and whether it was accepted.

Results and discussion: - A total of 57 interventions about dose adjustment were analysed (0.34 per day). From these prescriptions, 41 were made by oncologists, 12 by haematologists, 2 by paediatric oncologists and 2 by radiotherapists.

- The most frequent drugs were zoledronic acid (23%), trastuzumab (14%), metotrexate (7%) and rituximab (7%). 5 of them were drugs included in a clinical trial.
- The most frequent reason of recommendation (30 of 57, 53%) was an error in prescription (usually trastuzumab, metotrexate and rituximab), followed by lack of dose adjustment for renal failure (19%, always zoledronic acid) and wrong patient weight (12%, trastuzumab and bevacizumab).
- Only one recommendation was not accepted for the physician.

Conclusion: We found that errors in prescription were the most frequent reason of recommendation:

- Renal function must be systematically taken into account in zoledronic acid prescription due to the amount of doses not reduced. Many errors were with tratuzumab prescriptions; therefore these prescriptions must be especially reviewed.
- Pharmacist validation is essential to increase the number of patients receiving the right dose of chemotherapy.

P051 Educational programme for patients on oral chemotherapy: challenge for treatment adherence and quality of life

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Introduction: A patient educational programme dedicated for new patients on oral chemotherapy was initiated in Paul Strauss Cancer Centre (Strasbourg, France) in June 2014, initially for digestive cancer. The main objectives of this programme are adherence maintenance to oral antineoplastic therapy, promotion of a better understanding about patient treatment regimen and potential side effects, patient safety and implementation of self-care management.

Material and method: This study describes the educational process including medication reconciliation and counselling by oncology pharmacist, nursing monitoring, as well as adherence (Morisky-Green's scoring) and satisfaction assessment. A subset of patients following the educational programme was selected to analyse their performance status (PS) between the beginning and the end of neoadjuvant radiochemotherapy for rectum cancer using capecitabin. A retrospective case-control study compared this population to sex-, age- and disease-matched cohort without educational programme.

Results and discussion: Between June 2014 and December 2015, a total of 54 patients were enrolled in the educational programme, most of them taking capecitabin for colorectal cancer treatment (63%). Just after the first prescription for oral chemotherapy, medication reconciliations (including self-medication and specific foods records) were conducted in each patient and 17 pharmaceutical interventions were necessary for 15 patients (28%), meanly related to drug-drug interactions (59%). A total of 96 interviews (phone call or face-to-face) were planned with a nurse to evaluate and improve self-care management and treatment adherence. Early detection of chemotherapy related side effects resulted in 4 hospitalizations, 1 dose reduction and 1 treatment discontinuation. Only 13% of patients exhibited a Morisky-Green Score of 1 or 2 suggesting high level of adherence to oral treatment. Preliminary results of the case-control study on 32 patients indicated that PS is more stable in patients who completed the educational programme (Odds ratio = 0.32; CI = 0.05–1.95). Finally, 17 patients were requested to complete satisfaction questionnaire and 96% of them expressed their approval of the programme.

Conclusion: Altogether, we show a trend of treatment adherence and quality of life improvement by our educational programme, thus supporting the role of oncology pharmacy and nurse intervention in training and monitoring patients receiving oral chemotherapy.

P052 Evaluation of pharmaceutical interventions in Cancer Centre Paul Strauss

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Introduction: Computerized prescription order entry (CPOE) has been developed in Cancer Centre Paul Strauss since 2010. These prescriptions had to be validated by a pharmacist. In 2014, a new tool has been performed for registering pharmaceutical interventions (PIs). The aim of the study was to evaluate PIs performed during the validation of prescriptions.

Material and method: PIs were registered according to the instrument established by the French Society of Clinical Pharmacy (SFPC). Collected data were ATC classification, drug-related problem (10 items), type of intervention (7 items), and intervention follow-up. Analysis has been performed between the first of May 2014 and the first of December 2015 in four long-term care units (50 beds).

Results and discussion: 46,558 prescribed lines were validated and led to 1,177 PIs (2.5 %), among which 74% (n = 873) were accepted by the physicians. The most involved were alimentary tract drugs and metabolism drugs (n = 264), nervous system drugs (n = 257) and anti-infective drugs (n = 247). Only 2% (n = 24) of PIs were concerned by antineoplastic agents. Most common drug-related problems were 'supra-therapeutic dosage' (36.9%; n = 433) 'non conformity to guidelines or contra-indication' (26.2%; n = 308) or 'drug without indication' (14.5%; n = 171). Drugs implicated in 'non conformity to guidelines' belonged to the alimentary tract and metabolism (n = 53), the nervous system (n = 54) and the cardiovascular system (n = 73). Alimentary tract and metabolism drugs (n = 136) and nervous system (n = 112) drugs were the most concerned by supra-herapeutic problems. Drugs prescribed without indication are the

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anti-infective (n = 56) and the alimentary tract and metabolism drugs (n = 48). 22 PIs were represented by drug-drug interactions. Detected interactions were addition of side effects (n = 13), antagonism (n = 3), pharmacokinetic interactions (n = 3), physicochemical incompatibility (n = 3). On 1,177 PIs, 36% (n = 420) had led to the interruption of the treatment, 29% at the dosage adaptation and 21% at substitutions. Physicians' acceptance depended on type of intervention: addition of a new drug was less accepted than drug monitoring.

Conclusion: This study led us to make evolving therapeutic equivalent drugs, to inform the setting of maximal doses in the CPOE for the most frequents PIs. This analysis showed the need to develop or register PIs on antineoplastic agents. Actions have to be made for some drug-related problems that were not detected yet (such as, 'adverse drug reaction', 'failure to receive drug').

P053 Experience of three-year oncology pharmacy services in a Greek hospital

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Introduction: Preventable medication errors (PME) occur in all oncology centres with potential severe consequences, such as enhanced toxicity or impaired disease control. Clinical pharmacist's participation in multidisciplinary oncological teams is associated with prevention of such errors and as a result better quality services as well as cost saving. However, the role is still not well established in Greece. Our aim was to analyse the clinical pharmacist's contribution in patient's safety and the economic impact of the interventions.

Material and method: Analysis of the clinical significant interventions made by clinical pharmacists during chemotherapy order check before administration from January 2013 until December 2015. All of the interventions were documented and accepted by physician.

Results and discussion: A total number of 836 patients were treated and 9,794 chemotherapies were administrated. 717 interventions were recorded, 395 (55%) in dose, 126 (17%) in pre- and post-medications, 62 (9%) in protocol application, 56 (8%) in dilution, 48 (7%) in administration and 30 (4%) in drug-drug interactions. Of the 395 dose interventions 63% regarded inappropriate increased and 37% decreased dose. The reasons for increased and decreased dose were wrong creatinine clearance (CrCl) calculation 48%–21%, protocol deviation 24%–34%, wrong body surface area calculation (BSA) 14%–39%, impaired liver function 3%–2% and toxicities 11%–4%, respectively. The most common PME were incorrect dose calculation mainly due to CrCl, BSA and protocol deviation.

According to literature 17% of PMEs will lead to hospitalization. In our institution the average bed stay is 4 days with cost Euros 1,400/day. So, the interventions lead approximately to a saving of Euros 682,000. Furthermore, hospital will avoid bed capacity reduction of 257 bed-days. The annual cost for a clinical pharmacist responsible to check that amount of orders is less than Euros 35,000.

Conclusion: Consequently, pharmacist participation in oncologic team leads to decrease in costs and to a significant improvement in safety and quality of patient care.

P054 Analysis of the interactions pharmacological with antineoplastic oral in patients with renal cell carcinoma

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Introduction: About 80% of malignant renal tumours are renal cell carcinoma (RCC). Oral anti-angiogenic therapy (OAT) in advanced RCC has resulted in promising results, highlighting personalized treatments based on molecular characteristics of the tumour. Most of these drugs are given by oral route, taken this an advantage in terms of adherence, but there are some factors that can compromise patient safety and treatment efficacy, such as drug interactions (DI), very important in patients with polypharmacy.

Purpose: Detect and evaluate DI in advance stage RCC patients treated with OAT.

Material and method: Observational, descriptive and retrospective study. The study population were patients diagnosed of advanced stage RCC treated with OAT (sunitinib, pazopanib, sorafenib, axitinib, and everolimus) between October 2014–October 2015.

Electronic medical records were reviewed from the outpatient database (Farmatools®) and the community pharmacy prescription system (Turriano®).

We considered demographic data (age, sex), OAT prescribed by the oncologist and any other medication patients were prescribed by community doctors considered as concomitant therapy (CT).

Interactions between oral medication and CT were tested using Medscape database 2015 Drug Interactions® and database published for scientific associations SEFH (2014 Gedefo®).

Results and discussion: 35 RCC patients were taking OAT (27 men, 8 women), mean age 62 years (min. 47–max. 74). 10 patients (28.6%) were taking sunitinib, 9 (25.7%) everolimus, 8 (22.9%) pazopanib, 4 (11.4%) sorafenib and 4 (11.4) axitinib.

42 interactions were detected between OAT and CT: 4 were for contraindications or association not recommended (axitinib with fluconazole amiodarone and dexamethasone) and 38 were for potential interactions that require dose adjustment or pharmacokinetic level of OAT monitoring.

The distribution of interactions related to OAT drug was: 10 (23.8%) for sunitinib, 2 (4.7%) everolimus, 16 (38.1%) for pazopanib, 1 (2.4%) sorafenib and 13 (31%) for axitinib.

The most important drugs prescribed by community doctors involved in these interactions were 9 (21.4%) with omeprazole, 7 (16.7%) dexamethasone, 3 (7.1%) fluconazole, 3 (7.1%) metformin, 2 (4.8%) atorvastatin, 2 (4.8%) escitalopram, 2 (4.8%) paracetamol, 2 (4.8%) repaglinide, 2 (4.8%) amiodarone, 2 (4.8%) amlodipine, 1 (2.4%) citalopram, 1 (2.4%) dextromethorphan, 1 (2.4%) ketoconazole, 1 (2.4%) pitavastatin, 1(2.4%) prednisone, 1 (2.4%) rosuvastatin, 1 (2.4%) simvastatin and 1 (2.4%) with vildagliptin.

Conclusion: Patients diagnosed with advanced RCC and treated with OAT are due to be monitorized trying to reduce and control interactions related to the use of other CT they are prescribed by community doctors, to increase safety and assuring the most efectivity in the use of OAT.

It is important to improve pharmaceutical care to detect possible DI and interventions to avoid contributing to greater treatment efficacy and patient safety.

P055 Patients' satisfaction with information on oral anticancer agents

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Introduction: Medication adherence is an issue of concern in the oral treatment of several types of cancer. Patient education is a key component of adherence-improving interventions. The present study was

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aimed to examine to what extent cancer patients believe to have been sufficiently informed about their oral anticancer agent (OACA) and to explore influencing factors.

Material and method: An observational study in four Dutch academic hospitals in the period October 2010–March 2012 was conducted. The validated Satisfaction with Information about Medicines Scale (SIMS) was used, along with the validated Beliefs about Medicines Questionnaire (BMQ), Brief Illness Perception Questionnaire, and European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30). Logistic regression analyses were used to determine influencing factors. The median scores of all patients were used to define dissatisfaction (< 14 of 17, < 8 of 9, and < 6 of 8 items for responses. Overall satisfaction rating, subscale 'action and usage' and subscale 'potential problems').

Results and discussion: SIMS was completed by 208 patients using capecitabine (35%), lenalidomide (15%), imatinib (14%), temozolomide (12%), sunitinib (11%), thalidomide (5%), dasatinib (4%), erlotinib (2%) and nilotinib (2%). Few patients indicated that no information was needed (< 8%) or received too much (< 2%). More often information was provided 'too little' or 'not received': how the OACA works (17%, 8%), how long it will take to act (16%, 22%), how you can tell if it is working (19%, 26%), the risks of getting side effects (16%, 13%), what you should do if you experience side effects (13%, 11%) and what you should do if you forget to take a dose (12%, 17%). Items associated with dissatisfaction with information on 'action and usage' were: positive perception of the consequences of cancer and indifferent attitude towards OACA versus accepting attitude. Items associated with dissatisfaction with information on 'potential problems' were: younger age, an haematological malignancy, the experience of dyspnoea and low treatment control.

Conclusion: The need for information on OACA is high; for each of the 17 items 92–99% of patients wanted information. A negligible number received too much information. A considerable proportion of patients received too little or no information on OACA, especially on the action of OACA and its side effects. Providing information on OACA needs to be improved.

P056 Osteonecrosis of the jaw secondary to intravenous bisphosphonates treatment

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Introduction: Bisphosphonates are a group of drugs with hypocalcemic action by inhibiting bone resorption, used among other disorders, in malignizante hypercalcemia and bone metastases of tumours. Our objective is to assess the incidence and describe the cases of osteonecrosis of the jaw (ONJ) in patients with neoplastic disease who are treated with intravenous bisphosphonates.

Material and method: A literature search in PubMed® about ONJ related to the use of bisphosphonates was performed and the clinical record of patients with ONJ who were treated with bisphosphonates was revised during the last five years, selected by the dispensing program to outpatient DIPEx®.

Results and discussion: 247 patients were treated with bisphosphonates during the period under study, one of which had ONJ. It was a 51-year-old female with a personal history of rheumatoid arthritis, asthmatic bronchitis and obesity diagnosed with stage IV breast cancer due to pleuropulmonary and bone involvement. She received chemotherapy with adriamycin and docetaxel and intravenous therapy with zoledronic acid 4 mg monthly was started. After 2 years of treatment with zoledronate, a solid periosteal reaction of 4 mm thick in left mandibular branch was observed on CT neck, so she was evaluated by Maxillofacial Surgery who dismissed intervention and recommended conservative treatment with analgesics and antibiotherapy. She was admitted to the hospital several times for acute pain and haemifacial edema, with no evidence of changes at ONJ, and symptoms were controlled by analgesia, anti-inflammatory and antibiotic treatment readjustment. She was reassessed by Maxillofacial team who discarded surgical attitude and remained symptomatic treatment.

Conclusion: Osteonecrosis as an adverse reaction to the use of bisphosphonates causes significant morbidity to patients significantly impairing their quality of life. The coordinated participation of different professionals for an integrated approach is desirable. In our study, the incidence of ONJ was 0.4% lower than published data with values ranging from 0.8% to 12% according to the literature consulted.

P057 Congestive heart failure induced by trastuzumab in real clinical practice

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Introduction: Cardiac dysfunction is one of the most serious and/or common adverse reaction to trastuzumab treatment. HERA study (1,698 patients), published in 2007, found an incidence of congestive heart failure (CHF) of 2.7% with trastuzumab vs 0.2% in the control group. In a subsequent observational study, which includes Spanish population (Serrano et al. 2012, 45 patients), a trastuzumab-induced CHF incidence of 8.9% was described. The aim of our study was to analyse the CHF incidence in patients with breast cancer under trastuzumab treatment in our hospital

Material and method: Retrospective observational study. All patients diagnosed with HER2+ breast cancer under trastuzumab treatment between 2008 and 2015 in a 450,000 population health area were included. We research all patients with actual possible diagnosis of CHF (patients under IECA or ARA-II and beta-blockers therapy). All patients who developed CHF during or after beginning with trastuzumab treatment were identified, and in these cases, we confirmed CHF diagnosis by review of medical clinical history. The primary endpoint was patients who developed CHF per 100 patients-year treated with trastuzumab. The following data were searched: trastuzumab treatment duration, date of CHF diagnosis, FEV decreased and discontinuation of trastuzumab treatment because CHF diagnosis.

Results and discussion: 252 patients treated with trastuzumab were included. The mean of duration with trastuzumab treatment was 0.98 years (CI95%: 0.88–1.08). Five patients with CHF diagnosis were detected, all following the initiate into trastuzumab treatment. The incidence of CHF was 2 per 100 patients-year of treatment. The mean of time from start to trastuzumab treatment until CHF diagnosis or FEV decreased was 0.71 years (CI95%: 0.53–0.90). The CHF diagnosis led to trastuzumab treatment suspension in 4 patients, all with FEV ≤ 50% on the CHF diagnosis moment

Conclusion: The CHF incidence in patients under trastuzumab treatment in our centre is lower than that it found in previous studies with smaller population, and similar to that it found in the pivotal clinical trial of trastuzumab. All cases of CHF occurred during treatment with trastuzumab leading to discontinuation in the majority.

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P058 Importance of pharmacist interventions in Indus Children Cancer Hospital

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Introduction: Children Cancer Hospital is a 42-bedded charity-based specialized care unit for managing and treating cancer in children and in this paediatric hospital setting, pharmacist most frequently perform drug therapy changes on the cancer ward. Pharmacists interventions improve the health of a patient and change the conditions which have negative impact on the well-being of the patient. The primary objective of this study was to determine the number and types of medication errors intervened by clinical pharmacists during August to October 2015. The clinical pharmacist, reviews profiles of all the admitted patients through software. While reviewing profiles pharmacists take into consideration the following points: (1) The basic diagnosis of the patient; (2) Date and reason of admission for which patient is admitted on the ward; (3) Consultant notes about the condition of the patient; (4) Progress notes (duty doctor enters necessary points about the current condition of patient); (5) Chemo status of the patient; (6) Vitals (including blood pressure, temperature, pulse rate, respiratory rate, height, weight, body surface area, pain scale); (7) Check all the medicines prescribed in medication order for: a) correct doses, b) drug-drug interactions, c) correct frequency, d) duration of therapy, e) contraindication, f) unnecessary drug, g) drug missing; (8) Recent laboratory tests (for example, CBC, serum electrolytes, culture and sensitivity, urea, creatinin, LFT) also reviewed by pharmacist; (9) Once profiles are completely reviewed, the pharmacist goes for a round and visits every patient, asks about their condition; (10) Discuss the interventions with the physician and make necessary corrections; (11) Pharmacist also fills the intervention form, for the intervention he/she has made, intervention parameters are: dose variation, wrong drug, wrong frequency, duplication of drug, drug missing, excessive duration, contraindication, drug-drug interaction, inconvenient form.

Material and method: The present study is a systematic retrospective study carried out by collecting the intervened prescriptions by clinical pharmacists of Indus Children Cancer Hospital. All prescriptions of 3 months (August to October) intervened by the pharmacist are included in the study. Utmost care was taken to include only those prescriptions which were intervened by the pharmacists and documented well by their comment on the prescription. Confidentiality of the information is maintained by not disclosing patient name, patient ID, name of the doctor who prescribed, and name of the pharmacist who did the interventions. Lexi-Comp's drug information handbook, The Harriet Lane Handbook and British National Formulary are used as standards to substantiate correct interventions by the pharmacists. Throughout the study's observation period of, clinical pharmacist reviewed 618 admitted patient's prescription, during this period the number of prescription clinical pharmacist reviewed are 5,562. Among those patient reviews, the pharmacist documented a total of 244 interventions.

Results and discussion: These 244 interventions include total of 74 (30%) antibiotic and antifungal drugs, 70 (29%) chemo drugs, and 100 (41%) supportive drugs.

These clinical interventions include the following main variables: (1) dose adjustment, (2) drug missing, (3) unnecessary drug, (4) wrong frequency, (5) duplication, and (6) wrong drug.

Discussion: The study shows that the clinical pharmacist made total 244 interventions during the period of three months, August, September and October. In August, 85 interventions, in September, 72 interventions, and in October 87 interventions were made. Among them 30% interventions are of antibiotics and antifungals, 29% interventions are of chemo drugs and 41% interventions are of supportive drugs. Major variables on which interventions were done are dose adjustment 40%, wrong drug 10%, wrong frequency 14%, drug missing 18%, drug duplication 10%, and unnecessary drug 8%.

It is hard to believe that 10% of interventions were to change medication order or to clarify the reason for prescribing that medication and 8% are of unnecessary drug (prescribed without indication). It is a concern in pharmacy practice and needs to be addressed.

One of the most important thing noticed by the clinical pharmacist was problem with the wrong frequency medication order which is 14%, it happens when physician mistakenly select the wrong frequency in system or might not know the right frequency.

Intervention of dose adjustment is 40% which includes prescribe dose is too high or dose too low according to patient's body weight.

This study showed that 18% of the interventions were about drug missing, physician did not prescribe supportive drugs with the main therapeutic drugs and 10% of pharmacist interventions were of drug duplication in which physician prescribed two drugs belonging to same drug class.

These interventions lead to prevent complications and morbidity, to rationalize the treatment, improve compliance and cost. Pakistan is an underdeveloped country where pharmacist role is not acknowledged by the other healthcare providers, many hospitals do not even have the clinical pharmacist and in few hospitals where clinical pharmacist works and intervene, the acceptance level is very low. The best thing found in the study is that the interventions undertaken by the ICCH pharmacists are well received and accepted (98%) by the working physicians in the hospital symbolizing that the healthcare system in the Indus Children Cancer Hospital is patient centred.

The Director of Hospital Pharmacy recommended documentation of pharmacists' interventions which can help in enhancing the communication with other healthcare providers, justifying workload, and identifying opportunities for focused drug use review. Also, they pointed out that these interventions reflect the wide range of services provided by pharmacy.

Conclusion: The acceptance rates of the pharmacists' active recommendations were high, about 99%, thus strengthening existing evidence that the role of pharmacists in Children Cancer Hospital improves the quality of paediatric care. We recommend more numbers of such research-based studies to bring awareness among healthcare professionals, provide solution to the prescription and dispensing problems, as it can also improve the documentation system, emphasize the importance of it, reduce prescribing errors, and update the knowledge of pharmacists and other healthcare professionals.

P059 Improving wait time for chemotherapy in an oncology day unit

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Introduction: Cancer patients usually spend long hours in hospital to receive their treatments. We believe this may be influenced by the way healthcare is organized. The objective of this study was to identify the issues behind the chemotherapy process in order to reduce the average patient´s waiting time and stress cancer patients are experiencing.

Material and method: A prospective study of four weeks was undertaken in September 2015 in the Oncology Day Unit in a General Hospital. We identified the main steps throughout the chemotherapy process and designed a process mapping and a data sheet to register the exact time every step happened for every patient: hospital arrival (T1), blood test is taken (T2), blood test results (T3), doctor´s prescription (T4), pharmacist´s validation of medication order (T5), treatment is prepared and checked in the pharmacy (T6), nurse starts infusion (T7), end of drug administration (T8), patient leaves the hospital (T9). We made a distinction between scheduled and not scheduled patients.

Results and discussion: A total of 47 patients were admitted to the Oncology Day Unit, corresponding to 85 appointments, in order to receive

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their treatment. Every patient had a blood test and an appointment with the oncologist on the same day they received the chemotherapy. The average time patients spent in the Oncology Day Unit (T9–T1) was 270.71 min. The average time they were waiting for the treatment (T7–T1) was 118.64 min. It took the laboratory (T3–T2) an average time of 56.92 min. to get the results for the blood test and the pharmacy (T6–T4) needed an average time of 36.42 min. to prepare the complete treatment for a patient.

Conclusion: Waiting times found in the study (118.64 min.) are higher than other studies published (96 min.). Some reasons may be that every patient had a blood test and the oncologist visit on the same day they received the treatment. Nevertheless, further research is required to improve the process and shorten wait time for these patients.

P060 Achievements and new perspectives of oncology pharmacy in Morocco

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Introduction: Over the last 10 years, Morocco has developed strategies to improve management, treatment and safety of cancer patients.These strategies are based on the principle of providing accessible quality care across all the structures of the kingdom. The importance of human factors was particularly highlighted and actions aimed at improving the conditions of the oncology pharmacy are heavily promoted.

The objective of this work was to evaluate the hospital pharmacist strategies implemented to roll back the disease and consider the achievements made in this direction at the national level and discuss new perspectives.

Material and method: This is a prospective observational survey nearby pharmacists exercising in cancer centres and ensure the activities of hospital and clinical pharmacy and also the preparation of the injectable chemotherapy. The study was conducted in December 2015.

Results and discussion: In order to provide quality care to cancer patients through accessible to all structures of the kingdom, many actions have been launched. The main actions undertaken concerning the oncology pharmacy are: equipment Centralized Unit Cytotoxic preparations, materials for individual and collective protection, personnel training, management of drugs and medical devices, the development of pharmacovigilance systems, theraputique of education programmes. The opportunities are good cooperation and communication established with various national and international health professionals in the field.

As part of the improvement process of the oncology pharmacy in Morocco, scholarly society was created in Morocco, Moroccan Society Oncology Pharmacy at the Faculty of Medicine and Pharmacy of Rabat. The objectives of this scientific society is the development of various disciplines of oncology pharmacy, national and international collaboration, to improve patient pharmaceutical care with cancer.

Conclusion: In future years, some challenges exist to stimulate the development of the oncology pharmacy in Morocco. This will be particularly projects of certification Centralized Unit Cytotoxic preparations of certification projects, improve oncology pharmacy in Morocco liberal and state level, and do not forget to expand international cooperation and diversify its fields of action, by extending the training, qualification, technology transfer and exchange of experience.

P061 Retinold therapy in the treatment of neuroblastoma

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Introduction: Neuroblastoma is the most common extracranial solid tumour in child population. This type of tumour is the fourth most abundant of all paediatric tumours. Treatments include a combination of surgery, chemotherapy, radiation therapy and stem cell transplant in oncology patients.

Material and method: This survey was conducted in order to determine the most appropriate way of using isotretinoin in patients with neuroblastoma. This information was based on the information obtained as a systematic review of the medical literature.

Results and discussion: The US Food and Drug Administration (FDA) has approved the use of isotretinoin for the treatment of paediatric patients with high-risk neuroblastoma.

Isotretinoin is a type of retinoid. Also called 13-cis-retinoic acid. This medicine may be used alone or in combination with other chemotherapeutic agents.

Isotretinoin is available only in oral pharmaceutical form as a soft gelatin capsule and it is used in paediatric population in an off-label indication for treatment of high-risk neuroblastoma.

The majority of patients will have some sort of adverse reactions during taking isotretinoin. The most frequently adverse reaction of isotretinoin is dryness of lips. Dryness of skin or eyes is also possible, dryness of nasal mucosa, epistaxis, myalgia and arthralgia, and changes in the nails. These side effects almost always disappear when the treatment is completed.

Additionally, it is important that it must be safe and secure in handling with this medicine because it can cause severe birth defects in pregnant women.

Conclusion: In children with neuroblastoma this drug can provide significant health benefits when it is used properly. Some adverse reactions of isotretinoin can be very serious and it is important that the child be carefully monitored by parents and his or her physicians and pharmacists together.

Pharmacist can have a significant role in supportive treatment of adverse reactions of isotretionoin.

P062 Analysis of prescribed pharmacotherapy through clinical case

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Introduction: Oncology pharmacy has been related exclusively to hospital pharmacy for many years. In the first place it involved safe handling of antineoplastic drugs, then the central preparation of these drugs, but today it also has its place in community (external) pharmacy. This is the result of of nowadays well-known fact that a community pharmacist is in everyday contact with oncology patients and their families. Moreover, the number of oral formulations of antineoplastic drugs is on the rise. However, the affirmation of oncology pharmacy in community pharmacies is still not satisfactory, which indicates that there is a need for additional education of community pharmacists in this particular field of pharmacy.

Material and method: For the purpose of this poster, we will display a patient who comes to a community pharmacy to pick up her usual medications. She suffers from breast cancer, and in addition to medications used for the treatment of comorbidities, in pharmacy she takes

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capecitabine, drugs for the pain treatment and antinauseants. Except the drugs listed above, that are given via prescription, the patient also buys painkillers and supplements which are claimed to be improving immunity.

Results and discussion: Through case of oncology patient and the analysis of her pharmacotherapy, pharmacy interventions in everyday work are shown, as well as management of side effects which resulted from the application of anticancer drugs or radiation.

It was found out that our patient duplicates the therapy of ibuprofen (Rx) and ibuprofen (OTC), paracetmol (Rx) and paracetamol (OTC). On top of that, she lacked knowledge of proper administration of capecitabine.

Having an insight into an e-card (which is not yet available to community pharmacists in Croatia) and whole medication history and dietary supplements that patient often uses, it is easier to identify and avoid potential medication errors and drug interactions. That way a pharmacist in a community pharmacy would be more able to check the patient's adherence and influence the course of treatment.

Conclusion: As part of a multidisciplinary team, pharmacist is obliged to cooperate actively with other health professionals and share their observations and activities related to the common oncology patient.

This work is the result of collaboration of colleague Dahna Arbanas and Working Group for Oncology Pharmacy, employees of Hospital Pharmacy and Department of Medical Oncology in Clinic for Tumors of Clinical Hospital Centre Sisters of Mercy, Zagreb, Croatia.

P063 Cancer patients counsulting about self-medication

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Introduction: According to US data, about 60% of patients use Complementary and Alternative Medicine (CAM) self-medication products. In Croatia, these products can be classified as medicines (both synthetic and traditional herbal medicine OTC products) or food supplements, which are under the same regulation as food. However, it is well known that people with cancer tend to use other non-registered products, as well as products which can be bought via the Internet.

Material and method: A survey was conducted on 36 patients undergoing cancer treatment at University Hospital Centre Sisters of Mercy, Tumor Clinic, Zagreb, Croatia, where they were examined whether they use CAM products and to what extent.

Results and discussion: We found out that 30 out of 36 questioned patients (83%) have used some self-medication products. The complexity of the therapeutic care of oncological patients certainly requires greater attention - not only a conventional therapy needs to be observed, but also non-prescription drugs and dietary supplements, as well as any other forms of self-medication, whether it is the use of home-made herbal products, the use of traditional medicines or drastic dietary changes.

Conclusion: By thorough patients examination about pharmacotherapeutic history, a review of patient medical records, drug interactions, side effects, dosage of drugs, preparations for self-treatment (CAM), and using tools-database Lexicomp, UptoDate and PubMed, we obtain a good pharmacotherapeutic healthcare plan for patients.

This work is the result of collaboration of colleague Maja Koroman and Working Group for Oncology Pharmacy, employees of Hospital Pharmacy and Department of Medical Oncology in Clinic for Tumors of Clinical Hospital Centre Sisters of Mercy, Zagreb, Croatia.

P064 Pharmaceutical consulting of oncologic patient about the enteral nutrition

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Introduction: Cachexia is often associated with various types of carcinomas, especially with pancreatic and gastric carcinomas which have a high incidence of cachexia. Cachexia is causing worsening of the prognosis and reduces a quality of life. It takes a multimodal approach aimed at treating the cause of the disease that can eventually lead to cachexia. In addition to medical therapy, nutritional support can improve symptoms of the disease [1, 2]. The case of a patient with metastatic gastric cancer is presented. After extensive surgery, a patient became cachectic and was given nutritional support under the supervision of the healthcare team.

Material and method: A 47-year-old patient was hospitalized on 25 August 2014 in the department of internal oncology in order to continue treatment according to the chemotherapy regimen of cisplatin and 5-fluorouracil. In early 2013, the patient began to feel severe pain in the abdomen and had lost 5 kilograms.

A gastroenterology procedure found an extensive neoplastic process of the stomach, which resulted in surgery. A total gastrectomy, splenopancreatomy and lymphadenectomy had been performed. Histopathological findings verified a metastatic stomach adenocarcinoma. Chemotherapeutic advisory board decided for a patient to be given five cycles of adjuvant chemotherapy with concomitant irradiation, with the second and third cycle being done by Macdonald protocol. Control tests conducted in May and June 2014 showed the dissemination of the disease for which antineoplastic treatment was prescribed. Post-operatively, the patient started to lose weight despite normal appetite. Laboratory findings during hospitalization showed hypoalbuminemia, decreased creatinine and decreased level of glucose.

Results and discussion: A nutritional support with a formulation designed specifically for oncology and cachexic patients was initiated along with megestrol acetate, which served as a hormonal support. The patient was discharged with an improved general status. This case pointed at the clinical problem of cachexia which can go unnoticed and thus lead to a reduced chemotherapy response, lower functional performance and increased mortality [1].

Conclusion: Body weight loss after surgery occurs due to stress caused by surgery or trauma, which can all lead to a hypermetabolic state and consequent malnutrition. This situation can be additionally worsened by gastrectomy if the establishment of normal intestinal function is significantly delayed [3].

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Therefore, a multidisciplinary approach is needed. A team consisting of doctors, pharmacists and a nurse can timely and effectively deal with the mentioned condition.

References

1. Merck Manuals. Chabner BA, Chabner Thompson E. Cachexia in Cancer. Metabolic and nutritional aspects of cancer. Last full review/revision: July 2013. Content last modified: September 2013.
2. Krawczyk J, Kraj L. Ziarkiewicz M, Wiktor-Jędrzejczak W. Metabolic and nutritional aspects of cancer. Postepy Hig Med Dosw (Online). 2014;68:1008-14.
3. Fairfield KM, Askari R. Overview of perioperative nutritional support. UpToDate. Last full review/revision: September 2014. Content last modified: February 2014.

This work is the result of collaboration of Working Group for Oncology Pharmacy, employees of Hospital Pharmacy and Department of Medical Oncology in Clinic for Tumors of Clinical Hospital Centre Sisters of Mercy, Zagreb, Croatia.

P065 Safety and tolerability of tyrosine kinase inhibitors in the treatment of renal cell carcinoma metastatic

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Introduction: Analyse the safety and tolerability of sunitinib (Sutent) and pazopanib (Votrient®) in the treatment of metastatic renal cell carcinoma.

Material and method: Retrospective observational study of patients starting treatment with sunitinib and/or pazopanib from July 2012 to September 2014, diagnosed with metastatic renal carcinoma.

Demographic variables (sex and age), line of treatment, transaminase (ALT and AST) and total bilirubin at baseline and during treatment, adverse effects, whether or not to decrease the dose of the drug and causes suspension were recorded.

The data were obtained from the Electronic Health Record (SIAS®) and the application for dispensing medication to outpatients (Abucasis®).

Results and discussion: From July 2012 to September 2014, 19 patients (16% female and 84% male, 62 ± 13 years) with metastatic renal cell began treatment with inhibitors of tyrosine kinase (TKIs): 10 patients with pazopanib and 9 sunitinib.

Regarding pazopanib, 7 patients began treatment as first-line treatment, 2 as second line, and 1 as fourth line (the latter as compassionate use). As for sunitinib, 7 patients initiated it as a first line and 2 as second line.

During treatment with pazopanib, 6 patients developed liver toxicity (increased levels of ALT, AST and total bilirubin): 4 of them during the first month of treatment; the remaining 2 after 3 months of treatment. Other reported adverse effects were gastrointestinal disorders (60%), anaemia (10%), increased blood pressure (40%), increased thyroid hormones (10%), change in hair color (30%), alteration flavour (30%) and skin disorders (20%). They caused the decrease in dose in 5 patients and 3 patients had to enter by thrombotic events, cholangitis or hypertensive crisis.

40% of patients discontinued treatment because of the developed liver toxicity, 30% due to disease progression and 10% were exitus after 17 days of treatment. The remaining 20% continue treatment after a period of 10 ± 0 months.

During sunitinib treatment, 2 patients developed liver toxicity between the first and the second month of treatment. Other reported adverse effects were: increased thyroid hormones (33%), hand-foot syndrome (44%), increased blood pressure (55%), dyslipidemia (44%), blood disorders (44%), gastrointestinal disorders (77%), mucositis (33%), skin disorders (44%) and decreased LVEF (ejection fraction - 22%). They caused the decrease in dose in 5 patients and 1 patient had to enter through pericarditis.

55% of patients discontinue treatment for disease progression and 2 patients died after 13 and 120 days, respectively. The remaining 22% continue treatment after a period of 26 ± 19 months.

Conclusion: The TKIs produce adverse events in most patients. Although the sample size is limited (n = 19), it seems that pazopanib has a lower incidence of adverse events; It is better tolerated. However, patients treated with pazopanib develop greater liver toxicity, which forced the suspension of treatment. Sunitinib has improved liver safety profile.

P066 Antineoplastic oral: preparation of a guide for safe handling

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Introduction: There is a need to educate health professionals, patients and families in the safe handling of oral cytostatics. The purpose was to develop a guide for the safe handling of oral antineoplastic.

Material and method: A systematic review of the literature was conducted to update the recommendations on the safe use of oral antineoplastic. Search by direct consultation and online access to the literature collected in databases Scielo, Osh and MEDLINE (Medical Literature Analysis and Retrieval System Online) via PubMed was performed, finding better results in MEDLINE; Search strategy MEDLINE ('Antineoplastic Agents' [Mesh]) OR ('Cytostatic Agents' [Mesh]) AND 'Administration, Oral' [Mesh]). Publication: from 2010 to 2015 (last updated 31 April 2015) .The guide was also reviewed by other pharmacists and oncologists hospital prescribers.

Results and discussion: An analysis was performed on 72 papers on the safe handling of oral antineoplastic. We reviewed 47 drugs for adults, of whom 24 are also used in paediatrics, 21 for oncological, 17 for haematological and 9 for both. Liver failure specific recommendations were found for 10, for renal insufficiency 14.

The recommendations regarding the handling of drugs, both for professionals and patients at home, were general while adverse effects and interactions varied by drugs. Regarding the administration should be taken with liquid (26%), without food (23%), and food (17%); and some at specific times: morning, evening ...

Recommendations for professionals were related to hospital dispensation, especially focusing on the detection and management of adverse reactions and more common interactions, information and handling.

The recommendations for patients were associated with home handling these drugs, regimens of administration, food interactions, potential fragmentation of tablets, utensils, cleaning, what to do in case of accidental contact, and recommendations for the management of excreta for these patients in treatment.

A general operating oral chemotherapy for patients, parents and carers were established.

Conclusion: The collection of information was used to develop a guide for the safe handling of oral antineoplastic based on available evidence and specially adapted for use in hospital outpatients. This guide is useful and easy to use and helps prevent operating errors and administration.

P067 Pomalidomide for multiple myeloma in real practice

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Introduction: Pomalidomide in combination with dexamethasone is indicated in the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimens,

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including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy. The efficacy and safety of pomalidomide in combination with dexamethasone were evaluated in a phase III multicentre, randomized, open-label study (CC-4047-MM-003).The primary efficacy endpoint was progression-free survival (PFS) was 15.7 weeks and the estimated 26-week event-free survival rate was 35.99%. We wanted to evaluate the efficacy of pomalidomide in our cohort in real practice.

Material and method: Retrospective review of medical records of all patients receiving pomalidamide for multiple myeloma in our hospital from November 2014 to October 2015.

Results and discussion: 20 patients have received pomalidomide. 60% women, median age 72.5 (51–86)-year-old.

Median number of previous treatments is 3 (2–7).

10 patients (50%) have received pomalidamide dexamethasone but the other 10 have added clarithromycin and cyclophosphamide at some point of the treatment course.

After 4 months of treatment 8 out of 17 evaluated patients were still on treatment (47%) but at 26 weeks only 3 out of 14 (21%) were event free. 12 patients have withdrawn pomalidomide. Causes are: progression 6 patients (50%), toxicity and progression 3 (25%), toxicity 2 patients (17%) and death 1 patient.

16 patients (80%) have experienced one or more adverse reactions, among them blood disorders were most frequent 12 (60%) (thrombocytopenia 4 (2%), and neutropenia 5 (2,5%), infections 11 patients (55%) including respiratory tract 4 patients (2%), pneumonia patients (2%), sepsis 1 patient. Neuropathy was reported in 1 patient, reactivation of CMV in 1 patient and of GVHD in 1 patient. A cerebrovascular accident was also reported

Conclusion: - Our cohort is 9 years older than the reference study.

- Every patient has followed a unique treatment plan. More than half of them have added clarithromycin and cyclophosphamide to their treatment.
- At 26 weeks 21% patients were still on treatment versus 36% from the reference.
- Incidence of toxicity was lower than expected but new adverse reactions occurred.

P068 Outcomes associated with place in therapy of tyrosine kinase inhibitors in metastatic non-small cell lung cancer

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Introduction: Clinical benefit associated with the place in therapy of tyrosine kinase inhibitors (TKI) used in metastatic non-small cell lung cancer (mNSCLC) are unclear. The aim of the present study is to analyse differences in effectiveness of erlotinib and gefitinib in first- versus second-line therapy and different epidermal growth factor receptor (EGFR) mutation status in patients with mNSCLC in a real world approach.

Material and method: All patients with mNSCLC treated with erlotinib or gefitinib during September 2009 to July 2014 period, in first or second line were included. Two effectiveness endpoint was considered in the analysis: mean of months to completion of treatment with the total received lines (mMCT) and mean estimated progression-free survival (ePFS) treatment with TKI. The mMCT was defined as the time from the date of the first line start to the end date of the last treatment corresponding to subsequent lines. ePFS was defined as the duration of treatment with TKI. mMCT and ePFS were compared between patients who received the drug in first or second line. Patients with different EGFR mutation status were separately analysed.

Results and discussion: A total of 15 mut-EGFR and 42 wt-EGFR patients were included. In the mut-EGFR group, 10 patients received the drug in first line, with an mMCT of 8.6 months (95% CI 4.5 to 12.8), and 5 received TKI in second line, with an mMCT of 14.3 months (95% CI 10.2 to 18.3). Among patients with wt-EGFR, 7 patients received TKI in first line, with an mMCT of 4.4 months (95%CI 1.2 to 7.6), and 35 received TKI as the second line, with an mMCT of 12.2 months (95% CI 9.7 to 14.8). Among mut-EGFR patients, the difference between first and second line was –5.7 months (95% CI –13.0 to 1.6). In wt-EGFR patients the difference between first and second line was –7.8 months (95% CI – 14.0 to –1.6). Regarding EGFR mutation status, the first line ePFS was 7.0 vs 3.9 months for patients mut-EGFR and wt-EGFR, respectively (difference: 3.1, 95% CI –2.4 to 8 6). In the second line ePFS was 8.6 vs 3.7 months for patients mut-EGFR and wt-EGFR, respectively (difference: 4.9, 95% CI 1.4 to 8.4).

Conclusion: The greatest benefit of the TKI in mNSCLC could be obtained in patients who receive it as a second-line treatment. In second-line treatment, the presence of EGFR mutation duplicates the benefit in terms of ePFS.

P069 Sunitinib in metastatic breast cancer

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Introduction: Sunitinib is a protein kinase inhibitor indicated for the treatment of gastrointestinal stromal tumour, metastatic renal cell carcinoma and pancreatic neuroendocrine tumours. Our objective is to assess the efficacy and safety of sunitinib in a patient with metastatic breast cancer.

Material and method: Medical record was reviewed and the dispensing program to outpatient Dipex® was consulted, as well as the software application Farmis® for oncology treatments management. Also a literature search in PubMed® about the use of sunitinib in breast cancer was performed.

Results and discussion: 58-year-old female diagnosed with triple negative breast cancer in January 2012. She received 6 cycles of docetaxel/adriamycin/cyclophosphamide (TAC scheme) achieving partial response. Subsequently, the patient received 6 cycles of eribulin 1.4 mg/m² days 1 and 8 every 21 days with no response. After finding tumour progression to pleural level it was decided to treat with taxol/gemcitabine. In control studies conducted, new pleural progression and multiple foci of osteogenic activity suggestive of metastases were evidenced. In this situation and also considering the resistance observed in microarray study of the active drugs used in this disease, off-label treatment with sunitinib 50 mg/day for 4 weeks in 6-week cycles was requested. During the second cycle, the dose was reduced to 12.5 mg/day due to pancytopenia, being later increased to 25 mg daily based on pharmacokinetic study. Overall tolerance to sunitinib was acceptable, although some episodes of headache, diarrhoea and mild as thenia were recorded. After 48 weeks of treatment and due increased levels of the marker CA 15.3, an mTOR inhibitor was added in combination with sunitinib by a private oncologist team in second opinion. Currently, and due to hepatic progression, compassionate use of Palbociclib in expanded access trial is being considered.

Conclusion: In our case the off-label use of sunitinib in metastatic breast cancer maintains stable disease over a period of 48 week with no evidence of progression in the number and size of lesions.

Regarding safety profile, pharmacokinetic reports allow us to make individualized dosage adjustments and manage adverse effects, which were generally mild to moderate and in no case drug discontinuation was required.

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P070 Clinical outcomes of cabazitaxel in metastatic castration-resistant prostate cancer

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Introduction: Cabazitaxel (Cab) has received approval for treating metastatic castrate-resistant prostate cancer (mCRPC) patients after first-line docetaxel (Doc) therapy. The objective of this study was to provide clinical outcome data of mCRPC patients who received cabazitaxel after the failure of docetaxel, anti-androgens therapies (AAT) or both.

Material and method: Retrospective analysis was conducted of an oncology database to identify patients who progressed after docetaxel and received cabazitaxel. The primary endpoint was PSA response defined as a reduction ≥ 50% over nadir PSA. Secondary endpoint included: progression-free survival (PFS), estimated from the number of treatment cycles received and dose reductions for toxicity related with cabazitaxel.

Results and discussion: From January 2012 to the present, 23 mCPRC patients received cabazitaxel after docetaxel at our institution. Of these, 20 patients were evaluable in the present retrospective study. The median age was 68 years (range: 51–80). The median of previous lines of treatments was three: 6 patients received cabazitaxel as second-line therapy, 11 as third-line therapy and 3 as fourth-line therapy. The sequences of treatments post-docetaxel were: 13 patients Doc→Cab (docetaxel prior to cabazitaxel) and |7 patients Doc →AAT →Cab (docetaxel and antiandrogens prior to cabazitaxel). The PSA response rate was 20%, in these patients the median of reduction of PSA was −62.4% (95% CI, −84.7 −40%). In the no responders the median of PSA increased over nadir: +16.4% (95% CI, −5.1 +38%). The median number of treatment cycles was 5 (95% CI, 2.5–7.5). The primary reason for treatment discontinuation was disease progression. The estimated PFS was 2.6 months (95% CI, 1.4–3.7). Dose reductions were reported for 3 patients (15%). In our study the response rate was lower than the observed in the pivotal clinical trial of cabazitaxel, although the PFS was quite similar.

Conclusion: This study provided data in a real-world setting of the outcomes of patient who received cabazitaxel. Although the PFS is similar to the obtained in the pivotal trial of cabazitaxel, the PSA response rate is far lower. The estimation of PFS from the number of treatment cycles received and the limited number of patients can influence the results obtained.

P071 Establishment of a European best-practice model to support pharmacists in their care for patients in oral anticancer therapies

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Introduction: With more and more orally available anticancer drugs introduced to the market, patients are increasingly required to manage their cancer care at home. As antineoplastic agents have a narrow therapeutic range, medication errors, drug interactions and non-adherence can severely compromise the outcome and the patient's well-being. Thus, such patients need profound counselling not only by the oncologist, but also in the community pharmacy.

Material and method: Within this project, tools to support pharmacist counselling will be developed, refined, evaluated and transferred from Germany to two selected partner countries, i.e. Slovenia and Estonia, in order to create a best-practice model within the EU. The methods employed will be international cooperation and field research. The ultimate aim is to empower pharmacists to make a difference in the safety and effectiveness of oral anticancer therapy.

Results and discussion: Expected results of the project will be: i) the tools consisting of training programmes and a database for quick reference to the most relevant drug facts needed for the consultation; ii) an overview about the logistics, the current counselling practice and the need for postgraduate training concerning oral chemotherapy in the European Society of Oncology Pharmacy (ESOP) Member States as well as; iii) experience with transferring the tools to another country that may have a slightly different framework for the care of cancer patients.

Conclusion: The project results will be available for other EU countries and facilitate implementation of the supporting tools to the benefit of patients in oral chemotherapy. It will be finished in 2018.

P072 Pegylated liposomal doxorubicin and carboplatine combination in the treatment of recurrent ovarian carcinoma. Comparative long-term effectiveness and tolerability

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Introduction: Pegylated liposomal doxorubicin (PLD) can be used in combination with carboplatin as a first line for the treatment of advanced ovarian cancer or in monotherapy for the treatment of advanced ovarian cancer in women who have failed a first-line platinum-based chemotherapy regimen.

The encapsulation of doxorubicin in a pegylated liposomal potentiates intratumour accumulation giving a different toxicity profile and improving clinical utility. New combinations with cytotoxics, in particular with carboplatin, have demonstrated an acceptable safety profile and clinical utility in platinum-sensitive ovarian cancer. However, the comparision of the effectiveness and tolerability of PLD monotherapy or in combination with carboplatine has not been established yet.

The main aims of this study are: i) to compare the effectiveness of the PLD in terms of biochemical progression-free survival (BPFS) used alone or in combination with carboplatin, in first or second line for the treatment of recurrent ovarian carcinoma (ROC); ii) to compare the tolerability; and iii) to analyse the safety profile of PLD.

Material and method: Retrospective observational study of all patients treated with PLD for ROC over a period of 3 years (2012–2015) in a secondary hospital. Data were collected from medical records which also stored patient characteristics, their disease, adverse drug events related with the treatment, CA-125 levels and treatment received. Effectiveness was mainly evaluated with the BPFS.

Descriptive statistical analysis and cohort comparison was done. Demographic and clinical parameters were collected from the clinical history.

Results and discussion: 16 patients were included, with an average age of 64 years (95% CI: 45–79). 15 (94%) of patients had stage III or higher at diagnosis.

The combination of PLD with carboplatin was used in 11 (69%) of the patients and 5 (31%) received PLD in monotherapy. In more than 90% of cases PLD was used as second-line treatment. The median BPFS in PLD monotherapy group was 2.6 (13 weeks) vs 9.2 (46 weeks) in PLD-carboplatine combination (p = 0.031).

In addition, 69% (11) of all patients presented one or more adverse drug effect (ADE) with a total of 12 (2 were from the same patient). 4 (80%) of the patients treated with PLD monotherapy had at least one ADE: 3 (75%) of patients presented palmar-plantar erythrodysesthesia (PPE), 1 of the patients who had PPE also developed haematologic toxicity and 25% (1) myocardial toxicity. On the DLP-carboplatine combination group, 8 (73%) of the patients suffered an ADE: 4 (50%) PPE, 3 (37%) haematologic toxicity and 1 (13%) nausea. 3 patients did not develop any ADE.

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There were no significant statistical differences (p = 0.635, OR: 1.50 (0.08–51.7)) on the number of ADE in women treated with PLD monotherapy or PLD-carboplatine.

Conclusion: The addition of PLD when treating ROC was associated with increase in BPFS.

The benefit obtained was greater in the subgroup of patients with platine combination than that with DLP monotherapy. The proportion of adverse drug effects on patients treated with PLD (monotherapy or with carboplatin) in our hospital was higher (68%) than what it is reported (50%), especially in PPE. It could be explained by the major limitation of our study which is the low number of patients included. Nevertheless, we can conclude that adding carboplatine to PLD is not associated with a lower tolerability, which confirms that PLD is an ideal partner for combination regiments with other cytotoxics like carboplatine.

P073 Cost-effectiveness analyses of capsaicin patches in the management of neuropathic pain in cancer: preliminary results

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Introduction: The purpose of this study was to compare the cost-effectiveness of capsaicin patches, recently introduced in our regional cancer centre for the management of neuropathic cancer pain, to the current treatments (antidepressants, antiepileptics ...).

Material and method: A cost-effectiveness study started in January 2015. 10 patients treated with capsaicin patch were prospectively included and matched to 10 patients who received standard therapy. Matching was performed according to the origin of the pain (post-surgery or post-chemotherapy) and the number of analgesic treatment lines. The efficacy parameter was the reduction of at least 30% of pain intensity on the numerical rating scale after 3 months. The cost evaluation was performed from hospital perspective and was limited to direct costs. Those included data from the French funding system where we have substituted the cost of medical staff by those from an internal micro-costing.

Results and discussion: There was no significant difference between groups except for age; the historical cohort was significantly older than the prospective cohort. Reduction of pain intensity was greater in the cohort treated with capsaicin patch (27%) than in the cohort treated with standard therapy (15%).

For the costs, the average time to apply and remove patches was estimated at 75 minutes. The average cost for one day hospitalisation is Euros 16.58 in the capsaicin's cohort. The incremental cost-effectiveness ratio (ICER) is calculated at Euros 41.51 per responder patient.

The univariate sensitivity analysis showed a strong impact of the number of capsaicin patch applied (+4049% for 4 patches) and a more limited effect (less than 110% variation) of the other parameters (cost of medical staff, logistics ...).

Conclusion: Capsaicin patch is a cost-effective strategy to support neuropathic cancer pain in the hospital's perspective. However, the results seem affected considering the societal perspective or according to the number of patches applied.

P074 Supporting adherence to oral anticancer agents: clinical practice and clues to improve care

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Introduction: With the oral administration of anticancer agents, the issue of medication adherence is urgent. Patients' adherence is influenced by many factors and includes the influence of the healthcare providers (HCPs). The aims of this study were to assess current clinical practice of supporting adherence to oral anticancer agents (OACA) in Belgium and The Netherlands, to explore its relationship with HCP's perceptions of OACA adherence management and to find clues to improve adherence management.

Material and method: A cross-sectional, observational study among HCPs in (haemato-)oncology settings in Belgium and The Netherlands was conducted in 2014 by means of a composite questionnaire. A total of 47 usual care activities were listed and categorized in eight domains. Furthermore, HCPs were asked about their perceptions of adherence management on the items insight into adherence, patients' communication, capability to influence, knowledge of consequences and insight into causes. Validated questionnaires were used to assess beliefs about Medicines Questionnaire (BMQ) and shared decision-making (SDM).

Results and discussion: 208 HCPs (53% male) participated; 107 from 51 Dutch and 101 from 26 Belgian hospitals. The median scores per domain for, respectively, physicians, nurse practitioners, nurses and pharmacists were: Knowledge: 86-100-71-29%; Awareness: 75-75-63-0%; Self-efficacy: 60-80-50-0%; Intention Formation: 67-100-83-50%; Implementation: 25-50-25-0%; Social Support: 67-67-67-0%; Adverse Events Management: 100-100-100-29%; Facilitation: 64-73-55-27%. Belgian physicians reported more activities than Dutch physicians, whereas in The Netherlands nurses and pharmacists reported more activities than Belgian colleagues. The perceptions of adherence management were related to the level of care provided by HCP. SDM and BMQ were not related to provided care.

Conclusion: Though a wide range of activities was reported, some domains received less attention. Enhancing patients' knowledge and adverse event management were reported most whereas supporting self-efficacy and adherence during ongoing use were frequently missed. HCPs should improve addressing adherence directly, e.g. by questioning patients' (expected) barriers and discussing strategies to overcome them, asking after missed doses and offering (electronic) reminders to support long-term treatment. Enhancing HCP's perceptions of management of adherence may enhance the level of provided care. A multidisciplinary approach is advised in which the role of the pharmacist could be expanded.

NB: We prefer an oral presentation, combined with the abstract 'Adherence to oral anticancer agents: healthcare providers' beliefs and perceptions of adherence management'.

P075 Adherence to oral anticancer agents: healthcare providers' beliefs and perceptions of adherence management

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Introduction: With the oral administration of anticancer agents, the issue of medication adherence is urgent. Patients' adherence is influenced by many factors including healthcare providers (HCPs) related factors. The aim of this study was to explore HCPs' perceptions of oral anticancer agents (OACA) adherence management, beliefs about OACA, and shared decision-making (SDM) in Belgium and The Netherlands.

Material and method: A cross-sectional, observational study among HCPs in (haemato-)oncology settings in Belgium and The Netherlands was conducted in 2014 by means of a composite questionnaire. HCPs were asked about their perceptions of adherence management on the items insight into adherence, patients' communication, capability to influence, knowledge of consequences and insight into causes. Validated questionnaires were used to assess beliefs about medication (BMQ) and SDM.

Results and discussion: The sample of 254 participating HCPs consisted of 15% medical oncologists, 17% haematologists, 15% nurse practitioners (NP), 30% nurses, and 24% pharmacists working in 106 hospitals. Only 56% of physicians, 50% of NP, 27% of nurses and 23% of pharmacists indicated to know the level of adherence of their patients, and 59%, 53%, 43% and 10%, respectively, think that patients discuss adherence with them. Most HCPs indicated to have sufficient knowledge on the consequences of non-adherence (79%), and less had this on the causes of non-adherence (67%). 80% felt able to influence the adherence of their patients. Overall, physicians and NP scored higher than nurses and pharmacists. Nurses and NP had lower perceptions of the necessity of OACA than the other HCPs. Lower concerns beliefs were associated with higher scores on perceptions of adherence management.

Conclusion: A considerable part of HCPs reported that they do not know the adherence of their patients, nor do they think their patients discuss adherence to OACA with them. However, most HCP feel to have enough knowledge about adherence and perceive to be able to influence adherence of their patients.

Poster session: Managing side effects in oncology pharmacy/oncology pharmacist intervention

P076 Pharmacotherapeutic counselling by a clinical pharmacist on a paediatric haematology and oncology unit

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Introduction: Pharmacotherapy in paediatric haematology and oncology (PHO) patients is complex. To improve the quality of treatment and care, a team of 4 clinical pharmacists is involved in the PHO unit of the University Hospitals Leuven. To guarantee optimal continuity, standardization of the interviews is essential.

Material and method: Different types of interview are defined: first discharge interview, basic discharge interview, start-up of corticosteroids, start-up of an oral chemotherapeutic, maintenance therapy, tapering of corticosteroids. After each interview, the pharmacist registers patient and type of interview.

Results and discussion: From February 2014 until March 2015, 205 patients (0–18 years) were followed: 64 new diagnoses, 141 patients already on treatment. A total of 924 interviews were performed. The greatest attention is paid to the basic discharge interviews (n = 619, 67%), followed by start-up of corticosteroids (n = 74, 8%) and first discharge interviews (n = 65, 7%). Most of the interviews (74%) are done during hospitalization. Only 26% of the interviews are performed at day clinic.

Conclusion: Given the great amount of interviews, a full-time presence of a clinical pharmacist on a PHO unit is needed. As 74% of all the interviews are discharge interviews, and performed by a team of 4 pharmacists, a structured approach of these interviews is needed to guarantee content quality. In the near future a qualitative survey will be carried out at the physicians, nurses, patients and their families to evaluate the content of the interviews.

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P077 Pharmacist interventions in paediatric oncology: descriptive analysis and variables associated with prescription errors

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Introduction: Systematic prescription analyses by clinical pharmacists results in pharmacist interventions (PIs), to reduce prescription errors and improve medication safety. PIs are particularly required in oncology, because antineoplastic drugs are highly toxic with low therapeutic index especially in paediatric population. Medical prescription was based on an electronic order system with double-check by two physicians. Pharmaceutical validation is also achieved by two clinical pharmacists and each PI was kept. The aim of this study is to describe PIs in an oncology paediatric department and to identify potentials risk factors associated with prescription errors.

Material and method: A 20-month monocentric observational study in an oncology paediatric department (40 beds) focused on intravenous chemotherapy prescription. We standardized a database with gender, age, drugs, medical double-check hour, and kind of prescription: 'standard protocols' or 'non-standard' (as a manual prescription in our software). PIs were analysed for drug-related problems (DRP), type of intervention, involved drugs and potential risks factors identified. Three age range were defined as follow: 0–1, 1–10 and > 10 years; Double-check hour was also defined in three ranges as follow: 8–14 hours, 14–21 hours and 21–8 hours. Data were analysed with the statistical software RÂ®.

Results and discussion: Clinical pharmacists achieved 90 PIs for the 10,214 antineoplastic prescriptions. The most DRP involved vincristine, etoposide phosphate (also most prescribed) and carboplatin. Majority of DRP are dosage errors (61.8%) higher than > 50% in 17.5% of PI. This DRP can be imputable to measurements in 47.4% (weight and/or height) or no-reported dose reduction. Most age range was 1–10 years and 14–21 hours for double checks. There were statistically more prescription errors for standardized protocols ($p < 0.001$). In contrast to standard protocols, prescription and double check for a 'non-standard' are only performed by senior physicians and do not have prefilled items that may reduce dose error reporting.

Conclusion: Not surprisingly, PIs are predominantly for dose errors, half of which related to non-updated measurements. No significant error risk factors were identified except standardized status of prescription, which appears to be linked in part to software non-updated dose reduction. Medical double check follow by double clinical pharmacists' validation seems to be secure in medical prescription. Especially, double check with two seniors improved safety of non-standard protocols.

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P078 Study of cases of abiraterone suspension due to toxicity in pre-chemotherapy after one year's experience

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Introduction: Metastatic castration-resistant prostate Cancer (MCRPC) is defined by tumour growth despite lower testosterone levels of 50 ng/dL, and causes around 258,400 deaths per year worldwide. In the past, the only agent with proven survival benefit was docetaxel, but in the last five years, abiraterone, cabazitaxel, enzalutamide, radium-223, and sipuleucel-T have been developed concurrently, increasing the number of treatment options.

Abiraterone acetate is a potent and irreversible inhibitor of cytochrome p450 17A1 that suppresses androgen synthesis and may also act as an androgen receptor antagonist. It was studied in two large randomized clinical trials, first for docetaxel-treated MCRPC patients and then for chemotherapy-naïve MCRPC patients.

The development of a protocol for the use and selection for chemotherapy-naïve MCRPC patients is problematic, because patients with symptomatic disease were excluded from the phase III trial. New clinical trials focus on determining the optimal sequencing and combination between treatments. Few studies have been published about safety studies and clinical management for the approved indications.

The aim of this paper is to describe the selection protocol for MCRPC naïve patients treated with abiraterone candidates, and to evaluate, after one year of implementation of the programme, the cases in which the severity of adverse events led to the discontinuation of treatment.

Material and method: After the publication of COU-AA-302, the Galician Health Service (SERGAS) promoted a programme of abiraterone treatment for patients with chemotherapy-naïve MCRPC with public funding and at no cost to the patient. The cornerstones of the programme are the development of patient inclusion criteria and intensive monitoring by a multidisciplinary team of urologists and hospital pharmacists in coordination with primary care.

Inclusion criteria: good general condition, longer life expectancy than 6 months, no uncontrolled hypertension, cardiac or liver disease at the moment of initiating treatment, PSA doubling rate greater than 55 days, and no liver, cerebral or visceral metastases. The urologist responsible for evaluating the inclusion criteria for prescribing abiraterone carries out general analytical laboratory follow-ups (chemistry and blood count) and full quarterly reassessment of the patient with computed tomography (CT) and bone scintigraphy if necessary. The hospital pharmacist providing treatment dispenses pharmaceutical care every 4 weeks, checking the degree of compliance and tolerance. The pharmacist also gives the patient and their family full pharmacotherapeutic training and provides phone and email contact for any queries. The pharmacist informs primary care about the patient's inclusion in the programme, through electronic medical records.

After one year of implementation of the protocol 23 patients were included in the programme, 3 of whom have had serious adverse reactions to abiraterone requiring treatment to be discontinued.

Results and discussion: Case 1: 85-year-old patient with no known allergies. Diagnosed with prostate adenocarcinoma, Gleason VIII (IV + IV) in 2010. Treatment was started with an LH-RH agonist, adding bicalutamide since 2011.

Other antecedents were hypertension (controlled at the start of treatment), history of ischaemic heart disease resolved after stent placement in 2012, slight ventricular dysfunction (ejection fraction 44%) and light stenosis aortic valve.

After starting treatment with the standard dose of 1,000 mg abiraterone + prednisone 10 mg/24 hours, after 48 hours the patient began to feel a crushing chest pain that subsided with an oral dose of nitroglycerin. After several hours the episode repeated and the patient was transferred to hospital by the emergency services, with an arterial pressure of 190/108 mmHg.

After 48 hours in hospital, the patient was discharged, and treatment with abiraterone was halted.

Case 2: 92-year-old patient, Gleason VII (III + IV) diagnosed since 2003, treated with androgen deprivation therapy (leuprolide and bicalutamide).

Other antecedents of interest: controlled hypertension, chronic renal disease at the start of treatment, FGE 443.81 mL/min and creatinine 1.58 mg/dL, normal liver function. The patient was allergic to penicillin with a suspected allergy to other drugs (nystatin and quinolones).

Six days after starting treatment with abiraterone, the patient had pruritic erythematous lesions on the trunk, which increased over the next few days despite discontinuing AP and administering an antihistaminic (hydroxyzine 25 mg/8 hours) and increasing the corticosteroid dose (prednisone 30 mg/24 hours). Two weeks later, the patient was admitted to hospital, where the dermatologist added a topical corticoid (methylprednisolone) to the treatment, decreasing the oral corticosteroid dose and changing antihistaminic hydroxyzine for bilastine, leading to the almost complete disappearance of the lesions one month later.

Case 3: 56-year-old patient without known allergies. Gleason VII (III + IV) diagnosed in 2012, treated with androgen deprivation therapy (triptorelin).

Other relevant history: normotensive, no toxic habits, with liver function at the start of normal treatment (GOT 18 IU/L, ALT 18 IU/L and GGT 26 IU/L) and normal renal function (Cr 0.93 mg/dL). Transaminase levels were normal in all of the analyses carried out since the diagnosis of prostate adenocarcinoma in 2012.

Two weeks after starting abiraterone treatment, the transaminases were normal (GOT 23 IU/L, ALT 38 IU/L GGT 21 IU/L), but within 4 weeks of initiation the values were very high (GOT 243 U/L, ALT 586 IU/L and GGT 24 IU/L).

Treatment was stopped, and two weeks after discontinuation the serum levels of transaminases reached a peak (GOT 898 UI/L, ALT 2211 UI/L, 300 UI/L), which began to decline 4 weeks after cessation of treatment (GOT 39 IU/L, ALT 170 IU/L, GGT 159 IU/L) becoming almost normal six weeks after suspension (GOT 26 IU/L, ALT 40 IU/L, GGT 83 IU/L).

Conclusion: The development of a protocol for the use and selection of candidate MCRPC patients treated with abiraterone should be guided by the available studies (COU-AA-302 and COU-AA-301). This is problematic in the case of chemotherapy-naïve patients, as those with symptomatic disease were excluded from the phase III trial. The candidates for treatment should be asymptomatic or minimally symptomatic patients. It seems reasonable that patients with high Gleason scores, poor symptom control, rapidly progressive illness or poor response to initial antiandrogen treatment receive greater benefits from chemotherapy; however, no studies support this hypothesis.

In the COU-AA-302 trial, 19% of the patients had to discontinue treatment with abiraterone, compared to 13% in our centre.

The side effects in these three cases do not differ from the profile described in the literature, although they do highlight both the severity and the speed of their appearance.

Close transaminase monitoring should be recommended, especially during the first four weeks, as grade 3 or 4 hepatotoxicity was observed in 8% of the patients being treated with abiraterone, and the mechanism for abiraterone hepatotoxicity is still unknown. Abiraterone appears to be safe in patients with cardiovascular comorbidities, and has no significant QT/QTc interval effect, although these patients may benefit from modulation of the drug monitoring blood pressure, fluid retention and

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potassium levels. In the case of dermatological side effects, it is known that the incidence of bruising can reach 13% and skin rashes 8% in patients treated with abiraterone, although the intensity and severity of the reaction we observed in our patients was lower.

Based on all the above, we can say that even if the general condition of patients is good at the start of treatment, it is essential to monitor them, especially in the first four weeks.

The three cases have been reported to the Spanish pharmacovigilance system.

P079 Usage of granylocyte colony-stimulation factors to reduce the risk of febrile neutropenia – are our patients safe?

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Introduction: Chemotherapy-induced febrile neutropenia (FN) is a potentially life-threatening side effect of chemotherapy. Prophylactic use of granylocyte colony-stimulating factors (G-CSF) can reduce the risk, severity and duration of FN. The aim of our study was to assess the use of G-CSF among patients with solid tumours receiving chemotherapy regimens with high risk (> 20%) and intermediate risk (10–20%) of FN.

Material and method: We conducted a retrospective medical record review in tertiary hospital in Estonia. A total of 550 chemotherapy order forms from January to February 2015 were analysed. The use of G-CSF was compared to national Comprehensive Cancer Network (NCCN) guideline.

Results and discussion: In the current study, we used the data of 550 patients, of whom 230 were male and 321 female. The patients were 22 to 93 years old, the average age was 63.2 years. The most common diagnose among men was colorectal cancer (100 patients) and among women breast cancer (132 patients). Chemotherapy regimens with high risk of FN were prescribed to 4.2% of patients and regimens with intermediate risk of FN to 7.5% of cancer patients. According to the NCCN guideline, prophylactic use of G-CSF is indicated for all patients with high risk regimens and for selected patients (with additional risk factors) with intermediate risk regimens. We found that only 13% of patients with high risk regimens received G-CSF. Moreover, 37% of patients with intermediate risk regimens received G-CSF. Most of the patients with intermediate risk regimens who did not receive G-CSF had 1 or more additional risk factor (age 65 years, female gender, previous chemotherapy/radiation, pre-existing neutropenia, recent surgery, poor performance status, poor renal function, liver dysfunction), due to which the prophylactic use of G-CSF would have been indicated.

Conclusion: FN is a frequent and the most dreadful side effect of chemotherapy. Our study indicated a rather significant underutilization of G-CSF, especially in patients receiving regimens with high risk of FN. Since the risk of FN can be substantially decreased with appropriate use of G-CSF, further studies are needed to investigate the causes and consequences of this underutilization.

P080 Adverse drug reactions reporting in ESOP member countries

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Introduction: Adverse drug reactions (ADRs) reporting is very important especially in terms of patient safety, as it allows a better understanding of adverse events and their consequences, detection of risk factors and still undiscovered side effects, ascertaining the safety profile of medicines, updating guidelines for prescribing and use of medicines to ensure their maximum safety and the withdrawal of marketing authorization (if it is based on an assessment of collected data that the benefits of treatment does no longer outweigh the risks).

Material and method: In October 2015 we sent out the questionnaire to determine status of ADRs reporting in European Society of Oncology Pharmacy (ESOP) member countries. By the end of November we received 132 responses from 33 countries from across the world. Results of the questionnaire were reviewed and statistically analysed.

Results and discussion: High response rate from 33 different countries gave the insight to ADRs reporting status across the world. The majority of respondents come from hospital pharmacy (92%). 70% of respondents have reported any ADRs, out of which 53% are using special online programme for ADRs reporting, other 47% are sent out in paper form. Special online programme is used in 20 ESOP member countries. 58% of respondents are reporting only to national agency, 37% are reporting to both national agency and pharmaceutical companies. Among reasons for reporting, the predominant response was seriousness of reaction (49%).

Conclusion: ADR reporting is still highly underrated. For health professionals represents extra work and although it is regulated in most of the countries, the report rate is very low. Generally we are not aware of the importance of ADRs reporting so contribution of pharmacists across the world is highly recommended.

P081 Non-pegylated liposomal doxorrubicin for the treatment of breast cancer: study of 53 patients

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Introduction: Non-pegylated liposomal doxorubicin in combination with cyclophosphamide is indicated in previously untreated patients with metastatic breast cancer. This drug is associated with lower cardiac toxicity than conventional doxorubicin, and for that reason it has been used in old patients or patients with cardiac disease.

Objectives: The objective of this study was to evaluate the use and safety of chemotherapy schedules including non-pegylated liposomal doxorubicin in patients with breast cancer.

Material and method: Observational and retrospective study of breast cancer patients treated with non-pegylated liposomal doxorubicin in a general hospital since January 2014 to August 2015. In each patient demographic data (age and sex), clinical and biological variables, as well as therapy and toxicity were recorded.

Results and discussion: 53 patients were included, all of them were women. Median age was 64 years. The most frequent cardiovascular risk factor was hypertension, seen in 20 (38%) patients. 2 (4%) patients had received previous treatment with anthracyclines. Only one (2%) out of the 53 women was suffering from metastatic breast cancer, the rest (98%) were diagnosed with non-metastatic locally advanced breast cancer. No one received the drug as first-line treatment; 32 (60%) as adjuvant treatment and 21 (40%) as neoadjuvant treatment. In all cases non-pegylated liposomal doxorubicin was administered as part of the AC schedule (non-pegylated liposomal doxorubicin and cyclophosphamide). Neutropenic fever was observed in 4 (8%) patients, requiring growth factor-e-stimulated, nausea or vomiting in 4 (8%), requiring antiemetic drugs, while only two (4%) patients developed post-chemotherapy anaemia, requiring epoetin injections. 2 (4%) patients had a left ventricular ejection fraction lower than 50% at the time of starting treatment. A decrease of value of the left ventricular ejection fraction was observed in 11 (21%) patients, this value remained constant in 12 (23%) and, in the rest, it was not possible to study due to lack information.

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Conclusion: The use of non-pegylated liposomal doxorubicin does not meet to indications of European public assessment reports (EPAR) in all of patients. All patients with prior anthracycline exposure should undergo baseline cardiac assessment. In this cohort of patients, most of them old and with cardiovascular risk factors, the administration of non-pegylated liposomal doxorubicin was effective and safe.

P082 Chemotherapy induced mucositis: utilization of a compounded oral suspension

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Introduction: Mucositis is a common complication in patients undergoing chemotherapy and radiotherapy. This adverse effect may limit patients' tolerance to therapy and, therefore, its effectiveness.

Currently, there is no standard treatment and its management is based on an adequate oral hygiene, mouthwashes with local anaesthetics for pain control, and topical antifungals for the prevention of fungal infections. In our hospital, the Pharmacy Department compounds an oral mucositis compounded suspension (MCS) which contains sodium bicarbonate, gentamycin, nystatin, mepivacaine and hydrocortisone.

The objective is to evaluate the utilization of the MCS in patients with chemotherapy and/or radiotherapy induced mucositis during their hospital stay.

Material and method: Observational, descriptive retrospective cohort study. Patients that developed mucositis during their hospital stay between June 2014–2015 were included.

The electronic prescriptions and the medical records were reviewed and the following data was collected: patients' characteristics (gender, age, diagnostic), clinical variables (grade of mucositis, neutropenia), suspected treatment causing mucositis, treatment: dosage regimen and duration of the MCS, additional treatments, and date of resolution of mucositis. The severity was assessed using the World Health Organization toxicity scale.

Results and discussion: Seventy patients were included (80% women). Median age 69 years (SD:1.85). The most common diagnoses were: acute myeloid leukaemia (10%) and head and neck cancer (9%).

Mucositis severity distribution was: grade I (65%), grade II (24%), grade III and grade IV (11%). At admission, 32% of patients presented neutropenia. Suspected causes of mucositis were chemotherapy (73%) and radiotherapy (27%). The drugs most commonly associated were: cisplatin (14%), etoposide (13%), oxaliplatino (11%) and 5-fluorouracil (9%).

The most frequent dosage regimen was three times a day (87%). The median duration of treatment was 6 days (IQR: 3–12). No adverse reaction was recorded. In 35% of patients other mouthwashes were used: bicarbonate (47%), lidocaine (50%), nystatin (41%) and chlorhexidine (7%). 90% of patients required analgesia: orally (12.7%), intravenously (87.3%) and 32.9% require morphine.

Also 35.7% of patients needed antimicrobials for the prevention of fungal infections. In 50% of the patients mucositis was resolved by the 8th day (IQR: 14–3).

Conclusion: Platinum salts, etoposide, and fluorouracil were the drugs related with the development of mucositis. The management of oral mucositis has been effective with the use of the MCS and well tolerated, but for pain control it has been necessary administration of analgesia, highest by systemic via. Having a proper oral hygine are essential to reduce the incidence and severity of mucositis complications that can threaten the effectiveness of the oncology therapy.

P083 Pharmaceutical interventions following thoracic oncology prescriptions

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Introduction: The anticancer drugs process is computer-assisted and pharmaceutical validation of prescriptions is mandatory for pharmaceutical preparations of anticancer drugs. The pharmaceutical analysis is based on the anticancer protocol, the biological analysis and the chemotherapy doses of patients and leads to pharmaceutical interventions (PI). The objective of this study is to review PI in thoracic oncology unit and assess their impact on treatment.

Material and method: This is a retrospective study of PI recorded between January 2012 and December 2014 conducted on thoracic oncology prescriptions. The data collected are problem identified, type of PI proposed and their impact on prescribing (accepted or rejected by the prescriber).

Results and discussion: A total of 4,656 anticancer drugs were prescribed and 101 were followed by a PI equivalent to an intervention rate of 2.2%. The most commonly reported problems were over-dosing (42.5%) or under-dosing (18%), improper prescription (protocol error, too short delay between two cycles) in 30% of cases, not suitable monitoring including the use of a laboratory analysis older than three days for 6% of cases. We identified 14 cases of over- or under-dosing of carboplatine due to an incorrect value of creatinine indicated in the prescription software. Following interventions have been made by the pharmacist: dosage adjustment (56.5%), new prescription (23%), treatment discontinuation or change date of chemotherapy (13%) and therapeutic monitoring (7%). The interventions were accepted in 90% of cases by prescribers.

Conclusion: More than half of the PI concerned a dose adjustment. Despite the security provided by computerized process, we identified some errors: lack of creatinine actualization for each cycle, dose reduction maintenance or stop for the previous chemotherapy cycle. The identification of such problems leads to improve and secure anticancer treatment for cancer patients.

P084 Validation of a specific tool elaborated for coding pharmaceutical interventions in oncology

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Introduction: Pharmaceutical analysis of prescriptions in oncology contributes to secure cancer patients' management. Indeed, it allows detecting and preventing medication errors. In France, the only instrument for the documentation of pharmaceutical interventions (PI) is validated and published by the French Society of Clinical Pharmacy since 10 years ago. A recent study has allowed us to demonstrate that their tool was adaptable, but not specific enough in the field of oncology. Based on this reference support, we have developed a tool to code the PI specific to oncology in order to standardize and enhance this clinical pharmacy activity (http://bit.ly/1Q0a4Fa). The aim of this study is to assess the level of agreement between pharmacists using this tool in order to validate it.

Material and method: A panel of 13 pharmacists from 6 hospitals had to analyse 19 clinical cases collected in participating hospitals with standardized and harmonized presentation. They had to identify drug-related problems [PROBLEM], pharmacist intervention [INTERVENTION] and

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clinical or economic impact [IMPACT]. The categories PROBLEM, INTERVENTION and IMPACT contain 20, 13 and 4 items, respectively. We assessed the level of agreement with Kappa (Îº) coefficient of concordance (interrater agreement), using the R software. Îº equal to 1 corresponds to highest level of inter-rater agreement and p values < 0.001 is the accepted level of significance.

Results and discussion: The level of concordance observed was substantial for PROBLEM [Îº = 0.71, p < 0.001] and INTERVENTION [Îº = 0.74, p <0.001], and fair for IMPACT [Îº = 0.28, p < 0.001]. On 33 PROBLEM and INTERVENTION items assessed, 43% of items had an inter-rater agreement considered almost perfect, 24% substantial, 15% moderate, 6% fair and 9% as none to slight. Only, one item (3%) is reported with no agreement but not significate (p = 0.87). The impact is only assessed by pharmacists and it would require a medical analysis. The variability of results may be due to the low number of clinical cases tested. The results led to remove 3 items because they were redundant, specify 5 items, and 4 items have been preserved but have switched category due to a misuse.

Conclusion: This is the first coding instrument specific to oncology PI developed, in France, and a satisfaction study is underway. The final version of the tool is already used by different hospitals in our region in order to collect PI in a harmonized way and we aim to distribute it nationally and internationally.

P085 Evaluation of appropriate glucarpidase prescription to prevent iatrogenic incident and reduce medical cost

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Introduction: Glucarpidase is prescribed as rescue therapy in patients with an overexposition following high-dose methotrexate (HD-MTX) of more than 1g/mÂ². Although it is an unlicensed and very expensive medicine available on a named patient basis authorization, complexity lies in lack of national consensus about rules of its prescription.

Material and method: Our university hospital specialized in haematology and paediatric oncology conducted a retrospective study on glucarpidase clinical use. Descriptive analysis reports clinical and biological data about methotrexate administration, management of overdosage and adverse effects. We assessed compliance of glucarpidase prescriptions with the referentials widely used [1].

Results and discussion: From March 2005 to October 2015, on 1,982 patients who received HD-MTX (1–12 g/m²), 12 adults and 9 children required rescue by glucarpidase given as a single dose at 50 mg/kg. Median age was 31 years (range 6–75 years) and sex-ratio was 2.5. Methotrexate was infused over 0.5 to 24 hours according to the therapeutic procedure for the underlying disease including lymphoblastic leukaemia or lymphoma (n = 7), diffuse large B-cell lymphoma (n = 5), Burkitt's lymphoma (n = 4) and osteosarcoma (n = 5). Patients were naïve from HD-MTX (n = 13) or have already received 1 cycle (n = 4), 2 cycles (n = 3), 15 cycles (n = 1). All subjects have normal creatinine clearance before start of methotrexate and received alkaline hyperhydratation and prophylactic folinic acid. Glucarpidase was started 2 days after methotrexate infusion (range 1–4 days) when methotrexate serum levels ranged between 0.35 and 96 µmol/L.

The main adverse effect was reversible acute renal failure grade 1 (n = 8), grade 2 (n = 10) or grade 3 (n = 3). Other grade 3 to 4 toxicities were cytopenia, febrile aplasia concomitant with cutaneous desquamation, uncontrollable vomiting, mucositis. Only 3 patients completed the planned treatment, while 9 patients received adapted treatment (dose, delay, switch) and 5 treatment were discontinued.

We reported adequate management of methotrexate overdosage but salvage by glucarpidase seems increased since last 4 years (n = 16) without change in our local protocol.

Conclusion: In front of these results, we constituted a working group with physicians and the pharmacovigilance department in order to identify risk factors. This study highlights the need for consensual guidelines about glucarpidase use and the role of hospital pharmacists in the monitoring and the securing of HD-MTX prescription.

References

[1] OMEDIT Centre - Commission Anticanc©reux: fiche de recommandation Voraxaze®.

P086 Adverse drug effects related with capecitabine generic in comparision with Xeloda®

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Introduction: 5-fluorouracil (5FU) is among the most commonly used chemotherapy drugs in oncology practice. It is used to treat colorectal cancer, upper gastrointestinal cancers, breast cancer, and head and neck cancers, either as a single agent or in combination with other chemotherapy drugs. Capecitabine (Xeloda®) is an oral prodrug of 5FU and is increasingly replacing infusional and bolus intravenous 5FU. Capecitabine is a tablet formulation and is usually self-administered by patients at home. Common toxicities of 5FU and capecitabine include diarrhoea, mucositis and myelosuppression. Roche's blockbuster Xeloda® went off patent in December 2013, so it was inevitable that a generic would hit the market at some point.

The aim of this study is to assess the adverse drug effects in all patients treated with capecitabine in our Hospital and to compare it with what it is reported in the studies with Xeloda®.

Material and method: Retrospective observational study of all patients treated with capecitabine for any indication over a period of 1 year and a half (from March 2014 to November 2015) in a secondary hospital. Data were collected from medical records which also stored patient characteristics, their disease, regimen received and adverse drug effects graded according to the National Cancer Institute of Canada common toxicity criteria (NCIC-CTC). Demographic and clinical parameters were collected from the clinical history.

Results and discussion: We included 53 patients with a mean age of 68 years (95% CI: 37–81) and 51% were women.

32 patients were in treatment with capecitabine in monotherapy, 13 with capecitabine in combination with oxaliplatine, 3 in combination with bevacizumab, 4 with radiotherapy and 3 in combination with mitomicine. Capecitabine was used to treat colorectal cancer in 39 (73.6%) patients, breast cancer in 8 (15.1%), pancreatic cancer in 4 (7.5%), upper gastrointestinal cancer in 1 (1.9%) and ovarian cancer in 1 (1.9%) patient.

Of all patients, 8 (15.1%) had to reduce the dose, 11 (20.8%) had to stop the treatment and the rest of them, 34 (56.6%) had no changes in their treatment. Moreover, these events (stop or dose reduction) generally occured more frequently when capecitabine was associated with another chemotherapy.

The adverse drug effects were: diarrhoea in 10 (19%), hand-foot syndrome grade 2 or more in 8 (24.5%), asthenia in 5 (9%), dermical toxicity in 3 (6%), blood and lymphatic system disorders in 2 (4%), mucositis in 2 (4%), anorexia in 2 (4%) and vomiting in 1 (2%) patient, whereas the most commonly reported adverse event (all grades) in all studies for Xeloda® was hand-foot syndrome (also known as PPE), followed by diarrhoea, nausea and vomiting, and in all cases they were slighly higher. Nevertheless, the exact percentage depends on the dose received, the indication and the regimen.

Conclusion: One limitation of this study is that we could not compare the adverse drug effects of capecitabine with the ones of Xeloda® in our

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hospital because we used it for a few patients, we preferably used 5FU. Nevertheless, we can conclude that:

- Generally, we saw slightly less adverse drug effects in our patients treated with capecitabine regarding what it is reported about Xeloda®.
- Adverse effects occurred more frequently when capecitabine was associated with another chemotherapy.

Symptoms are usually reversible following discontinuation of capecitabine. Moreover, previous studies have demonstrated that there is no significant increase in the risk of progression [hazard ratio (HR) 1.07, Wald test p = 0.73] in patients in whom the dose has to be reduced compared with those not requiring dose reduction, so we can conclude that capecitabine is a useful treatment, but careful monitoring during the first and subsequent cycles of treatment is recommended for all patients.

P087 Prevention and treatment of chemotherapy-induced nausea and vomiting in adults with ovarian cancer

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Introduction: Pharmacists prescribe and monitor, in consensus with oncology, individualized post-chemotherapy antiemetic regimes for all patients in our hospital. Antiemetic therapy prescribed to ovarian cancer (OC) patients in the last four years is evaluated.

Material and method: Retrospective observational study of OC patients treated with standard chemotherapy who received antiemetic therapy between November 2011 and October 2015 (both included). Depending on emetogenic potential (EP) of the chemotherapy scheme, the pharmacist assigned and explained to the patient/family the most suitable antiemetic regime as:

- Low EP: metoclopramide 10–20 mg tds as needed (PRN)
- Moderate EP (Kit-1): dexamethasone 4 mg tds 2 days, then 4 mg bid 2 days, then 4 mg od 2 days, and metoclopramide 10–20 mg tds PRN
- High EP (Kit-3): Kit-1 plus granisetron 1 mg at evening of chemotherapy

When patient had no emesis on previous cycle, a reduction on regime was done, but if nausea/vomiting were felt, there was reinforcement on the regime: dosing metoclopramide around-the-clock, adding dexamethasone/granisetron of the next higher group, aprepitant on those with cisplatin-based therapies or lorazepam in anticipatory nausea/vomiting. Patient/family was always involved in treatment decisions. Patient data, prescriptions and monitoring were collected from Oncofarm® application and 'Antiemetic Therapy' Pharmacy's Database, and analysed using SPSS statistical package.

Results and discussion: 54 OC patients (average age 58; 38–80) received a total of 605 chemotherapy cycles. 497 antiemetic prescriptions were dispensed, so 82.17% of times a patient received chemotherapy, came to pharmacy for antiemetic drugs. 34 (63%) patients came every time they had a cycle, 3 (5.5%) never did it, and 17 (31.5%) were absent in some cycles (8 for optimal control and no antiemetics needed). 39 (72.2%) patients started with Kit-3 and the other 15 with Kit-1. Reduction of antiemetics was performed in 47.6% of patients and 25.9% required reinforcement, adding metoclopramide around-the-clock (20.4%) and/or lorazepam (5.5%).

Conclusion: The large number of antiemetic prescriptions states the good acceptance from patients of the healthcare provided by the pharmacy. Although progressive reduction of antiemetics was performed in almost a half of patients, this ratio was lower, and the reinforcement ratio higher than in another chemotherapy groups studied (lung, colon), being female, sex, and age (younger than in other groups) possible factors of this finding.

P088 Regorafenib-induced grade 4 acute diarrhoea

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Introduction: Regorafenib is an oral multi-kinase inhibitor which targets angiogenic, stromal and oncogenic receptor tyrosine kinase (RTK). It is indicated in metastatic colorectal cancer (mCRC) in patients who have been previously treated with available therapies or are not considered candidates for such therapies. The most common adverse reactions are asthenia/fatigue, hand-foot syndrome, diarrhoea, decreased appetite, hypertension, dysphonia and infection. In the CORRECT study, the incidence of diarrhoea in patients with mCRC treated with regorafenib was 34%, with less than 1% grade 4 diarrhoea. The objective of the study is to describe a case of grade 4 diarrhoea induced by regorafenib.

Material and method: Review of the patient's medical history and analytical data of haematology, biochemistry and microbiology laboratories.

Results and discussion: 63-year-old male patient diagnosed with mCRC (liver and peritoneal) native RAS, who received a first-line treatment with FOLFOX + cetuximab. After hepatic progression, he received a second line with FOLFIRI + aflibercept and, after the evidence of new liver and perirectal progression, was decided to start treatment with regorafenib (120 mg/day). Four days after starting treatment, the patient came to the Emergency Unit referring hypogastric pain and diarrhoea loose watery stools up to seven without pathological products, one day of evolution, associated with vomits four times, and severe fatigue that caused falls with patellar injuries and incapacitated him for standing. During his hospitalization in the Emergency Unit presented dysuria and hypotension requiring treatment with dopamine and catheterization. The analytical data (haemoglobin 20.5 g/dL; haematocrit: 62.7%; mean corpuscular volume: 90.1 fl; creatinine 2.40 mg/dL; potassium: 3.33 mEq/L) showed a clear dehydration secondary to diarrhoea. Radiography thoracic and abdominal showed no significant findings. Stool cultures, urine and blood cultures were all negative. With all these findings was diagnosed diarrhoea G4 induced by regorafenib, prerenal renal failure secondary to diarrhoea and fatigue G3 caused by his advanced disease and drug toxicity. After the administration of supportive care and discontinuation of regorafenib the patient had a favourable evolution, with decreased number of diarrhoeal stools and normalization of hemodynamic parameters.

Conclusion: Although our patient has diarrhoea G4, which appears in the CORRECT study as a rare adverse reaction (<1%), the fact that hemodynamic parameters and the symptoms were normalized after withdrawal of the drug, which was administered at a lower dose than that specified in data sheet and in only four days, it suggests that diarrhoea is an idiosyncratic, not dose-related, side effect of regorafenib.

P089 Notification of adverse effects of anticancer drugs in oncology

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Introduction: Chemotherapy treats many types of cancer effectively. But like other treatments, it often causes side effects. These are different for each person. They depend on the type of cancer, location, drugs and dose, and your general health. The notification in oncology is, therefore,

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a necessity so as to permanently evaluate the relation benefit/risk of every anticancer drug, this study aims to present the most important side effects of anticancer drug, to follow and to prevent their occurrence. Also, we will present the case of reporting of adverse effects of chemotherapy at the National Institute of Oncology of University Hospital Center of Rabat.

Material and method: We present a descriptive study conducted at the National Institute of Oncology in Rabat. The study was performed in the period from January 2014 to June 2014.

The oncology pharmacist notified adverse events to drugs and other health products on register of notifications and reported the anticancer drugs failures.

Results and discussion: We found at the day hospital reserved for daily chemotherapy, various adverse events were detected:

- Oxaliplatin: respiratory problems with a dry cough.
- Oxaliplatin: skin reaction with facial redness and at arms.
- Bleomycin, etoposide, cisplatin in association: flagellate eryhtema in all the body of the patient.
- Oxaliplatin: tingling in the mouth and feet and loss of taste.
- Fluotouracile, irinotecan, bevacizumab, folinate de calcium: severe mucositis grade IV.

Conclusion: Notification of any defects such as it is, especially in oncology, is the only strategy and solution to monitor the safety of cytotoxic and subsequently improve patient health.

P090 Extravasation of antineoplastic drugs

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Introduction: When antineoplastic drugs are administrated intravenously there is a possibility of extravasation, which is one of the worst complications associated with injecting of medicines. It can result in heavy tissue damage, but also in necrosis. Extravasation of antineoplastic drugs is associated to their involuntary outflow or infiltration in perivascular or subcutaneous area during the time of their intravenous application. Our goals are to present frequency of extravasation, to classify antineoplastic drugs and to show how this phenomenon can be prevented or cured.

Material and method: We collected data by examination of relevant scientific literature, oncology societies' guidelines, national guidelines, and by searching through bibliographic databases containing keywords like: chemotherapy, cytotoxics drugs, extravasation and management.

Results and discussion: Extravasation incidence ranges from 0.1% to 6%. According to possibility to cause local tissue damages, cytotoxic medicines are divided into: vesicant, irritans and non-vesicants. Some tissue injuries that heal slowly and hardly can result in decrease function of extremities, and even amputation. Because of these reasons, extravasation significantly affects quality of patient's life, which is reduced in the first place by disease itself and chemotherapy side effects, influences delay of chemotherapy protocols, extends hospitalization, but also causes lawsuits worldwide. Thus, it is of high importance to prevent extravasation. This includes both specific and non-specific procedures; specific procedures are non-pharmacological and/or pharmacological therapies, and if they fail, surgical methods have to be conducted. Antidotes are given according to the type of antineoplastic drug.

Conclusion: Extravasation is a serious chemotherapy complication. Prevention and constant education of medical personnel is of highest importance in reduction of extravasation, but if it comes to that a correct treatment according to the type of extravasated drug has to be conducted. Supervising extravasation of antineoplastic drugs is a part of direct pharmaceutical care for oncology patient.

This work is the result of collaboration of Working Group for Oncology Pharmacy, employees of Hospital Pharmacy and Department of Medical Oncology in Clinic for Tumors of Clinical Hospital Centre Sisters of Mercy, Zagreb, Croatia.

P091 Importance of clinical pharmacist on oncology ward regarding evaluation of side effects

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Introduction: Role of the clinical pharmacist on oncology ward is still not appropriately validated in many countries worldwide. In this case report we are going to present the value of clinical pharmacist on the outcome of the treatment.

Material and method: Patient with hormone positive (ER 100%, PR 10%) and HER-2 (1+) negative metastatic breast cancer was admitted into the hospital because of the rash over his body after he received CMF (cyclophosphamide, methotrexate, fluorouracil) protocol. His medication history included ablation of his left breast and adjuvant treatment with FAC protocol (fluorouracil, doxorubicin and cyclophosphamide) and later adjuvant treatment with hormone therapy including tamoxifen. Three years after he was diagnosed with metastatic breast cancer disease with metastases on liver. Council for systemic antineoplastic treatment decided to treat him with docetaxel and capecitabin protocol and later after progression with cisplatin and etoposide protocol.

Because of progression couple of months later, council decided to treat him with CMF protocol. In the middle between first and second cycle, patient was admitted in hospital because of symptoms of serious rash which improved after the symptomatic treatment (dexam ethasone and chloropyramine). As the rash occurred, suddenly his treatment with CMF protocol became questionable. After clinical pharmacist reviewed his medication history, chronic use of cetirizinum became suspicious. In addition his medication history revealed allergy on ragweed, hazel and birch. Then clinical pharmacist lead couple of structured conversations in which he found out that patient started to use many herbal product bought in a local shop and not approved by national drug agency. He started to use it couple of days after his first cycle of CMF was applied.

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Patient was advised not to use any of herbal products during his chemotherapy treatment because of their lack of evidence on benefit in cancer treatment and possible harmful effects.

Results and discussion: After discussion of clinical pharmacist and oncologist, council for systemic antineoplastic treatment decided to continue treatment with CMF protocol.

Second cycle of CMF protocol was very well tolerated without any serious toxicities and allergic reactions. In this case we demonstrated importance of the structured communication between clinical pharmacist and oncology patient on an oncology ward. Also we demonstrated that pharmacist as a part of multidisciplinary team can improve communication between oncology patient and healthcare personnel which can have positive impact on healthcare service.

Conclusion: Result of good communication between clinical pharmacist and oncology patient on an oncology ward can have impact on treatment decision and consequently on outcome of the treatment.

This work is the result of collaboration of: Pharmacy and Medical Biochemistry College University of Zagreb, Working Group for Oncology Pharmacy, employees of Hospital Pharmacy and Department of Medical Oncology in Clinic for Tumors of Clinical Hospital Centre Sisters of Mercy, Zagreb, Croatia.

Poster Session: Organization and management

P092 Use of oncology drugs through a compassionate use in a specialty hospital

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Introduction: The access to investigational drugs for patients who are not included in a clinical trial and without authorized therapeutic alternatives is known as compassionate use. The incorporation of the evidence-based medicine in the area of onco-haematology has implied that an important part of clinic therapy validated by evidence that could not be controlled from an administrative point of view. This is due to the continuous and progressive development of investigation and information on cancer treatment and the delay of the administration regulation. The use of drugs in this way is regulated by Royal Decree 1015/2009 (19/6).

The objective of the study is to describe the use of cancer drugs through compassionate use in the last 5 years in a specialty hospital.

Material and method: Descriptive retrospective study on a specialty hospital. All the applications for a compassionate use drugs were analysed from January 2011 until October 2015. The data were obtained from medical records programme Diraya® and from an Excel database of medicines in compassionate use of the Pharmacy Service. The following variables were registered:

- Number of patient clinic history
- Authorized medicine
- Authorization date
- Applicant Service.

Results and discussion: We recorded 80 requests of cancer drugs in compassionate use during the five years of study. Oncology was the service that recorded more authorizations with 95%, followed with Gynaecology with 2.5% and finally Endocrinology and Haematology with 1.25%.

64 drugs of the 80 requests were approved (80%) and 16 unauthorized (20%) in the 5 years of study. The year in which more applications were received was 2013 (31.25%) and the least requests were received in 2012 (6.25%), being the year where all requests were authorized.

In 2015 fewer applications were authorized, 75%. In the years 2011, 2013 and 2014 were authorized 88.3, 76 and 88.3%, respectively. A total of 34 different active drugs were received during the study, the most requested Bevacizumab (24%) for grade III oligoastrocytoma, ovarian cancer (monotherapy), metastatic gall bladder cancer and metastatic platinum-resistant ovarian cancer, Everolimus (18%) for indications of neuroendocrine carcinoid tumour and metastatic breast cancer, Nab-paclitaxel (18%) for invasive lobular carcinoma indications of high-grade and metastatic pancreatic cancer, ipilimumab (12%) for the indication of metastatic melanoma, and Regorafenib for indications of colorectal cancer and metastatic GIST I pretreat with imatinib (12%).

Conclusion: The solicitude of drugs through compassionate use needs effective commissions of Pharmacy and Therapeutics, along with the Medical Management to establish an agile and faster requesting circuit and the consequent use monitoring.

P093 Specialization of a hospital pharmacist resident in oncology – a Dutch example

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Introduction: Oncology is an important area of interest within hospital pharmacy where collaboration with the department of clinical oncology and responsibility of the hospital pharmacist has been established. Currently, oncology education of hospital pharmacists in The Netherlands is limited and focusses on composing therapy protocols, compounding, and logistics. As the field of oncology is changing rapidly, a more thoroughly educated and specialized oncology hospital pharmacist is needed for involvement in oncology patient care. A new curriculum for educating hospital pharmacists comprising one year of 'differentiation' offers an opportunity for a more profound specialization in oncology pharmacy practice. In the Leiden University Medical Centre, we designed and tested a draft for this oncology differentiation within the hospital pharmacy education programme.

Material and method: From July to December 2015, a hospital pharmacy resident performed a clinical oncology specialization during the last year of the current 4-years curriculum for hospital pharmacists.

Within these six months, the resident participated as a pharmacy consultant weekly in the clinical meeting with clinical oncologists and nurses, the multidisciplinary palliative care meeting and outpatient meeting of the clinical oncology department. Concurrently, the resident performed project assignments such as rewriting the dose modification in renal and liver failure patients' section of the oncology drug formulary, and the evaluation of the methotrexate blood level sampling protocol. Teaching nurses, pharmacy practitioners, oncologists and hospital pharmacists in clinical education sessions formed both an educational and competence training for the resident. Both an oncology specialized hospital pharmacist as a clinical oncologist supervised the activities. Finally, forming one of the end products, the resident wrote a draft for the oncology differentiation in the new national education curriculum for hospital pharmacists.

Results and discussion: Time spent on oncology pharmacy specialization turned out to be around 50% (57 of 125 days) due to sideline activities, such as routine pharmacy consultancy shifts and obligatory courses on other subjects. Participation in clinical meetings averagely led to one intervention per meeting, concerning dosing advice, therapeutic drug

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monitoring or drug interaction related interventions. The majority of time was spent on project assignments and preparing clinical educations. The regular attendance of the resident in the clinical oncology department led to an increase in requests from both doctors and nurses. Supervision and feedback were successfully given by two different disciplines of supervisors. A draft for the differentiation programme for the hospital pharmacist education was written and reviewed by the Special Interest Group Oncology of the National Association of Hospital Pharmacists (NVZA).

Conclusion: A differentiation in oncology for hospital pharmacists should contain clinical consultations, project assignments on implementation of new policy and teaching different target groups in order to educate the hospital pharmacist resident in all aspects of oncology pharmacy.

P094 Descriptive study of the impact of clinical trials in a tertiary cancer centre

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Introduction: Onco-haematology is one of the areas in which further research and development of new treatments exist. Clinical trials (CT) give patients the opportunity to receive novel treatments, contributing in turn to the development of therapeutics.

The aim of this study is to evaluate the impact of CT in the daily activity of a tertiary cancer hospital, regarding the treatment profile per pathology of patients receiving oncospecific treatment.

Material and method: Information about patients treated with chemotherapy during 2014 on our site was obtained from our electronic integral chemotherapy system. For the analysis, data was stratified according to patients being treated in the healthcare setting or included in a CT. From the same source data, diagnosis and route of administration of the chemotherapy was collected.

Results and discussion: During 2014, a total of 3,878 patients received oncospecific therapies on our site, 508 of whom did so in a CT setting (13%).

Overall, 83% of patients were oncologic patients, with the main diagnoses being: breast cancer (686 patients, 17.7% of the total), colorectal cancer (436 patients, 11.2%) and non-small cell lung cancer (NSCLC) (307 patients, 7.9%). Regarding patients with haematologic malignancies (659 patients), the majority of them were patients with lymphoid malignancies (426 patients, 11% of all treated patients).

The 3 main pathologies in which more patients were included in CTs were: breast cancer (146 patients, 21.3% of patients with this diagnosis included in a CT), colorectal cancer (58 patients, 13.3% of all patients with such diagnosis treated in a CT setting) and lymphoid malignancies (54 patients, 12.7% of all patients with this diagnosis included in a CT).

Notably, despite the fact that, globally, melanoma patients treated on our site only accounted for 1.7% of the total (66 patients), 48.5% of them received treatment in a CT setting (6.3% of all patients included in a CT were melanoma patients). By contrast, in NSCLC, only 8.14% of the 307 patients with such diagnosis were treated within a CT, representing only a 4.9% of the 508 patients treated in a CT in 2014.

When evaluating treatments according to their route of administration, of all patients treated with oncospecific therapies in 2014 on our site, 1,122 (29%) received at least one oral drug in an outpatient setting. Of these 1,122 patients attended in the Outpatient Dispensing Unit in the Pharmacy Department, 232 (21%) were treated in the context of a CT. At the same time, 45% of the patients included in a CT received at least one oral drug in an outpatient setting, as part of their oncospecific therapy.

Conclusion: According to this data, cancer patients treated on our site are mainly diagnosed with oncologic malignancies. Three of the pathologies in which more patients were recruited for CTs match up with those for which a majority of patients were treated in the healthcare setting (breast cancer, colorectal cancer, and lymphoid malignancies). Much of the CTs currently ongoing include orally administered drugs on an outpatient basis. This together with the fact that 29% of the patients treated on our site receive treatment in an outpatient setting is actually changing the goal for pharmaceutical care into a more patient-centred care, in Outpatient Dispensing Units from Pharmacy Departments.

P095 Surgical thread between reality and perspective

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Introduction: The Pierre and Marie Curie Centre (CPMC) Algiers, is a hospital establishment specialized in cancerology, the centre contains three main surgical services: The Bloc A and Bloc C for General Cancer Surgery and Block B for mastology surgery. The distributed sterile surgical thread is under the responsibility of the hospital pharmacist. Misuse, lack of training and sometimes of information concerning the thread, the several brands represented in the Algerian market, cause a not easy management of surgical thread.

The objective of this work is to allow the hospital pharmacist to contribute in the surgical thread management improvement for a better patient's care.

Material and method: A retrospective study has been made from 2013 to 2015 on the different surgical services forcasts as well as the consumption, based on accounting data and purchase orders. We have made a comparative study of the actual consumption and the estimated quantity depending on the specificity of each surgical service within the CPMC.

Results and discussion: The economic estimation allowed us to have a balance consumption/cost for each surgical service, to classify the thread according to the type of surgery. Consequently, the balance gain/loss per service is obtained.

We have found that whatever the type of thread used, actual consumption is below the forecast of every service, up to 1/4 for the non-absorbable thread. This affects the overall cost.

For 2014 the overall cost of the surgical thread forecast rises to Da 28,001,494.32 or the equivalent of Euros 241.513 the cost of the actual consumption amounted to Da 8,997,822.24 equivalent of Euros 77,606 so just over 1/3 of forecasts

Conclusion: The difficulty for choosing surgical thread is a reality because of its diversity in the market, its cost and the lack of normalization until today. The hospital pharmacist's function is to ensure the quality and safety to the patient. He/She must make a wise judicious choice that meets the surgeons needs in conformity with the indication in a manner which minimizes losses and the high cost prices.

P096 Nivolumab: the concept of dose banding

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Introduction: Nivolumab is a human monoclonal antibody against PD-1 receptor and blocking thus its interaction with PD-L1, an immune checkpoint and inhibiting consequently T-cell activation and proliferation. Intravenous administration of nivolumab was approved by the European Medicines Agency (EMA) in August 2015 in Europe. Previously nivolumab was administrated in an early open access programme for patients with unresectable malignant melanoma, locally advanced or metastatic squamous non-small cell lung cancer or Hodgkin disease.

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The recommended dose is 3 mg/kg administered intravenously every 2 weeks. Treatment should be continued as long as clinical benefit is observed or until treatment is no longer tolerated by the patient. The increased activity of this drug leads pharmacists to consider implementation, in agreement with medical staff, of dose banding.

Material and method: A retrospective study over 7 months (January to July 2015) was conducted on the computerized prescriptions of nivolumab. All the patients who received nivolumab were included and the data (dosage, frequency, weight) were extracted from the prescription software Chimio®. The objective was to fix standardized rounded doses (+ or – 10% standard deviation) in order to cover all the doses most frequently prescribed corresponding to weight ranges.

Results and discussion: A total of 54 patients (26 women and 28 men) were included in this study. The median age was 55 years [26–83]; median weight was 75 kg [43–117]. They received a median of 6.15 cycles [1–15] of nivolumab and represent a total of 332 preparations. These preparations represent 18 different doses (130 mg to 350 mg). The distribution of the calculated doses follows a Gaussian curve. Indeed 66 prescripted doses (20%) are < 200 mg, 243 doses (73%) from 200 to 300 mg, and 23 doses (7%) are > 300 mg. The most prepared dose was 230 mg (n = 60 corresponding to 18% of the total preparations).

The maximum variation of the adjustment between the standard dose and the doses calculated for each band is 10% or less. 3 standard doses can be proposed: 200 mg [corresponds to the interval of 180 to 210 mg], 240 mg [220–260 mg] and 300 mg [270–330]. These proposed doses correspond to vial dosages of the commercial drug (100 mg and 40 mg or nivolumab) and adequate volumes. The dose of 200 mg represents 23% of the production, 240 mg represent 52% of the production and 300 mg represents 14%. 89% (295/332) of the prescriptions are covered with these 3 doses.

Conclusion: Because of its lack of stability, nivolumab cannot be prepared early. But these dose banding aim to improve quality and economy, optimization of time for preparation reducing thus the patient waiting time, and possibility of reattribution doses between patients (reduced drug wastage). The start of these dose banding began in September 2015 (date of marketing authorization). Moreover, these doses are within the concept of flat dose, in fact the 240 mg dose of nivolumab is being developed in future clinical trials.

P097 Role of drugs committee in management of expensive drugs in Moroccan hospital

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Introduction: The introduction of expensive drugs in hospital requires a special management of these molecules. It is desirable to create a committee which ensures the attribution and rational practices for the management and use of these medicines.

The aim is to describe the missions, and operational mode of 'expensive drugs committee' in our hospital.

Material and method: It is a medico pharmaceutical committee which was created by one pharmacist and two oncologists, in November 2015, in National Institute of Oncology Rabat, Morocco

Results and discussion: The 'expensive drugs committee' meets whenever it is necessary. It is responsible for managing four drugs: Denosumab, Everolimus, Sunitinib and Pertuzumab.

The principal missions of the committee are the evaluation of patient files and eligibility criteria, the attribution of anticancer treatment, the monitoring of patients and consummation of drugs, the evaluation of side effects. It ensures also the availability of the drugs.

Conclusion: The goal of the 'expensive drugs committee' is to improve the availability, accessibility and use of medicines. These activities can have substantial impact on the quality of care.

Poster Session: Palliative care in oncology pharmacy

P098 The oncology pharmacist as part of the palliative treatment team

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Introduction: Patients who are no longer eligible for curative treatment in an oncology setting are often complex and require a multidisciplinary approach. To achieve best support and symptom relief, different medical specialists should cooperate in developing a care plan for patients in the last stage of their lives. For this reason, many hospitals have set up integrated palliative treatment teams, generally including a specialized nurse, oncologist, psychologist, pain specialist (anaesthetist) and dietician.

According to the guidelines from the national cancer centre in The Netherlands, including a pharmacist is not a requirement to get reimbursement for the palliative team. Hence, most hospitals have palliative teams without regular participation of a pharmacist. The objective of this study was to evaluate the oncology pharmacist interventions in a palliative treament team.

Material and method: The oncology pharmacist was established as a full member of the palliative team in the OLVG Hospital in Amsterdam, making it a multiprofessional team.

The OLVG is a top clinical teaching hospital of 550 beds with a large in- and outpatient oncology department. The oncology pharmacist participated in all regular patient reviews and rounds. In addition, the oncology pharmacist was available for individual consultation by all members of the palliative team on a daily basis.

Results and discussion: From 2012 to 2015, 196 patients were discussed and treated by the palliative team. In 60% of the cases, the oncology pharmacist made an intervention or contributed to optimizing patients medication. The most common interventions by the pharmacist were:

i) Initiating second- or third-line treatment for complaints that proved therapy-resistant on first choice drugs, such as fatigue, anorexia or neuropathic pain
ii) Stopping drugs that were no longer useful, and thereby preventing unnecessary overtreatment
iii) Optimizing sedative regimens in patients who were benzodiazepine-tolerant and/or had a history of drug abuse
iv) Starting local treatment to relieve local symptoms of cutaneous metastasis, ulcera or wounds
v) Advising the medical specialist on reimbursement options for second- or third-line drug regimens.

The average time investment of the oncology pharmacist was 35 minutes per patient.

Conclusion: The oncology pharmacist adds valuable knowledge to the palliative treatment team, helping to optimize patients' well-being in the palliative phase.

Poster Session: Treatment/regimen

P099 Off-label use of gemtuzumab ozogamicin in acute promyelocytic leukaemia – a case report

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Introduction: Acute promyelocytic leukaemia (APL) is a subtype of acute myeloid leukaemia (AML), characterized by t(15;17) fusing PML gene to the retinoic acid receptor (RARÎ±) gene.

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In 2000, Gemtuzumab Ozogamicin (GO), an anti-CD33 antibody carrying a cytotoxic derivative-calicheamicin - granted accelerated approval by US Food and Drug Administration (FDA) and European Medicines Agency (EMA) in CD33+ AML patients in a dose of 9 mg/m². Due to the outcome of SWOG-S0106 study, specifically the lack of overall survival benefit and increased rate of early mortality, Pfizer voluntarily withdrew the drug in the US in 2010.

However, emerging data from recent trials (ALFA-0701) indicate that GO in lower doses improves survival for many AML patients, supporting the conclusion that CD33 is a clinically relevant target.

Material and method: Clinical file and literature review on PubMed.

Results and discussion: A 71-year-old male patient was diagnosed with an intermediate risk APL on 13 August.

Treatment was started according with GIMEMA AIDA-2000 induction scheme. After 1st consolidation, a complete haematological response (CHR) and negative PML/RARÎ± - complete molecular response (CMR) was obtained. After 2nd consolidation cycle, the CHR was maintained but a loss of CMR was observed. Treatment continued with 3rd consolidation but a haematological relapse was observed on 14 February.

A salvage treatment with ATO monotherapy was proposed. After the 1st ATO cycle CHR was obtained, but remained PML/RARÎ± positive. Treatment continued with 1st consolidation ATO cycle and two maintenance ATO cycles but he remained PML/RARÎ± positive, so ATRA was added on the next maintenance cycle. However, after the 3rd maintenance cycle he still had a positive PML/RARÎ± result.

On 15 February, he was proposed for autologous stem cell transplant and started PETHEMA HD-AraC-Mitoxantrone as mobilization cycle. Nevertheless, CMR was not achieved at the end of chemotherapy and therefore transplant project was abandoned.

On 15 April, on a 2nd haematological relapse, he started GO 3 mg/m² with ATO-ATRA as induction scheme. Pancytopenia occurred as expected and red blood cell and platelets transfusion was supported as needed. At the end of this cycle the patient achieved again CHR. Minimal residual disease (MRD) monitoring by RT-PCR (real time polymerase chain reaction) was in a descending profile (May 736; June 162; July 0.2 PML/RARÎ± copies) so the patient started consolidation cycle with ATO-ATRA on 15 August. The GO was added in the 2nd consolidation cycle (GO-ATO-ATRA) on 15 October and the last MRD performed by RT-PCR monitoring on 15 November, was 0.5 copies.

Conclusion: As GO had their marketing authorization refused by EMA on 2008, our patient had access to the drug through a Pfizer compassionate use programme, and after approval by local Ethical Committee.

In our patient, with relapsed disease, 3 mg/m² GO showed improved anti-leukaemic activity, strongly supporting that lower doses of GO can be delivered with acceptable toxicity in APL and suggesting that the GO license status might be considered for review.

P104 Safety and effectiveness of bi-weekly docetaxel in frail/elderly patients with metastatic castration-resistant prostate cancer (MCRPC)

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Introduction: Treatment with docetaxel in combination with prednisone is the standard first-line treatment in patients with metastatic castration-resistant prostate cancer (mCRPC). Our aim is to review the available safety and effectiveness data of docetaxel in a bi-weekly (50 mg/m²) schedule as an alternative to the standard 3-weekly docetaxel (75 mg/m²) regimen in frail and/or elderly patients.

Material and method: A retrospective, observational study including patients with metastatic castration-resistant prostate cancer (mCRPC) treated with Docetaxel in a bi-weekly (50 mg/m²) schedule from January 2015 to November 2015. Data recorded: age, ECOG performance status, previous taxanes treatment, pre-treatment and mid-treatment serum prostate-specific antigen (PSA) levels, treatment starting and ending dates, treatment cycles and adverse events (AE). Effectiveness was determined by Response Evaluation Criteria In Solid Tumors (RECIST) and Common Terminology Criteria for Adverse Events v4.0 were utilized for AE reporting and safety assessment.

Results and discussion: Of the 12 patients reviewed, the average age was 75 years [standard deviation (SD) 5.0; range 61–79], all had baseline ECOG PS of 2 and all had metastatic castration-resistant disease. 4 patients had received prior treatment with 3-weekly docetaxel (75 mg/m²). The average number of cycles of Docetaxel in a bi-weekly (50 mg/m²) schedule administered per patient was 7 (SD 3.8; range 3–16). Pre-treatment average PSA level was 441 ng/mL (SD 366.1; range 28–1,001) and mid-treatment average PSA level was 228 ng/mL (SD 326.4; range 0.5–871). Objective response rate assessed was 25%, 3 patients with partial response. 4 patients (33.3%) achieved stable disease and 3 patients (25%) had progressive disease. 2 patients response had not yet been evaluated. 2 patients experienced grade 3 toxicity (asthenia and skin toxicity, respectively) requiring treatment discontinuation. 9 patients experienced mild adverse events (asthenia/fatigue (50%), anaemia (33%), skin toxicity (33%), neutropenia (17%), al opecia (8%), diarrhoea (8%)) requiring treatment delays, but no dose modifications or discontinuations. 1 patient did not experienced any AE and no treatment modification was required. In the TAX 327 study (considered the pivotal trial for US Food and Drug Administration (FDA) approval of docetaxel in prostate cancer) men treated with docetaxel administered every 3 weeks showed a tumour response rate of 12% and a toxicity profile including neutropenia (32%), febrile neutropenia (2.7%), neuropathy (30%) and diarrhoea (32%).

Conclusion: We conclude that bi-weekly docetaxel (50 mg/m²) is active, safe and well tolerated in heavily pre-treated frail/elderly patients with poor prognostic features, including low performance scores and multiple metastatic sites, who would not be eligible for treatment with the standard 3-weekly regimen. Further studies with a larger sample may strengthen our initial work and may allow considering this scheme as a new valid option for these patients.

P107 Therapeutic approach of lung epitheliod haemangioendothelioma

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Introduction: Pulmonary epithelioid haemangioendothelioma (HEP) is a multicentre tumour that appears most often in young women, with an unpredictable outcome. They usually have a slow course with poor metastatic activity. To confirm the diagnosis, histological findings (observation of Weibel-Palade bodies), and immunohistochemical (tumour markers as Factor VIII and CD34) are important. There is not a specific treatment regimen because of the few cases diagnosed. In this work we try to describe the case of a patient diagnosed with HEP, and the effectiveness and safety of the treatments used to control the disease and symptoms.

Material and method: Review of the available literature and the history of the patient, collecting clinical, pathological and immunohistochemical characteristics.

Results and discussion: 44-year-old woman with no history of interest which presented dry cough with fever, night sweats and pain in the left

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maxillary region radiating to the latero-cervical area to the left side of four weeks of evolution. The thoracic radiograph showed retrocardiac opacity with blurring of the left hemidiaphragm, suggestive of pleural effusion vs pneumonia. In the computerized tomography of thorax, abdomen and pelvis, multiple nodules in both lung fields were observed; LII atelectasis associated with left pleural effusion and left hilar lymphadenopathy of 13 mm. In the pathological examination it was observed neoplastic cell infiltrate affecting the subepithelial corium and which was composed of large cells with large cytoplasm and nucleus hyperchromatic, irregular. With immunohistochemical techniques, the cells described were positive for carcinoembryonic antigen, CD-34, D2-40 and vimentin and uncertain negativity to Factor VIII. With these findings was diagnosed a HEP.

The patient started first line of palliative chemotherapy according to the scheme paclitaxel 75 mg/m² on days 1, 8 and 15 and bevacizumab 10 mg/kg on days 1 and 15, in 28-days cycles, with remission of symptoms which were object of study and remaining stable disease during the first three cycles. This treatment was well tolerated, except gingivitis, moderate anaemia and neutropenia which did not require the use of erythropoietin and colony stimulating factors. After the sixth cycle, liver and uncertain bone progression was evident, therefore it was decided to initiate a second-line treatment with ifosfamide and adriamycin, in 21-days cycles, which currently continues the patient, having 4 cycles administered with good tolerance.

Conclusion: The combination of paclitaxel plus bevacizumab could be considered a valid option in the management of HEP, with a progression-free interval of 6 months, with good tolerability and improved quality of life. It would be necessary to control the evolution of the case to determinate the effectiveness of the second-line chemotherapy used (ifosfamide plus adriamycin).

P108 Evaluation of the use of fosaprepitant in cancer patients at AUBMC

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Introduction: Nausea and vomiting are common and serious side effects in cancer patients on chemotherapy. Fosaprepitant (Ivemend ®) is a selective neurokinin-1 receptor antagonist, which prevents chemotherapy-induced nausea and vomiting (CINV) in high and moderate emetogenic chemotherapy drugs. The aim of this study is to evaluate the use of Ivemend® in chemotherapy patients at the American University of Beirut Medical Center.

Material and method: This is a retrospective study of 1,350 patients above 20 years of age.They were on chemotherapy for a period of 1 year from: February 2014 to February 2015. Use of Ivemend® was evaluated according to the updated National Comprehensive Cancer Network (NCCN) guidelines 2015.

Results and discussion: 92.6% of the patients received high or moderate emetogenic intravenous antineoplastic agents. They took Ivemend® in compliance with the NCCN guidelines. 7.4% of the patients did not comply with the guidelines as they received Ivemend® with a low emetogenic antineoplastic agent. The use of Ivemend® requires ongoing patient evaluation to determine the best approach for each individual.

Conclusion: This study shows that there is general adherence to the NCCN guidelines in correspondence to the use of Ivemend® as a prophylaxis for chemotherapy-induced nausea and vomiting.

Poster Session: Other

P109 Body surface area and body weight of Czech adult cancer patients

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Introduction: Body surface area and body weight-based dosing dominate current chemotherapy protocols. Almost all new cytostatics tested in clinical studies follow this consensual approach. Body surface area is calculated from body weight and body height using various formulas, predominantly DuBois and DuBois formula, which, though developed for completely different purposes 100 years ago, plays the role of reliable standard. While in some countries, there is recent information describing the anthropometrics of the cancer population, no data were available for Czech population.

Material and method: Body surface area and body weight of adult patients who were administered intravenous chemotherapy at Masaryk Memorial Cancer Institute in 2013 and 2014 were recorded. The total number of evaluated patients was 3,873. Correlations between anthropometrics and age, place of residence, and diagnosis were evaluated statistically.

Results and discussion: The mean body surface area was 1.78 m² for women, 2.00 m² for men, and 1.86 m² in total. The mean body weight was 71.94 kg for women, 83.43 kg for men, and 76.09 kg in total. The patients with upper gastro-intestinal tract cancer were found to have significantly lower body surface area and body weight than patients with lung, or colorectal cancer (both genders, $p < 0.05$), or with breast or ovarian cancer (women, $p < 0.0005$).

Conclusion: Because highly innovative drugs are also highly expensive, the data are essential for therapy cost prediction. Secondly, the data offer an insight to the anthropometric characteristics of Czech population in general and can be of use in other fields of medicine. Furthermore, the data characterize contemporary Czech people and can act as baseline if some changes occur in the future.

P110 Surrogate endpoints in metastatic breast cancer in first- or second-line trials

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Introduction: In recent years, the number of anticancer drugs entering the market, after the completion of clinical trials in which the efficacy and safety results are evaluated based on surrogate variables, has increased. A surrogate endpoint for a randomized clinical trial (RCT) may allow assessment of the relative benefits of the treatment to be performed at an earlier time point and potentially with a smaller sample size. However, a lack of consensus exists regarding its validity.

Material and method:

Objective:

1. To evaluate the correlation between surrogate variables of disease-free survival (DFS) and response rate (RR) and overall survival (OS) in patients with metastatic breast cancer (MBC).
2. Develop a linear regression model to predict OS in patients with MBC based on the surrogate variables.

Methodology:

RCT phase III trials for first- or second-line chemotherapy in MBC were identified using a PubMed and EMBASE search. Endocrine therapy trials were excluded. Spearman's non-parametric correlation coefficient was used as a measure of correlation between the difference in the surrogate variables (DFS and RR) and the difference in OS (OS). The significance of the coefficients was determined using the normal approximation of the z-transformation of the coefficient and its standard deviation. Confidence intervals to 95% (CI 95%) were calculated for those correlation coefficients with a statistically significant result. Also, a linear regression model was used through the origin, considering the OS as a dependent variable and each of the surrogate variables (DFS and RR) as an independent variable

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Results and discussion: 34 trials, 73 arms, and 41 comparisons, for a total of 12,367 patients, were included in the analysis. The RR and the DFS, are the surrogate variables most frequently analysed in the RCTs conducted. Targeted agents are only evaluated in 6 RCT.

Spearman rank correlation coefficients (rs) between median DFS, and ORR with OS were 0.59 (95 % CI 0.39–0.73) and 0.17 (CI 95%: -0.05–0.37). The regression coefficient in â^†PFS and OS was 0.73 ($p < 0.004$); the slope of the regression line was 0.54.

Conclusion: The use of the variables DFS in RCTs that evaluate the efficacy of anticancer drugs in first- or second-line chemotherapy in patients with MBC may be appropriate, although it is important to consider the magnitude of their variations. Further analyses are required to confirm the surrogacy of surrogate endpoints with new targeted agents.

P112 Evaluation of chemical contamination of waste containers within a centralized cytotocix reconstitution unit

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Introduction: As part of an assessment policy and risk management, centralized cytotoxic reconstitution unit (CCRU) of our hospital has evaluated environmental contamination. The objective of the study was to determine the contamination of waste containers hermetically sealed by anticancer agents from production area. The platinum is considered as a model molecule because their derivatives represent more than 20% of preparations realized in our hospital. Furthermore, electrothermal atomic absorption spectrometry is a reliable technique for platinum trace assay surfaces.

Material and method: The surface samples at the gripping area (2 samples of 200 cm^2 per container) were performed on 3 types of containers: small containers used and sealed under isolators (J), large yellow and blue containers used in a controlled atmosphere area (GJ and GB). The analysis was performed according to the validated method of Chappuy and Co. Their method includes a linear calibration curve from 6 to 150 ng platinum per sample. The limit of detection and the limit of quantification were 2 and 6 ng of platinum per sample, respectively.

Results and discussion: A total of 19 J (n = 38 samples), 2 GJ (n = 4 samples) and 3 GB (n = 6 samples) were analysed. 4 of the 48 samples showed a contamination beyond the limit of detection: 2 in a J (6 and 9 ng/sample) and 2 in a GB (8 ng/sample). Despite the low level of contamination, personnel in charge of waste disposal is potentially exposed. These results allowed raising awareness of assistant pharmacist and hospital agents to individual protection. Wearing gloves is the only protective barrier between the manipulator and cytotoxic molecules. Gloves should guarantee optimal protection and their characteristic is of paramount importance. The use of powder-free gloves, latex or nitrile is recommended, and vinyl gloves should be avoided according to the literature.

Conclusion: Handling of waste containers may expose to risk as well as the transfer to the garbage of hazardous drugs and contaminated supplies. The management of anticancer drug waste containers must be carried out by qualified personnel. Disposable gloves and disposable gowns should be worn to preserve personnel from risk exposure and to prevent spread of contamination in the environment.

P113 Fatal interaction between brivudine and capecitabine: a case report

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Introduction: The metabolite of brivudine is an irreversible inhibitor of dihidropyrimidine dehydrogenase (DPD), the enzyme then inactivates the final active metabolite of capecitabine, 5-fluorouracil (5FU). Due to enhanced 5FU toxicity, the combination of brivudine with 5-fluorpyrimidines is absolutely contraindicated.

We report a fatal drug interaction with capecitabine and brivudine.

Material and method: We review the electronic medical record. A literature search in PubMed was conducted with the keyword terms 'brivudine' AND '5-fluorpyrimydine'.

Results and discussion: The case involved a 60-year-old male diagnosed with gastric carcinoma pT3NoMo. The patient was being treated with capecitabine 1,800 mg b.i.d for 14 days, followed by one week drug-free interval. The patient took the last dose of capecitabine 3 days before he was admitted to the hospital after a severe diarrhoea. After admission he was diagnosed with severe mucositis, Stevens-Johnson syndrome, myelosuppression and thrombocytopenia. He was treated with empirical broad spectrum antibiotics and other symptomatic treatments.

Two days later, and after the poor outcome after all treatments, it was confirmed with the family of the patient that he was treated with brivudine at dose of 125 mg QD for one week just before admission. It was prescribed by the general practitioner for a herpes zoster. After this finding, the clinical picture suggested DPD deficiency. The patient continued experimenting a clinical worsening so at the Pharmacy Department, we performed a review of the literature in order to look for any experimental treatment. We read one case of a patient with DPD deficiency after fluoropyrimidine administration who had a complete recovery after an intravenous infusion of thymidine. We found out that there was a hospital in Spain which was using sodium thymidine monophosphate, for oral use, for the treatment of a genetic disorder in a child. They were able to lend us just 100 g of the product and we prepared a neutral solution in the laminar flow chamber. It was administered to the patient at a dose of 8 g/m^2/day (15 g/day) under off-label use. We prepared it just for 6 days until it ran out. The product was imported from China and there was not enough time to purchase any more. The patient did not experience any drug adverse event associated to the infusion but we could not measure its real clinical effect. Finally, the patient was transferred to the ICU and later on he died from a septic shock.

The drug interaction was reported to the Regional Committee of Pharmacovigilance.

Conclusion: The combination of brivudine and capecitabine is a life-threatening interaction with not a current available etiological treatment. Therefore, it is crucial to improve the communication between all healthcare providers in order to prevent a concomitant prescription of both drugs despite visible warning labels on the package of brivudine.

P114 Environmental contamination with cytotocix drugs in European hospitals ESOP project

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Introduction: Evaluation of environmental contamination with cytotoxic drugs in hospitals is fundamental to ensuring the safety of all healthcare workers. Safe handling procedures should be closely monitored in all areas where antineoplastic drugs are delivered, stored, prepared, administered and disposed of. No multicentre and non-commercial studies have been conducted in European hospitals.

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The main goal was to conduct an overview of the levels of contamination in European hospitals in the areas identified. The secondary goal was to evaluate environmental contamination with cytotoxic drugs circulating within the hospital medication system (process flow of drug) and to evaluate the impact of changes in local working practices. The preliminarily results will help to develop additional steps and programmes to improve working conditions and quality control.

Material and method: A pilot study was conducted at 19 hospitals (results from 15) evaluating the surface contamination in the preparation and administration areas before (part 1) and after (part 2) the implementation of the cleaning recommendations. Assessments of surface contamination with 12 antineoplastic drugs were performed using wipe samples taken from 10 comparable surfaces (5 each in the preparation and administration areas). These samples were analysed by LC-MS/MS.

Results and discussion: The pilot study demonstrated the presence of surface contamination in preparation and administration areas in all hospitals, with measurable amounts of at least one agent detected on sampled surfaces. Before the implementation of the European Society of Oncology Pharmacy (ESOP) cleaning recommendations, 505 out of 1,764 results were positive (29%). In 11 of 15 hospitals (73%), substances were detected which were not prepared or administrated in the sampling day. After implementation, only 17% of samples were positive (274/1,584). Contamination was detected mostly on the work surfaces of BSCs/Isolators, floors (in pharmacies and on wards) and the armrests of patient's chairs. The highest number of positive results were recorded with gemcitabine, 5-fluorouracil (5FU), cyclophosphamide and paclitaxel, with the highest values for gemcitabine (171 ng/cm²) and 5FU (37 ng/cm²). A causal relationship between the number of preparations and the level of contamination could not be derived.

Conclusion: The pilot study provided an overview of the local procedures for safe handling of cytotoxic drugs in European hospitals. The results indicate that current cleaning procedures do not remove residual drug from the surfaces. In part 2 of the study, there were less positive samples, lower concentrations detected, and a reduction of the 90th percentile from 0.030 ng/cm² to 0.021 ng/cm². For the third part of the ESOP project, a strategy of wipe sampling, analysis and implementation of the cleaning recommendations will be used. The results of the ongoing study will be presented at the European Conference Oncology Pharmacy (ECOP), Dubrovnik, 19–21 May 2015.

P115 Dose banding of 5-flourouracil infusers on an oncology day ward: an assessment of feasibility and impact on current local practice

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Introduction: The increasing incidence of cancer places additional demand on the finite capacity of hospital Aseptic Compounding Units (ACUs) for chemotherapy supply. Cytotoxic drugs are dosed using body surface area to minimize inter-patient variability in therapeutic response; preparation of individualized doses adds to ACU capacity problems.

Dose banding is a chemotherapy dose-rounding system, agreed between pharmacists and prescribers. Patient doses are rounded to predetermined banded doses, which are outsourced as stock items. Dose banding has the potential to improve ACU capacity.

Material and method: The overall aim was to assess the feasibility and impact of introducing a dose banding system for 5-fluorouracil (5FU) 46-hour infusers in a defined patient cohort on the Haematology-Oncology Day Ward (HODW) in St James's Hospital (SJH).

A literature review, fieldwork and retrospective review of local dosing patterns were conducted to assess the feasibility of introducing 5FU 46-hour infuser dose banding. A consultant-approved dose-banding scheme was developed and introduced. The impact of dose banding was primarily assessed through pre- and post-implementation surveys of stakeholders.

Results and discussion: Rationalization of 5FU 46-hour infuser doses from 22 to 9 banded doses was achieved (3,250–5,424 mg dose range). The 5FU dose-banding table had > 90% capture for all 46-hour infusers prescribed at the HODW. Stakeholders were open to the concept of dose banding.

Dose rationalization was the primary benefit of dose banding in the context of the ACU in SJH. Dose banding offers two economic advantages: a reduction in wastage and the opportunity to negotiate prices with external suppliers. Regional dose banding strategies have been adopted in the UK to maximize these benefits.

Conclusion: Dose banding of 5FU 46-hour infusers was feasible in SJH. Dose banding is a viable option in SJH to rationalize outsourcing of chemotherapy with the aim of increasing ACU capacity.

P116 Return of non-administered chemotherapy preparations: pharmacoeconomic analysis

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Introduction: Chemotherapy preparations of the National Institute of Oncology are centralized into the centralized Preparation of Cytotoxic Unit (CPCU). When the drug administration to patients is cancelled, all these preparations are returned to the pharmacy in order to be treated according to the existing procedure. The main objective of this study is to show the ratio of cancellation of injections administrations with the cause's identification, economic impact and their implemented corrective actions.

Material and method: We conducted a prospective study of six months at Centralized Unit Cytotoxic preparations of the National Institute of Oncology at Ibn Sina Hospital in Rabat. We checked all anticancer preparations returns. The ratio of non-administered preparations, the associated costs and returns patterns were analysed and a corrective measure has been implemented.

Results and discussion: We recorded all non-administered preparations matched to 56 prescriptions of 18 different molecules (5-fluorouracil, calcium folinate, doxorubicin, gemcitabine ...). 85.72% of the preparations have been reused and 14.28% were destroyed because of the assignation failure or physico-chemical and microbiological product instability. Each returned preparation was accompanied by a return form. The causes were classified as: 67.86% preventable causes and 32.14% not preventable. The average cost of a single bag of returned preparations was MAD 880 (Euros 88). The overall cost of a bag ranged from MAD 29.06 (Euros 2.9) to MAD 20,056 (Euros 2,005) by preparation. The CPCU saved time of two hours and an economic average benefit of MAD 40,665 (Euros 4,066) per month, for the assignation/anticipation of standard doses.

Conclusion: In an optimization approach for the quality of entire drug circuit, these results will be able to target the implementation of corrective measures in terms of concerned information services and terms of prescriptions and preparations.

P117 Hospital pharmacy internship in Children's Cancer Hospital Egypt, Cairo (2015)

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Introduction: International Pharmaceutical Students' Federation (IPSF) carries out a Student Exchange Programme, a project which enables pharmacy students to do professional internship in a foreign country. Croatian pharmacy students have this opportunity due to partnership between Croatian Pharmaceutical Students' Association (CPSA) and IPSF. Internship can be done in community and hospital pharmacy, pharmaceutical industry, government, health agencies and at universities in about 70 countries around the world.

Material and method: In August 2015 five Croatian pharmacy students did their practice in Children's Cancer Hospital Egypt, where they joined oncology pharmacists in their work and learned about hospital pharmacy. During 10-day practice they were at different hospital departments: IV Admixture, Pharmacokinetic Laboratory, Dispensing Pharmacy, Operation Rooms, Multi-Specialty Clinics and joined pharmacist on his/her clinical rounds. They were calculating drug dosages, watching for drug adverse events, monitoring drug concentration in blood and checking interactions and suitability before administration of medicines to patients.

Results and discussion: Students learned about most frequently used cancer drugs, outcomes and comorbidities of cancer and the role of an oncology pharmacist in patients' care. They also discovered that oncology, as a rapidly growing field of medicine, offers huge variety of possibilities for development of clinical pharmacy within itself.

Conclusion: In professional environment in hospital pharmacy students can learn about the importance of teamwork and collaboration between healthcare providers, with an oncology pharmacist as an integral part of hospital interdisciplinary team, which fosters efficiency in patients' treatment. Over and above, the intercultural nature of the Student Exchange Programme itself gives a unique insight into educational system of pharmacy students in Egypt, or any other chosen country, and the opportunity to discuss and compare it to the one in Croatia, thus enriching young generations of pharmacists with not only a memorable professional experience, but also a private one.

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