

## **Goals and Objectives Banff SCT 2017 Meeting in Barcelona, March 27-31, 2017**

Welcome and Opening Remarks: History and Future of the Banff Classification, Where the Present Lesion Scoring Criteria Came From, and the Continued Need for Ease of Use and Time Efficiency

Kim Solez

### Goals

- To enumerate the published study findings that served as the basis for the original lesion scoring criteria in 1991.
- To share information about the transplant pathology slide workshops (two at the University of Basel) that were held in the first decade of the Banff Classification that illustrated individual cases from around the world that showed how lesion scoring threshold criteria were determined. Similar sessions were part of the Banff meetings themselves.
- To describe with examples how a whole new set of lesions will become important in the new Banff Classification of Tissue Engineering Pathology as transplant pathology morphs into tissue engineering pathology.

### Objectives

- Participants should be able to understand and explain to others how the original Banff lesions scores were established and the principles by which new ones would be added, and how lesions scores contribute to patient care.
- Participants should be able to conceptualize and be able to explain to others how a completely new set of lesions scoring criteria could be used in the Banff Classification of Tissue Engineering Pathology. Some of the criteria may go beyond anatomical pathology to soluble biomarkers.
- Participants should pay tribute to Daniel Salomon after his recent passing, know the details of his many contributions, including his contributions to the Banff Classification meetings in the early days, the lesions he espoused, and his place in the history of Nephrology, Transplantation, and Transplantation Pathology

DSA-monitoring as an end point

Anat Tambur

### GOALS

- Discuss refine methods to measure antibody strength
- Apply improved DSA monitoring
- Identify and provide reliable measure to support clinical trials

## OBJECTIVES

- Participants will explain the limitations of the luminex SAB assay in measuring antibody strength
- Participants will be able to explain how permutations of the assay that can overcome these limitations
- Participants will be able to demonstrate and assess the utility of DSA monitoring as an end point for clinical trials

### Refined histology scoring as a reliable end-point

Bob Colvin

#### Goals:

- Discuss the benefits of refined histology scoring
- To describe the need for histology scoring as a reliable endpoint
- To discuss **methods of** histology scoring as a reliable endpoint
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#### Objectives:

- Participants will learn how to apply scoring system and use it as a reliable end point
  - Participants will be familiarized **with** the advantages of refined histology scoring
- Participant will be familiarized **with** the use of scoring to predict long-term outcomes,

### The Molecular Microscope as an end point

Philip Halloran

Goals: 3 overall changes in learners' performance or health care outcomes the program is expected to achieve:

1. to describe the disease states and their time course in organ transplant recipients.
2. to describe and discuss the molecular basis of the disease states in organ transplants
3. to be able to interpret and evaluate the biopsy-based diagnostic tests (histology and molecular) available for problem solving in transplant management

#### Specific objectives

1. Will be able to explain the Molecular Microscope Diagnostic system (MMDx)
2. Compare MMDx vs. histology systems of interpretation
3. Will be able to explain the experience to date with MMDx in clinical trials in transplant biopsies

Clinical trials: the FDA unmet needs

Mark Stegall

Goals:

Participants will be able to:

- Look over and gain new information discussed at previously FDA workshops.
- Explain the FDA's unmet needs
- Discuss the future direction involving the FDA

Objectives:

- Discuss the proof of concept regarding animals and the need for animal studies
- the diagnosis criteria for acute AMR
- describe the current approaches to the treatment of AMR

Potential end points for response to treatment of ABMR in heart transplant recipients

LUCIANO POTENA

Goals:

- To describe unmet needs for ABMR management in heart transplant
- To analyze clinical markers of prognosis in ABMR patients
- To analyze ABMR endpoints that can be tested in therapeutic interventions

Objectives

Three overall changes in learners' performance or health care outcomes the program is expected to achieve:

- Recognize features of clinically relevant ABMR
- To be able to integrate and discuss the diagnostic information necessary to drive clinical decisions.
- Identify therapeutic targets

10 years development of Antibody characterization assays : progress, clinical relevance and unmet needs

Alex Loupy

Goals:

Participants will be able:

- To describe the progress that has occurring the in the last 10 years in antibody characterization assays

- To describe the clinical relevance that has occurring the in the last 10 years in antibody characterization assays
- To describe the unmet needs that has occurring the in the last 10 years in antibody characterization assays

Objectives:

Participants will be able to:

- Discuss the progress that has occurring the in the last 10 years in antibody characterization assays
- Discuss the clinical relevance that has occurring the in the last 10 years in antibody characterization assays
- Discuss the unmet needs that has occurring the in the last 10 years in antibody characterization assays

The Path toward Next Generation Sequencing application to Solid Organ Transplants

Peter Nickerson

Potential end points for response to treatment of ABMR in liver transplant recipients

Sandy Feng

Goals:

- Will able able to describe the long-term status of the liver allograft
- Discuss the allograft histology in liver transplant patients
- To learn how to examine the antigens present in liver transplants

Objectives:

- Participants will be able to describe how to evaluate the long-term status of the liver allografts
- Participants will be able to describe the treatment course for ABMR in liver transplant patients
- Participants will be able to discuss the care and outcomes of ABMR in liver transplant patients

Potential end points for response to treatment of ABMR in kidney transplant recipients

Mark Stegall

Goals

- Discuss the unmet needs in kidney transplantation

- Discuss some of the background studies needed to conduct novel clinical intervention trials
- Discuss adaptive trial design in renal transplantation

#### Objectives

Participants will be able to:

- Identify some of the unmet needs in transplant recipients
- Identify barrier to new therapy to meet these needs
- Identify possible novel trial designs to develop new therapy

Optimizing Statistical methods for generating robust end points

Dorry Segev

The goals are:

- To describe clinical trial design in transplantation
- To describe the role of clinical end points in trial design
- To describe the role of surrogate end points in trial design

The objectives are:

By the end of this presentation participants will be able

- To explain and understand clinical trial design in transplantation
- To discuss the role of clinical end points in trial design
- To describe the role of surrogate end points in trial design

Adopting a histo-immuno-clinico-laboratory composite end-point: The iBox

Alexandre Loupy

Goals:

To discuss integrative aspects of the iBox

To explain from start to finish how the iBOX is incorporated in giving out scores from big/smart data

To describe the need for adopting a histo-immuno-clinico-laboratory end point

Objectives:

Participants will be able to apply and incorporate histo-immuno-clinico-laboratory end points

Participants will be able to describe the composite end points and the use of different parameters

Participants will be able to differentiate between the classical approach and the approach with the iBOX

Proposal for new Banff Working Group: Transplantation HIV+ to HIV+

Serena Bagnasco

Goals:

Participants will describe and discuss the needs for a HIV+ to HIV+ transplant BWG

Participants will describe and discuss present research and future directions

Participants will describe the unique needs for HIV+ patients

Objectives:

Participants will discuss goals and objectives of the new BWG

Participants will join and suggest collaborations for the BWG

Participants will be able to outline the goals and research directions for the BWG

EM scoring BWG

Harsharan k. Singh

Goals

1. Discuss changes or improvements related to EM scoring over the last two years
2. Discuss future impacts and potential next steps in the development of EM scoring
3. Articulate the EM process and its current and potential uses in medicine

Objectives

1. Participants will be able to describe the changes of EM scoring over the last two years
2. Participants will be able to describe the potential next steps in the development and growth of EM
3. Participants will be able to discuss the EM process and understand it's current uses in the medical field

Highly sensitized BWG

Carrie Schinstock

Goals

1. Report survey results of antibody mediated rejection (AMR) treatment patterns by clinicians.
2. Report survey results of AMR identification and classification by clinicians.
3. Compare the identification and classification of AMR by transplant pathologists and clinicians.

### Objectives

By the end of this presentation participants should:

1. Describe the concept of AMR treatment pattern.
2. Describe the variation in AMR identification and classification by clinicians.
3. Describe the differences in identification and classification of AMR by transplant pathologists and clinicians.

### Recurrent GN BWG

Nada Alachkar

#### Goals:

Participants will be able to describe the progress over the last two years for the BWG

Participants will be able to increase understand and describe the current activities and aims/objectives

Participants will be able to discuss the future of the BWG

#### Objectives:

Participants will be able to describe the purpose of the recurrent GN BWG.

Participants will be able to describe current and future research directions

Participants will be able to describe and discuss the results presented by the BWG

### TMA in transplants BWG

Marjan Afrouzian

#### Goals:

1. Discuss Standardize diagnostic criteria of TMA in renal allografts
2. Apply the diagnostic criteria that would integrate clinical, pathological and molecular information
3. Improve collaboration among TMA investigators who would be using the diagnostic criteria

## Objectives:

At the end of this presentation, participants should be able to:

1. Recognize the necessity of developing standardized criteria for the diagnosis of TMA in renal allograft.
2. Discuss current questions expressed by the TMA Working Group participants
3. Describe the presented methodology for consensus generation

## TCMR/borderline BWG

Parmjeet Randhawa and Volker Nickleit

### Goals

Update from the Banff TCMR/BL Working Group

1. Enumerate the aims and objectives of the Banff TCMR/BL Working Group.
2. Cite the progress made by this group since the last Banff Meeting.
3. Articulate likely changes in the Banff Schema that will result from studies currently in progress.

## Objectives

1. Participants should be able to understand and discuss the purpose of the Banff TCMR/BL Working Group.
2. Participants should be able to understand and describe the progress made in this area since the last Banff meeting two years ago.
3. Participants should be able to conceptualize the changes in the Banff schema that will likely result from studies in progress.

## Molecular BWG

Michael Mengel

### Goals:

- to summarize the activities of the molecular Banff BWG over the last 2 years
- to list the ongoing activities of the Banff molecular BWG
- to review potential new collaborative studies of the Banff molecular BWG

## Objectives:



- to review results available to this point generated by the Banff molecular BWG
- to describe and understand the progress the Banff molecular BWG has made
- to discuss next steps and studies by the Banff molecular BWG

#### Pathomechanisms of ABMR

Rob Fairchild

##### Goals:

- To discuss the limitations of currently used animal models of antibody-mediated rejection of kidney allografts
- To discuss a novel mouse model of antibody mediated rejection of kidney allografts and the histopathological features that are shared with the clinical experience
- To discuss how this model can be used to identify mechanisms underlying antibody-mediated acute and chronic kidney allograft injury

##### Learning Objectives

- To describe the role of Natural Killer cells in antibody-mediated acute kidney allograft injury using a unique mouse model
- To be able to explain the NK cell response to kidney allografts
- To explain mechanisms leading to antibody-mediated chronic injury of kidney allografts

#### New drug targets in ABMR

Steve Woodle

##### Goals:

Objectives: What defines chronic-active TCMR

Roz Mannon

##### Goals:

To describe the clinical definitions of chronic TCMR

To discuss treatments utilized in this scenario

To discuss if there is impact on transplant graft outcome

##### Objectives:

In this session, participants will:

Develop new understanding of late active T cell based injury

Explain ways to interpret the clinical features of Chronic TCMR

Identify therapeutic strategies in this patient population

Fibrosis and Structural Decline of Liver Allografts: what and how to measure and potential underlying causes

Ian Gibson

Goals:

To discuss the potential underlying causes for decline of liver allografts

To discuss the how and what to measure in decline of liver allografts

To describe the functionality and structural decline that occurs in liver allografts

Objectives:

Participants will be able to explain potential underlying causes for decline of liver allografts

Participants will be able describe how and what to measure in decline of liver allografts and apply methods of measure to patients

Participants will be able to identify functional and structural decline progress and prognosis.

Pathology of the late post-transplant kidney and the role of non T cells

Lynn Cornell

Goals

- Discuss the pathology of late post-transplant kidney biopsies
- Analyze the causes of late renal allograft dysfunction and loss
- Be able to describe different phenotypes of late post-transplant rejection

Objectives

Participant should be able to:

- Summarize the trends in kidney graft histology with time post-transplant
- Analyze the relationship between fibrosis and inflammation
- Describe the types of cellular infiltrates seen in late post-transplant rejection

Molecular correlates of chronic TCMR

Enver Akalin

Goals:

To describe the molecular correlates of chronic TCMR

To describe the characterization of molecular correlates

To discuss TCMR scoring

Objectives:

Participants will be able to describe the molecular changes that occur in chronic TCMR

Participants will be able to evaluate molecular correlates in chronic TCMR

Participants will be able to discuss patient outcome in regards to chronic TCMR and the molecular correlates

Do we need different scoring rules in early and late allograft biopsies?

Martin Naessen

The goals are:

- To discuss the histological phenotype of late versus early renal allograft biopsies
- To discuss the importance of biopsy timing for prognosis
- To discuss the complex diagnosis of late renal allograft biopsies and the difficulties for clinical interpretation
- To discuss the reversibility of (chronic vs. acute) lesions with or without treatment, and the dilemma for treatment decisions

The objectives are:

- Participants will be able to understand and describe the importance of timing of a renal allograft biopsy for the interpretation of the histological picture
- Participants will be able to assess the impact of timing of a biopsy on kidney transplant outcome
- Participants will be able to see the difficulties of interpreting biopsies with complex (mixed) histological phenotypes
- Participant will be able to identify the therapeutic dilemma clinicians have with complex biopsy results late vs. early after transplantation

i IFTA: significance and prognostic value

Clement Gosset

Goals:

1. Determine the significance of the inflammation in scarred areas (iIFTA)
2. To assess the relevance and the prognostic value of iIFTA Banff score
3. To identify the determinants of i IFTA

Objectives:

1. Participants will be able to assess the relevance of i IFTA Banff score as a prognostic factor
2. Participants will be able to assess the relationship between i IFTA and rejection process

3. Participants will be able to find about the main contributors to i IFTA

Treatment of late and mixed rejection pathology

Brian Nankivell

The multidisciplinary approach to AMR in lung transplantation - reaching a consensus

Deborah Levine

Goals

1. Discuss why AMR occurs in lung transplantation
2. Discuss the multiple current diagnostic approaches that exist relating to AMR in lung transplantation
3. Discuss the proposed diagnostic standard to be used in future discussions of AMR in lung transplantation

Objectives

1. Participants should be able to describe why AMR occurs in relation to lung transplantation
2. Participants should understand the multiple current diagnostic standards that exist
3. Participants should understand the proposed unified diagnostic standards

Histopathology of AMR in the lung - Part 1

Fiorella Calabrese

Histopathology of AMR in the lung - Part 2

Gerry Berry

DSAs in lung transplantation      Adriana Zeevi

Goals:

- Discuss the risk associated with pre-formed donor-specific HLA antibodies (DSA) for lung allograft outcome.
- Discuss improvements of the analysis of DSA level and function in lung transplantation.
- Recognize the contribution DSA for the diagnosis of antibody mediated rejection in lung transplantation.

#### OBJECTIVES

- Participants will be able to discuss the evidence and limitations of current literature regarding the risk associated with pre-formed DSA for adverse outcomes in lung transplant recipients.
- Participants will be able to define DSA based on specificity, strength, titer and complement fixing ability.
- Participants will be able to discuss the DSA characteristics associated with the diagnosis of AMR in lung transplant recipients.

#### Molecular signals and lung transplantation

Phil Halloran

##### Goals:

- To describe how molecular signaling can help assess biological processes
- To describe distinguishing TCMR, ABMR and tissue injury using molecular signals
- To discuss the full view of injuries and immunological events that occur in transplant patients

##### Objectives:

Participants should be able to:

- To discuss advantages and pitfalls of molecular signaling
- To discuss incorporation of molecular signaling in transplants
- To discuss current molecular diagnostic systems used in lung transplants.

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#### Relevant endpoints in lung AMR treatment

Antoine Roux

Therapeutic options and strategies - the old and the new

Ramsey Hachem

##### Goals:

- Discuss the need to improve the detection of pulmonary AMR

- Discuss the need to improve the management of pulmonary AMR
- Identify gaps in knowledge of our understanding of pulmonary AMR

Objectives:

- Participants will be able to identify the characteristic clinical features of pulmonary AMR
- Participants will recognize the limitations of the current medical evidence guiding the management of pulmonary AMR
- Participants will identify opportunities for improving the evidence base in pulmonary AMR

Introduction - aims of liver sessions

Jake Demetris

“Pathology of Extra-corporeal perfusion of Liver Allografts - what to examine and how does it correlates with outcome

Annette Gouw

Goals:

- Review of the histologic features of extra corporeal machine perfused grafts.
- Discuss the histologic differences with conventional (non-EC perfused) grafts.
- Discuss with transplant clinicians the several types of EC-perfusion and the clinico-pathologic correlation of the outcome.

Objectives:

- Pathologists will understand and discuss the histologic features of EC-machine perfused grafts
- Participants will recognize the histologic differences with non-EC perfused grafts.
- Participants will recognize the possible histologic consequences of EC-perfusion on outcome.

The prospects of extra-corporeal machine perfusion of donor livers

Robert Porte

Goals:

To describe advances in machine perfusion and how it will aid organ preservation for transplantation

To clarify the differences in nomenclature and provide a unified set of guidelines relating to liver MP

To describe the need and advantages of an extra-corporeal machine perfusion

**Objectives:**

Participants will be able to discuss the prospects of extra-corporeal machine perfusion

Participants will be able to describe the advantages of an extra-corporeal machine perfusion

Participants will be able to discuss the role machine perfusion plays in transplantation and advances in recent years, Fibrosis and Structural Decline of Liver Allografts: what and how to measure and potential underlying causes

Carla Venturi Monteagudo

**Goals:**

- To discuss a general approach to the pathogenesis & evolution of the liver allograft fibrosis (LAF).
- To define and describe a novel fibrosis scoring system specifically designed for allograft fibrosis.
- To introduce and discuss the concept of fibrosis as a “dynamic process”.
- To evaluate the role of hepatic stellate cells in the development of LAF.

**Objective:**

Participants will be able to:

- Recognize the main contributors in the fibrogenesis scenario.
- Identify threat factors for the development of fibrosis.
- Assess & implement the new histologic scoring system as adequate tool for LAF.
- Discuss controversies in the application of invasive versus non-invasive methods for LAF monitoring

A Pathologists Guide to Evaluating the Long-Surviving Allograft: important features, stains, and approach to better understanding of chronic AMR

Stefan Hubscher

**Goals:**

To discuss important features of chronic AMR

To discuss stains of chronic AMR

To discuss approaches to gain a better understanding of chronic AMR

**Objectives:**

Participants will be able to describe approaches to gain a better understanding of chronic AMR

Participants will be able to describe important features and stains of chronic AMR

Participants will be able to discuss long-surviving allografts

DSA positive and then - To biopsy or not?

Peter Nickerson

HLA DSA properties assessment in the real life : what does it add?

Adriana ZEEVI

#### GOALS

- Recognize the risk associated with pre-formed donor-specific HLA antibodies (DSA) for lung allograft outcome.
- Discuss improvements of the analysis of DSA level and function in lung transplantation.
- Recognize the contribution DSA for the diagnosis of antibody mediated rejection in lung transplantation.

#### OBJECTIVES

- Participants will be able to discuss the evidence and limitations of current literature regarding the risk associated with pre-formed DSA for adverse outcomes in lung transplant recipients.
- Participants will be able to define DSA based on specificity, strength, titer and complement fixing ability.
- Participants will be able to discuss the DSA characteristics associated with the diagnosis of AMR in lung transplant recipients.

The value of DSA in managing ABMR diagnostic, prognostic, and response to therapy

Carmen LeFaucheur

Do we need DSA to diagnose ABMR - the pathologists view?

Mark Haas

#### GOALS

- Describe the advantages and disadvantages of potential surrogate markers for DSA
- Describe and discuss pathologist point of view on using DSA
- Discuss the current role that DSA currently plays to diagnose ABMR

Objectives:

1. Review the current criteria (2015 modification of Banff 2013) for diagnosis of acute/active and chronic, active antibody-mediated rejection (ABMR) in renal allografts
2. Present recommendations for how to proceed in situations where we are faced with a biopsy meeting morphologic criteria for diagnosis of ABMR, but where there are no detectable donor-specific antibodies (DSA)



3. Discuss potential surrogate markers for DSA, and the advantages and pitfalls of each

Cell therapy in lung diseases

Anna Serrano Molar

Goals:

- To describe the different cellular therapies proposed to treat pulmonary diseases (more precisely pulmonary fibrosis) and basic clinical studies.
- To describe the findings of published studies of type II alveolar cells for the treatment of idiopathic pulmonary fibrosis.
- To discuss how to improve cellular therapies in pulmonary fibrosis.

Objectives:

- Participants will be able to identify the limitations of the different cellular therapies
- Participants will be able to apply new knowledge to the alveolar type II cells therapy to treat pulmonary fibrosis
- Participants will be able to understand and describe the bases to develop a new cell therapy

Cell implantation after myocardial infarction: a 10 years experience from ICREC laboratory

Santiago Roura

**Cell implantation after myocardial infarction: a 10 years experience from ICREC laboratory**

Santiago Roura

Goals

1. Discuss the procedures and techniques used for cell implantation after myocardial infarction
2. Discuss the key points of the presenter's experience from the past ten years
3. Discuss the future impacts of cell implantation after myocardial infarction

Objectives

1. Participants will be able to describe how Cell Implementation after Myocardial Infarction works
2. Participants will be able to discuss how cell implementation has progressed in the last ten years
3. Participants be able to discuss and be aware of the potential future yields from Cell Implantation after myocardial infarction

Acellular human heart matrix repopulation

Francisco Fernández Avilés

fibrosis and Structural Decline of Liver Allografts: what and how to measure and potential underlying causes

Rector UB

**Antonio Román**

Goals

1. Discuss procedures used to measure Fibrosis
2. Discuss potential underlying causes of Fibrosis and other structural decline of liver allografts
3. Discuss what signs and objects to look for in order to measure Fibrosis

Objectives

1. Participants will be able to describe how to measure Fibrosis
2. Participants will be able to discuss the potential underlying causes of Fibrosis
3. Participants will be able to describe the signs and warnings of Fibrosis and the decline of Liver Allografts

The challenge of therapeutic innovation in organ transplantation

Josep M. Grinyó

Methodological constraints in the design of clinical trials

Daniel Serón

Goals:

- To differentiate predictive from surrogate variables
- To discuss and describe the enrichment strategies and risk stratification in the design of clinical trials
- To discuss non adherence as a source of bias in clinical trials

Objectives

- Participants will gain knowledge how to evaluate the utility of surrogate variables
- Participants will be able to apply different strategies to decrease sample size in clinical trials
- Participants will be able to propose enrichment strategies in the design of trials

New end-points for New Generation Clinical Trials: A Summary of Banff proposals

Julio Pascual

Clinical trials investment. The industry point of view

Joan Gibert

Pancreas perfusion with hypothermic machine: pancreas and duodenal histology up to 24 hours.

Julien Brancherau

Evaluation of transplanted islets ( Effect of immunosuppressive therapies on transplanted islets and pancreata)

Javier Trinanés Ramos

Goals

- Appreciate and discuss differential effects of calcineurin inhibitors on beta cell function and identity.
- Explore and assess potential mechanisms acting beyond calcineurin inhibition.
- Identify novel targets for preservation of beta-cell identity and function in diabetes to evaluate the effect of calcineurin inhibitors on beta cells.

Objectives

- Participants will describe novel pathways on tacrolimus-induced diabetes in beta cells.
- Participants will discuss the synergy between metabolic stress and calcineurin inhibitors on the development of beta cell failure.
- Participants will describe the similarities between type-2 diabetes and immunosuppression-induced diabetes.

Outcome of pancreas transplantation alone with portal venous drainage vs. systemic venous drainage      Stephen Bartlett

Goals:

To describe and compare portal and systemic venous drainage

To describe the immunologic and survival superiority of portal venous drainage

To discuss graft survival and rejection for portal and systemic venous drainage

Objectives:

Participants will be able to describe the advantages and disadvantages of portal venous drainage

Participants will be able to describe the advantages and disadvantages of systemic venous drainage

Participants will be able to discuss which drainage should be used in pancreas transplantation

Vascular remodelling following whole pancreas transplantation

Steven White

Impact of BK infection in pancreas transplant recipients

Maria Fernanda Toniolo

Histology of refractory rejection

John Papadimitriou

Goals:

- To recognize the occurrence of refractory pancreas allograft rejection.
- To understand and describe the clinical course and impact of refractory rejection.
- To evaluate the usefulness of diagnostic tests.

Objectives:

- To describe the features of TCMR and AMR refractory to treatment.
- To describe the consequences of refractory rejection to the various pancreas tissue compartments.
- To describe the differential diagnosis of refractory rejection

Comparison between rejection in pancreas and kidney biopsies in SPK patients with graft dysfunction.

Pablo Uva

Goals

- To describe the results of pancreas and kidney biopsies in the setting of graft dysfunction.
- To discuss the prevalence of synchronous rejection in pancreas kidney transplantation.
- To support in favor of pancreas biopsies in patients with graft dysfunction.

Objectives

- Participants will emphasize and evaluate the need for pancreas tissue analysis.
- Participants will be able to make decisions on when to biopsy dysfunctional grafts.
- Transplant physicians will have better comprehension of synchronous and asynchronous rejection in SPK transplantation.

Case presentation

Diego Cantarovich

Goals:

To discuss the impact of liraglutide on PTX patients

To describe the symptoms and complications of PTX patients with T1DM specifically focusing on hyperglycaemia

To discuss a case series with procedures, results and future directions

Objectives:

Participants will be able to describe the impact of liraglutide

Participants will be able to discuss the clinical implications of liraglutide

Participants will be able to discuss future directions for liraglutide in patient care.

The contribution of the pathologist to expand the donor pool in cardiac transplantation

Ornella Leone

Goals

- Discuss improvements current clinical criteria for evaluating and accepting donor hearts.
- Increase routine practice of pathology evaluation of donor discarded hearts in various heart transplant centres worldwide, as an essential tool for researching more accurate predictors in assessment of donor suitability and for safe valve tissue banking.
- Discuss additional pathology elements to clinical scoring systems for donor heart evaluation.
- Improve knowledge on donor heart atherosclerotic lesions and myocardial lesions underlying ventricular dysfunction associated with brain death adrenergic/hormonal stress.

Learning objectives

Participants will be able to assess:

- Methodology of pathology examination of donor hearts.
- Importance of anatomo-clinical correlation in heart transplantation.
- Myocardial lesions related to adrenergic stress, a still poorly known topic.

The multifaceted pathologies of CAV

Gregory Fishbein

Vasculitis process at the base of CAV

Marny Fedrigo

Immunopathology of CAV

Manon Huibers

Goals:

- Describe an overview in the (immune) pathogenesis of CAV
- Discuss (molecular) tissue analysis methods for studies on CAV
- Describe components of the immune system involved in CAV

Objectives:

- Participants will discuss the current knowledge in CAV (immune) pathogenesis
- Participants will be able to apply and place current methods for tissue analysis in the context of CAV research
- Participants will have an increased understanding in the current knowledge of immune cells (and components) on CAV development.

Chronic injury to the microcirculation in EMB

Dylan Miller and Patricia Revello

Goals:

- Characterize the tissue-level pathologic changes occurring in the microvasculature of failing cardiac allografts.
- Describe possible pathogenetic mechanisms accounting for microcirculation pathology in failing cardiac allografts.
- Review causal links between antibody mediated rejection (ABMR) and microcirculation pathology in failing cardiac allografts.

Objectives:

- Recognize tissue level histopathologic alterations in the myocardial microvasculature of failing cardiac allografts.
- Discuss possible mechanisms whereby microcirculation injury may lead to cardiac allograft failure and the reported histopathologic changes in this setting.
- Assess routine monitoring of microcirculation injury features in cardiac allograft biopsies to monitor long term effectiveness of anti-rejection therapy.

cfDNA in heart transplantation

Kiran Krush

## Gene expression on FFPE EMB for the diagnosis of rejection in Heart Transplantation

Michael Mengel

### Goals

- increase understanding of the molecular phenotype of heart allograft rejection decreasing mortality
- explain the advantages and limitations of the NanoString technology
- create and increase awareness for integrating molecular diagnostic into clinical practice for heart transplant patients

### Objectives

- to be able to describe the molecular correlates of heart allograft rejection and increase knowledge base
- to describe the NanoString technology for gene expression studies in FFPE material
- to discuss to potential application of gene expression studies in clinical practice for heart transplantation

## MicroRNA on FFPE EMB for the diagnosis of rejection in Heart Transplantation

Annalisa Angelini

### GOALS:

- To describe unmet needs/opportunities in heart transplantation
- To describe the role of molecular tests with particular emphasis of microRNA in monitoring heart transplantation
- To describe pros and cons in microRNA on FFPE EMBs as diagnostic tools in heart transplantation

### OBJECTIVES:

- Pathologists will better understand and discuss the time course and complexity of the different types of rejection in heart transplantation
- Pathologists/ physicians will understand and discuss the molecular mechanisms at the base of rejections in heart transplantation
- Pathologists/physicians will be able to integrate clinical data, and microRNA profile in EMBs monitoring to better diagnose rejections in heart transplant.

Does chronic ABMR exist in cardiac transplantation?

Patrick Bruneval

**Does chronic ABMR exist in cardiac transplantation?**

Patrick Bruneval

### Goals

1. Discuss the current understandings of cardiac allograft vasculopathy (CAV)
2. Discuss the nomenclature of the pathological lesions of CAV with the goal of a consensus nomenclature sticking to the pathophysiology of CAV.
3. Discuss the impacts of determining whether chronic ABMR exists in cardiac transplantation

### Objectives

1. Participants should be aware of the future potential of consensus nomenclature of the pathology of CAV
2. Participants will be able to discuss how chronic ABMR affects cardiac transplantation
3. Participants should be able to take the concepts applied here and relate them to other transplantations

Gerald Berry

### **Towards an uniform terminology for the pathology of CAV and Panel Discussion : Towards an uniform terminology for the pathology of CAV**

Gerald Berry

### Goals

1. Discuss the different terminologies currently used for the pathology of CAV
2. Discuss the advantages of disadvantages of these different terminologies
3. Discuss the proposed uniform terminologies

### Objectives

1. Participants should understand and discuss the current terminologies
2. Participants should understand and describe the shortcomings of the current terminologies

Participants should be able to conceptualize the proposed new terminologies and understand why the changes are proposed

Chronic rejection in VCA

Jean Kanitakis



## Goals:

- To present and discuss the clinical and pathological features of chronic rejection in Vascularized Composite Allografts (hands, face)
- To discuss possible treatments for chronic rejection in Vascularized Composite Allografts
- To present and discuss possible factors and mechanisms in chronic rejection.

## Objectives

- Participants will discuss how Vascularized Composite Allografts may undergo chronic, irreversible rejection.
- Participants will be able to describe the clinicopathological features of chronic rejection in Vascularized Composite Allografts and will thus be able to diagnose it with more confidence.
- Participants will be able to describe the factors affecting chronic rejection in case studies.

## VCA skin scoring system in a preclinical model

Ivy Rosales

The role of immunohistochemistry and additional tools in the diagnosis of VCA skin rejection

David Elder

Skin containing VCA as a monitoring tool for intestinal transplantation

Annemarie Weissenbacher

Goals will be to describe and discuss the following questions:

Does addition of a VCA have an impact on graft survival after transplantation?

Can rejection be diagnosed earlier?

Is the incidence of de novo donor specific antibodies different in VCA containing intestinal transplants?

## Objectives

Participants will discuss what does skin containing VCA mean?

Participants will discuss about the indication of combining intestinal (pancreas) transplants and VCA

Participants will be able to apply knowledge about the clinical and immunological follow-up procedure

Uterus transplant rejection: a provisional scoring system for rejection

Molne Johan

## Goals

- To assess biopsies from uterus transplants
- To grade biopsies from uterus transplants
- To monitor the effect of immunosuppressive drugs using biopsies from uterus transplants

## Objectives

- The participants will be able to detect rejection patterns in histological slides from transplanted uteri.
- The participants will learn how rejection is mediated in uterus transplants
- The methods available to detect rejection and immunosuppressive treatment will be discussed

## Immunoprofile in VCA rejection

George Murphy

Vascular changes in a transplanted organ

Louis Robert DiBernardo

Centralized Molecular diagnostics: Methods, platforms, pitfalls

Phil Halloran:

Goals: overall changes in learners' performance or health care outcomes the program is expected to achieve:

1. to describe the disease states and their time course in organ transplant recipients.
2. to discuss the molecular basis of the disease states in organ transplants
3. to be able to interpret and evaluate the biopsy-based diagnostic tests (histology and molecular) available for problem solving in transplant management

## Specific objectives

1. Examine recent experience with biopsy preparation: snap-freezing, RNAlater, OCT, FFPE
2. Review three ways of using molecules: means, single classifiers, multiple classifiers
3. Review the current MMDx results for kidney, heart, and lung transplant biopsies

Decentralized Molecular diagnostics: Pros and Cons

Bob Colvin

Goals:

To discuss the positives and strengths of decentralized molecular diagnostics

To discuss the drawbacks of decentralized molecular diagnostics

To discuss the advantages and disadvantages of centralized molecular diagnostics

Objectives:

Participants should understand the pros and cons centralized vs decentralized molecular diagnostics for different practice settings

Participants should be able to identify different strengths and weakness of different techniques, requirements for regulatory approval of a diagnostic test.

Participants will appreciate the role of the pathologist as the integrator of laboratory data including anatomic, molecular and clinical laboratory tests for improving guidance to the clinician on diagnosis and treatment.

The changing scenario for organ donation

Elisabeth Coll

Goals:

- To describe donor profile changes in recent years.
- To explain the different strategies approached by the Spanish Transplant Organization to maintain or even increase the donation and transplantation activity.
- To show and describe how these strategies have impacted on donation and transplantation activity in Spain.

Objectives:

- Participants will be able to explain different approaches to the changing scenarios in organ donation.
- Participants will be able to explain how these strategies impacted on organ donation.
- Participants will be able to identify those measures that they believe are best adapted to their scenarios and possibilities.

Donor quality assessment

Francesc Moreso

omics to assess quality of donated organs

Rainer Oberbauer

Goals:

- Improve the understanding of omics-wide data integration in acute transplant failure
- Apply systems medicine approaches to renal transplantation
- Guide and discuss rational strategies to prevent/treat acute renal allograft failure

Objectives:

- Delegates will be educated and discuss statistical approaches used to transform the myriad of omics-derived features into useful information for the rational treatment of acute renal allograft injury.
- A key learning discussion will be the rational selection of candidate markers for prophylactic and therapeutic interventions in acute renal allograft failure
- Participant will be able to evaluate the effectiveness of published interventions in acute renal allograft failure.

Staging and grading renal disease: The IgA experience

Ian Roberts

Grading of microcirculation inflammation in heart allografts

Jean-Paul Duong Van Huyen

Goals:

- Participants will be able to explain the heart pAMR classification
- To propose a scoring system for the grading of microcirculation inflammation in heart allograft
- To compare a scoring system of microcirculation inflammation with molecular data

Objectives

- Participants will discuss the utility of evaluating microcirculation inflammation in heart allograft
- Participants will be able to apply a scoring system of microcirculation inflammation in heart allograft
- Participants will be able to propose a scoring system of microcirculation inflammation in the design of trials in heart transplantation

Vascularized Allograft biopsies revisited

Linda Cendales

Goals

- To describe and update new challenges facing the histopathological diagnosis of vascularized composite allografts
- To discuss unmet needs in vascularized composite allografts
- To describe the current status of vascularized composite allotransplantation

Objectives

- The participants will be able to discuss advances in the diagnosis of vascularized composite allografts
- The participants will be able to outline the process in developing the Banff VCA scoring system
- The participants will be able to identify challenges in the diagnosis of vascularized composite allografts

Pharmacogenetics to tailor drug exposure and outcomes in kidney transplant

Dennis Hesselink

Goals:

- To explain the variability of immunosuppressive drug pharmacokinetics and its determinants.
- To describe the pharmacogenetic basis of inter-individual differences in immunosuppressive drug response.
- Participants will be able to explain the clinical evidence of the benefits pharmacogenetics-assisted tacrolimus dosing.

Objectives:

Participants will

- have a better reference of the causes of variability in immunosuppressive drug exposure
- and discuss the central role of genetic variability in cytochrome P450 3A therein.
- be able to explain the principle of model-based immunosuppressive drug dosing.

Conflicts of interest:

D.A. Hesselink has received consulting fees from Astellas Pharma, Chiesi Pharma, Glaxo Smith Kline, Novartis Pharma, has received grant support from Astellas Pharma, Chiesi Pharma and Bristol-Myers Squibb, and has received lecture fees from Astellas Pharma, Chiesi Pharma, Fresenius Medical Care, MSD, and Roche.

Monitoring memory B Cells responses in transplantation

Oriol Bestard

Goals:

- Discuss refine methods for monitoring the humoral immune response in Transplantation
- Describe transplant settings to monitor alloreactive memory B cells

- Identify the impact of alloreactive memory B-cell responses on kidney allograft pathology

#### Objectives.

- Participants will describe the complex mechanisms of the humoral alloimmune response in transplantation
- Participants will recognize the limitations of exclusively measuring circulating alloantibodies to detect humoral immune responses to the graft
- Participants will recognize the added value of measuring circulating alloreactive memory B cells besides circulating alloantibodies

#### State of the art: Finger prints of tolerance

Maria Hernández

#### Goals:

- Apply the knowledge of how to apply biomarkers of clinical utility in solid organ transplantation
- Will discuss the challenges of measuring tolerant immune responses. Why are B cell relevant?
- Apply and improve knowledge on Biomarker sets in solid organ transplantation tolerance

#### Learning Objectives

- Participants will be able to describe a biomarker of clinical utility strategy
- Participants will be able to discuss immunological effector responses or regulatory responses relevant to transplantation tolerance. The role of B lymphocytes will be addressed.
- Participants will be able to discuss differences in biomarker sets of transplantation tolerance for kidney grafts

#### Personalized medicine in Liver Transplantation

Miquel Navasa

#### Goals:

To review and describe immunosuppression regimes in different situations in Liver Transplantation:

- Kidney dysfunction
- Neurologic toxicity
- Autoimmune disease and neoplasia.

#### Objectives

- Participants will discuss how to evaluate complications of immunosuppression.
- Participants will be able to apply different immunosuppressive regimes according to the problems of the patients.
- Participants will be able to apply personalize medicine according to the profile of the patient.

#### Measuring patients alloreactivity to personalize treatment

Merce Brunet

#### Goals:

To discuss the types of biomarkers associated with rejection, individual response and graft dysfunction

To describe biomarkers that may be used to achieve better outcomes and improve long-term graft survival

To discuss the next steps for personalized immunosuppression

#### Objectives:

Participants will be able to discuss how personalized immunosuppression will offer better outcomes and long-term graft survival

Participants will be able to describe the types of biomarkers that play a role in rejection, individual response and graft dysfunction

Participants will be able to discuss new biomarkers lead to better patient outcomes with a high proportion either having too much or too little immunosuppression. Final decision on PVN scoring

Volker Nিকেleit

EM scoring system - are we ready for adoption into the classification?

Candice Roufosse and Harsharan k. Singh

Standardized Banff scoring - A web-based approach

Jan Becker

#### Goals are:

- Present and describe the advantages of standardized pathology reporting
- Present and discuss the requirements for standardized pathology reporting

- Compare the current status of the Banff Classification on kidney transplant pathology to these requirements
- Suggest and discuss predominantly web-based solutions to deliver standardized Banff kidney transplant reporting

Objectives are:

- Participants will know and be able to apply the requirements for standardized pathology reporting
- Participants will understand and discuss the advantages of standardized pathology reporting
- Participants will discuss the grown complexity of the Banff Classification for kidney transplants
- Participants will be able to discuss web-based solutions for standardized Banff kidney transplant reporting

Scoring of i-IFTA: potential rules and role in chronic TCMR

Parmjeet Randhawa

Goals:

1. Cite and describe the different conceptual paradigms that have been put forward to score inflammation and fibrosis in the kidney.
2. Enumerate the conclusions that can be drawn from existing studies that have scored these parameters in the allograft renal biopsy.
3. Articulate a consensus opinion reached by conference participants as to which method of scoring i-IFTA should be incorporated into the Banff Schema.

Objectives

1. Participants should be able to conceptualize and discuss the different schemas for scoring inflammation and scarring in the kidney.
2. Participants should be able to grasp the conclusions that can be drawn thus far from studies using these schemas in renal allograft biopsies.
3. Participants should be able to discuss and come to a consensus opinion about which method of scoring of i-IFTA should be incorporated into the Banff Schema.

Serum DSA in long-surviving liver allograft recipients: an algorithmic approach to determine potential clinical significance

Sandy Feng

Goals:

- Participants will be able to describe the long-term status of the liver allograft



- Discuss the prevalence of DSA in long-term liver transplant recipients with abnormal versus abnormal allograft function
- Review management options regarding DSA in transplant recipients with abnormal versus abnormal allograft function

Objectives:

- Participants will express how to evaluate the long-term status of the liver allografts
- Participants will be able to inspect if there is sufficient evidence to support incorporate DSA monitoring into their standard of care management of the long-term liver transplant recipient
- Participants will analyze whether there is sufficient evidence to guide clinical-decision making regarding DSA in long-term liver transplant recipients.

Focusing the “molecular microscopic” on liver allografts: integration of genomics and tissue pathology Alberto Sanchez-Fueyo

Goals:

Objectives:

Subclinical liver allograft rejection and "tolerance-related" liver infiltrates

Richard Taubert

Goals:

- To create awareness of subclinical rejection
- To improve the understanding of the immune regulation behind subclinical rejection
- To improve the understanding of the role of T cells in operational tolerant patients

Objectives:

- Participants will describe the prognosis and clinical relevance of subclinical rejection
- Participants will be able to discuss the role of T cells in subclinical rejection and tolerance related infiltration
- Participants will describe the molecular patterns of subclinical rejection and tolerance related infiltrates

Kidney summary Mark Haas

Liver summary Jake Demetreis

Pancreas summary      Cinthia Drachenberg

Heart summary Patric Bruneval

DCD Donors in Spain: pearls and pitfalls

Elisabeth Coll

Goals:

- To describe what was the strategy to promote DCD in Spain.
- To detail and discuss the difficulties encountered, the strategies with greater acceptance and success and the areas of improvement still pending.
- To describe the results of these strategies in terms of donation, organ utilization and transplantation.

Objectives:

- Participants will discuss the different strategies carried out in Spain to promote DCD.
- Participants will be able to know the advantages of disadvantages of every strategy in the Spanish experience for the promotion of DCD.
- Participants will be able to identify those measures that they believe are best adapted to their scenarios and possibilities.

Risk factors associated with DCD kidney function and survival

José Maria Portolés

Goals:

To describe the data collection and results for the midterm results.

To discuss the risk factors associated with DCD kidney function and survival

To describe some of the future prediction for patients in the study

Objectives:

Participants will be able to describe the results of the research thus far

Participants will be able to describe the risks associated with DCD kidney function and survival

Participants will be able to discuss the differences and similarities between DBD and cDCD

Will normothermic perfusion become the new standard for the maintenance of DCD donors?

Abdominal normothermic perfusion

Constantino Fondevila & Steve Large

## GOALS:

- To describe the principles behind normothermic regional perfusion (NRP) and how it works to improve the quality of organs previously injured by warm ischemia.
- To describe how NRP may be applied in the context of donation after circulatory determination of death (DCD) and recent results following its clinical application.
- To describe how the application of NRP in DCD is expected to evolve in the near future.

## OBJECTIVES:

Attendees will leave the session with critical knowledge about:

- The scientific basis supporting the use of NRP in DCD and how its clinical use has impacted the field of DCD organ transplantation.
- The results of recent clinical work detailing the use of NRP in DCD.
- How, in the future, NRP may be improved to generate more quality organs for human use.

Will normothermic perfusion become the new standard for the maintenance of DCD donors?

Thoracic normothermic perfusion

Steve Large

## Goals:

1. to describe how the DCD heart is viable
2. to describe how the DCD heart has good function
3. to demonstrate that the DCD heart is an excellent donor heart

## Objectives:

1. to present and discuss our DCD heart transplant experience to date February 2017
2. to offer a Q&A session to present and discuss identified problems
3. to present and describe our vision for future DCD activity

Update on the result of recent clinical trials on organ machine perfusion prior to transplantation: Lung David Gómez de Antonio

Update on the result of recent clinical trials on organ machine perfusion prior to transplantation: Liver Ruben Ciria

Update on the result of recent clinical trials on organ machine perfusion prior to transplantation: Kidney Mike Nicholson

## Lung summary

David Hwang

### Goals

- Participants will be able to explain the current concepts in the diagnosis and management of antibody-mediated rejection (AMR) in lung transplantation.
- To discuss emerging technologies for investigating AMR in lung transplantation.
- To discuss opportunities for collaborative research into AMR in lung transplantation.

### Objectives

- Participants should be able to identify current approaches and limitations to the diagnosis of AMR in lung transplant recipients.
- Participants should better describe the biologic basis of AMR, as a foundation for refining its diagnosis and management.
- Participants will gain awareness and use of research opportunities in AMR in lung transplantation.

## Vascularized Composite Allografts summary

Linda Cendales

## LUNG – ANTIBODY-MEDIATED REJECTION, TO BE CONTINUED!

### Histopathology of AMR in the lung – Part 1

Fiorella Calabrese – University of Padova (Padova, Italy)

### Goals:

- Describe why lung AMR surrogates are useful and what kind of surrogates are currently or will be used in the next future
- Discuss the principal strategies to improve the knowledge in lung AMR pathology

### Objectives:

The participants will be able to

- Understand the weakness of current histological features
- Describe the old and new lung AMR surrogates and stigmata
- Understand the significance and importance of several educational strategies

## Histopathology of AMR in the Lung – Part 2

Gerald Berry – Stanford University, Stanford, CA, USA

### Goals:

- To review the current histopathology criteria for the diagnosis and reporting of AMR in the lung
- To describe the immunophenotypic findings in AMR

### Objectives:

The participants will be able to

- Understand the development of pathologic criteria
- Identify potential avenues for research and advancement of pulmonary AMR