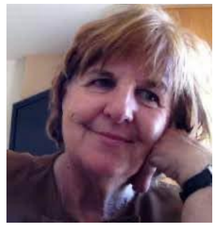
Challenges of participating at European Level

-in European Commission
-in European Regulation
-in European Networks

- **E**uropean **M**edicines **A**gency's (**EMA**) & Antimicrobial Resistance Network (**AMR**)



Mary MacCarthy (UEMO former Vice President)

- European **H**ealth **E**mergency Preparedness and **R**esponse **A**uthority (**HERA**)

Patrick OUVRARD (UEMO former Vice President)

- **H**ealth **T**echnology **A**ssesment (**HTA**)

Hermenegildo Marcos Carrera (UEMO Vice President)

Union **E**uropéenne **M**édecine **O**mnipraticienne

UEMO

CMGF
MYTHES ET RÉALITÉS EN MÉDECINE GÉNÉRALE
Organisé par le Collège de la Médecine Générale
DU 21 AU 23 MARS PARIS2024
palais des congrès de paris

Challenges of participating at European Level

-in European Commission
-in European Regulation
-in European Networks

European Medicines Agency and AntiMicrobial Resistance

(EMA) and **One Health Network (AMR)**

Mary McCARTHY (UEMO former Vice President)

Union **E**uropéenne **M**édecine **O**mnipraticienne

UEMO

European Medicines Agency

History of involvement

- Formed in 1997 with stakeholders from health care professions
- Representatives from secondary care (Paediatrics, CVD, Oncology etc) pharmacy and patient groups
- UEMO has been an observer since 2011
- Memorandum of Understanding signed in June 2019 to improve GP engagement

Current Involvement

With EMA Health Care Professionals Working Party

- To attend meetings, discussions and debates
- To contribute the family doctor/generalist perspective in discussions about medications
- To take part in the Professional Officers Group – current topics are AMR, Medicines Shortages, Prescribing in Frailty
- To contribute to papers on these topics – Paper on “Prescribing in Frailty” recently published in the Lancet

Challenges

With EMA work

- The work before the meeting, reading papers, gathering opinions

- Time pressure – 33 meetings in 2023

- Although 60% of meetings are on-line, it is still a significant time commitment, and reports need to be written about the main points discussed

Challenges

With EMA work

- Time/Travel to Amsterdam
- Getting the Family Doctor/GP voice heard among hospital doctors, special interest groups and the pharmaceutical representatives
- Making an impact in a diverse community

Benefits

Of being in the EMA Health Professionals Working Party

- Influencing decisions - recently on restrictions on prescribing of quinolones and fluoroquinolones
- Recognition of neurodevelopmental disorders when valproate has been prescribed for either parent
- Advice on ways to alert the issuing of inappropriate prescriptions
- Recommending the use of warnings in the software of electronic prescribing systems

Benefits of engagement

With the European Medicines Agency

- Opportunity to bring a family medicine perspective to discussions
- Reminder that GPs/FDs are the major prescribers for all drugs
- GPs/FDs can warn of practical problems
- Ability to warn of adverse events

One Health Project - AMR

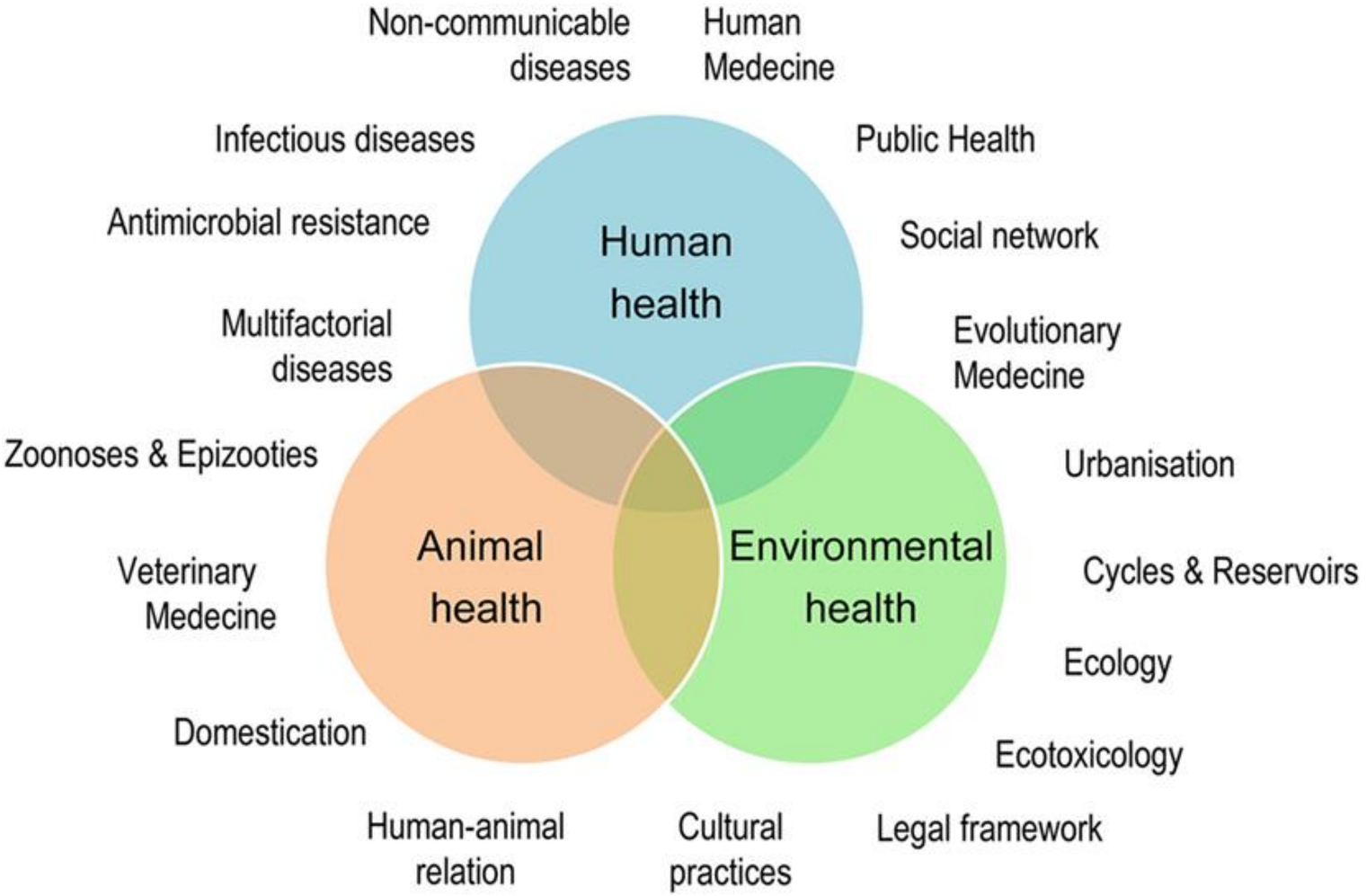
History of involvement

- Project started in 2017 – UEMO attended the meeting in Rome and was on a discussion panel
- Complicated process to become a stakeholder – individual application and CV requested
- There is an intention to avoid working in silos and to bring multidisciplinary teams together
- Human, animal, plant and environmental health are all connected and intertwined

One Health

Current involvement

- Three meetings in 2023 (one cancelled in April)
- Preliminary meeting in September 2023
- High level meeting in Luxembourg November 2023
- Update meeting in Brussels 29th February -1st March 2024



Challenges

With One Health Project

- Time for engagement
- The travel expenses for UEMO
- Chance to network at a high level with Health Policy Groups
- Opportunity to put the Family Medicine perspective – UEMO were able to speak on three topics

Benefits

Conference on One Health

- Reminding, when trust in experts was seen as diminishing, that GPs/Family Doctors retain their patients' trust and the confidence in their doctor's advice
- Pointing out that early and local microbiology advice was helpful in restricting antibiotic use
- Emphasising that first line antibiotics should be used first line
- Value of delayed prescriptions where appropriate

Benefits of Engaging with European Networks

EMA and One Health Network

- To make Health Policy Groups recognise the value of General Practice/Family Medicine
- To influence health decisions within the European Union
- To publicise the essential and difficult work GPs/FDs do – we see 90% of first medical contacts, we deal with 80% of medical problems
- To emphasise that every cost-effective health care system is founded on the rock of robust general practice/family medicine

Thank’s for your Attention

5’ questions

CMGF DU 21 AU 23 MARS PARIS2024
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European **H**ealth **E**mergency Preparedness and **R**esponse **A**uthority (**HERA**)

Patrick OUVRARD (UEMO former Vice President)

Union **E**uropéenne **M**édecine **O**mnipraticienne

Déclaration des liens d'intérêts

I DECLARE under my responsibility:

That I am not involved in any conflict of interest that could compromise my impartiality and independence with respect to my participation in this congress

HERA Health Emergency Preparedness & Response Authority

UEMO is part of Civil Society Forum

- The Health Emergency Preparedness and Response (HERA) department's mission is to **prevent**, **detect**, and r**apidly respond to health emergencies**.
- HERA, created in the aftermath of the COVID-19 pandemic, will anticipate threats and potential health crises, through intelligence gathering and building the necessary response capacities.
- When an emergency hits, HERA will ensure the development, production and distribution of medicines, vaccines and other medical countermeasures – such as gloves and masks – that were often lacking during the first phase of the response to the COVID-19 pandemic.
- HERA is a key pillar of the European Health Union will fill a gap in the EU's health emergency response and preparedness.

HERA Health Emergency Preparedness & Response Authority

UEMO is part of Civil Society Forum

AIM :

to be the dedicated European authority that will strengthen the EU's preparedness and response capability:

- Addressing serious cross-border health threats.
- Addressing vulnerabilities and strategic dependencies within the Union related to the development, production, procurement, stockpiling and distribution of medical countermeasures.
- Contributing to reinforcing the global health emergency preparedness and response architecture.

HERA Health Emergency Preparedness & Response Authority

HERA, Civil Society Forum, European Commission:

- UEMO submitted its application in April 2022 and was accepted at the HERA's Civil Society Forum in June 2022.
- By being part of this network, UEMO's members are enabled to exchange information and discuss ideas linked to HERA's activities as well as be a space for Member States to share their views.
- This sub-group, will help to ensure that the HERA Advisory Forum will receive regular input, views and opinions from civil society stakeholders

Representative: Dr Patrick Ouvrard

HERA Health Emergency Preparedness & Response Authority

rescUE exemple

rescEU takes the form of a reserve of European capabilities, financed entirely by the EU

HERA Health Emergency Preparedness & Response Authority

rescUE exemple

It includes :

- A fleet of water-bombing aircraft and helicopters,
- Medical evacuation aircraft,
- A stockpile of medical supplies and field hospitals to deal with health emergencies.

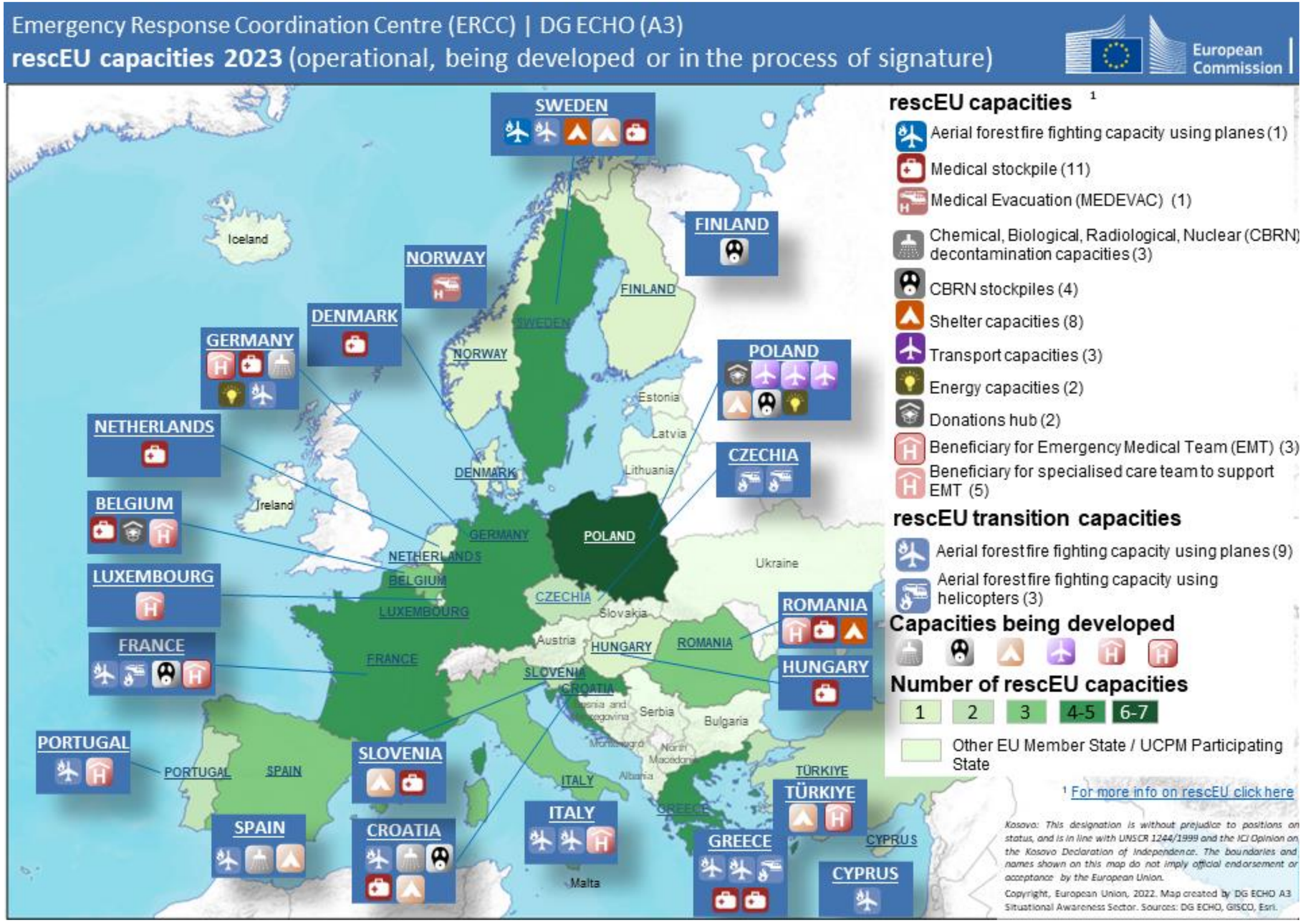
The rescEU reserve also includes :

- Shelters,
- Transport and logistics equipment,
- Energy supply systems.

Reserves are also being developed

- To deal with chemical, biological, radiological and nuclear risks :
  - Decontamination and detection equipment,
  - Reserves dedicated to medical countermeasures specific to these risks.

rescEU Capacities 2023



HERA Health Emergency Preparedness & Response Authority

What can GPs actively participate in Hera ?

- to exchange information
- to share their views.
- to receive regular input, views and opinions from all civil society stakeholders.
- to provide the Advisory Forum with observations and assessments
- to support the work of the Advisory Forum and contribute to its informed opinions and conclusions.

HERA Health Emergency Preparedness & Response Authority

Exemple

- Diffuse to GP such infographic as previously projected
- Improve the reaction to a new crisis (with regard to what happened during the last pandemic (COVID)
- I recently participated in a working group on training necessary to improve the dissemination of information

Thank’s for your Attention

5’ questions

HEALTH TECHNOLOGY ASSESSMENT (HTA)

Dr Hermenegildo Marcos (UEMO Vice President)
Dr Daniel Widmer

Union Européenne Médecine Omnipraticienne

Déclaration des liens d'intérêts

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WHAT IS HEALTH TECHNOLOGY ASSESSMENT

- **Procedure for assessing** the added value, effectiveness, costs and broader impact of health care interventions including medicines, medical devices and procedures.
- **Considers the evidence** about medical, economic, social and ethical aspects in relation to the use of health technology.
- **The objective of HTA** is to contribute to the promotion of innovation which provides the best results for patients and society.
    - It is an important tool to ensure the appropriate application and use of health technologies.
    - Look for maximum quality and transparency.

HTA DOMAINS

- CLINICAL DOMAINS
  - Health problems and currently used health technologies (e.g. medicines, medical devices, surgical procedures).
  - Description of health technology under assessment.
  - Relative clinical effectiveness.
  - Relative safety.

- NON-CLINICAL DOMAINS
  - Economic evaluation.
  - Organizational aspects.
  - Social aspects.
  - Legal aspects
  - Ethical aspects.

WHAT'S IN THE EU HTA REGULATION?

- FRAMEWORK FOR JOINT HTA COOPERATION
  - Joint clinical assessments (JCAs).
  - Joint scientific consultations (JSCs).
  - Identification of emerging health technologies.
  - Common procedures and methodologies across the EU

KEY PRINCIPLES OF THE HTA REGULATION

- Only on clinical and scientific domains of the assessment: No economic assessment or any conclusion on pricing and reimbursement.
- Driven by EU HTA bodies who remain responsible for drawing conclusions on added value for their health systems and make pricing and reimbursement decisions
- High quality, timeliness and transparency.
- Use of joint work in national HTA processes.
- Input from independent experts.
- Stakeholder engagement and inclusive. Ensure stakeholder involvement
- Progressive implementation

TIMELINE

- 12 January 2025: New oncology medicines and advanced therapy medicinal products will be assessed at EU level.
- 13 January 2028: Orphan medicinal products to be added to the joint work.
- 13 January 2030: All new medicines will come under the scope of the regulation.

WHAT WILL BE ASSESSED AT EU AND AT NATIONAL LEVEL?

EU ASSESSMENT
(jointly done by the Member States)

NATIONAL ASSESSMENT

MEDICINES

CLINICAL ASSESSMENT
(benefits compared to existing treatments)

NON-CLIN ICAL ASSESSMENT
(economic, social and ethical aspects)

MEDICAL DEVICES

High-risk devices with high impact on patients, public health and EU health systems

CLINICAL ASSESSMENT
(benefits compared to existing treatments)

NON-CLIN ICAL ASSESSMENT
(economic, social and ethical aspects)

in national decision-making.

CURRENT VS. FUTURE

CURRENT HTA

- Member states have different HTAs
- Different legislations and procedures
- Different methodology and assessment criteria

FUTURE HTA

EU HTAR

- Single clinical assessment framework
- Common methodology for clinical assessment and scientific consultation

NATIONAL

- Use of Joint clinical assessment in the national decisión-making
- Non-clinical assessment
- Price and reimbursement decisions

STAKEHOLDER NETWORK

- Patient associations
- Consumer organisations
- Health technology developer associations
- Health professional organisations
- Other non-governmental organisations in the field of health, including clinical and learned societies.

43 stakeholder member organisations and two observer organisations participated (European Institute of Innovation and Technology Health (EIT Health) World Health Organisation EURO (WHO EURO) EMA

How can stakeholders contribute as information sources to the report on emerging health technologies?

- Academic organization to identify key opinions leaders.
- Additional information from horizon projects that are/will be developed in a near future. Identify current and future needs.
- Clinical trials.
- Scientific meetings.
- National strategies-priorities. Identify national needs.
- Follow the recommendation by coordination group to prioritize and to know what kind of technologies will be used/developed.
- Collaboration with EMA.
- To prepare the system to cope with changes like.

What are the important issues for stakeholders regarding the joint work on medical devices?

- Evidence-Based Decision Making and access data.
- Clinical Effectiveness: to improve the data on clinical effectiveness.
- Frame the health problem to project the best benefit at the population level. Cost-Effectiveness:
- Patient Safety: Quaternary prevention.
- Health System Integration

ROLE OF THE UEMO

Challenges

- To assess the impact of treatment in real life
- Opinions and attitudes of GPs facing new technologies in their everyday practice
- **Workforce**. For any introduction of a new device, the commitment of the involved medical staff must be taken into account
- Involvement of experts
- Utility and practical applicability in daily consultation.
- Quaternary prevention.
- Environmental and socioeconomic aspects.
- Innovation providing something new to what already existed previously

ROLE OF THE UEMO

Challenges

- First step for discussion with the patient about indication
- Discussion with the patient of tolerance or side effects
- Discussion with the patient and family about ethical problems: surveillance, confidentiality, where are the data, right to die…
- Psychosocial problems: increasing awareness - overinformation and anxiety
- Dangerous devices
- Maintainance staff
- Teaching for users
- Long term side effects
- Duration – replacement.

Thank’s for your Attention

5’ questions