

CHU
de Liège

TRAINING DAY FOR SEARCH AND TRANSPLANT COORDINATORS
14 NOV 2014

- Going deeper into cell banking activities (including ATMPs)
- News from WMDA Fall meeting

E. BAUDOUX

CHU
de Liège

Law of 19 December 2008

- Implementation of EU directives
- Human bodily material (MCH-MLM)
 - ❖ Bodily material for human applications or research
 - Incl. stem cells, cord blood, bone marrow
 - Excl. Hair, nails, maternal milk, stools, tears, sweat
- Law
 - ❖ Royal decrees (AR-KB)
 - Quality standards
 - Control (FAGG-AFMPS) and Inspection
 - License
 - Biovigilance

CHU
de Liège

MCH-MLM Bank

The diagram shows a central blue arrow pointing right, labeled 'AFMPS-FAGG'. Above the arrow are three grey circles representing regulatory bodies: 'JACIE/FACT' (center), 'C...' (left), and 'tion' (right). Below the arrow is a white box labeled 'ational production establishment'. On the left side, there is a list of items:

- ro...
- Apho... (HPC-...)
- Maternity (HPC-CB)

CHU de Liège **MLM-HBM-MCH involved structures**

Hospital	Bank	Intermediate structure	Production establishment
<ul style="list-style-type: none"> Runs the bank 	<ul style="list-style-type: none"> Obtention Control Processing Storage Distribution (incl Import-Export) 	<ul style="list-style-type: none"> Processing Storage Distribution 	<ul style="list-style-type: none"> Industrial production of cellular therapies (autologous) All operations except control

Biobank

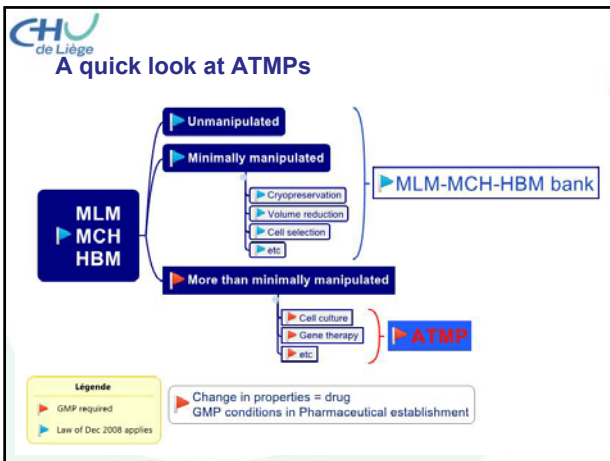
- No human application
- For research only

CHU de Liège **Imports and exports of MLM-MCH-HBM**

- From inside EU
 - No import involved as long as it happens between two licensed HBM-MCH-MLM banks
 - No additional controls in theory
- From outside EU, it is the responsibility of the bank to:
 - Document compliance to current legislation, OR
 - Perform controls for compliance

CHU de Liège **Examples of issues pointed by FAGG-AFMPS**

- Missing or incomplete documentation of informed consent
 - Usually done but not notified
- Missing or incomplete infectious safety parameters
 - Some tests may not be done at all at the CC
- Difficulty to identify the counterpart center as licensed MLM-MCH-HBM establishment
- Lack of proper convention-SLA between accepting bank and counterparts abroad



CHU de Liège

REPORT FROM WMDA FALL MEETING

CHU de Liège

Training program for search coordinators

- Online program for search coordinators started with pilot registries
- High quality contents
- Will be broadened to all soon
- Discounts to WMDA members


CHU de Liège

Global Registry Identifier (GRID)

GRID

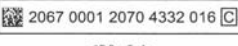
2067 0001 2070 4332 016 C

Registry Identifier Donor Identifier Check Character



2067 0001 2070 4332 016 C

Linear Bar Code
Label is 65 mm x 20 mm
(Approximately 2.5 in. x 1.5 in.)



2067 0001 2070 4332 016 C

2D Bar Code
Label is 65 mm x 10 mm
(Approximately 2.5 in. x 0.75 in.)

- Phase 1
 - ❖ Definition of rules
 - ❖ Guidance to registries
- Phase 2
 - ❖ Implementation in EMDIS and BMDW
 - ❖ Non-mandatory use
- Phase 3
 - ❖ Use in communication as well as on product labels

CHU de Liège

WMDA accreditation

Donors	72%
Qualified	2
Accredited	19
Letter of intent	4

- France
 - ❖ 173 documents
 - ❖ Cost +/- 16K€
 - ❖ 3 months/1 person
- Benefits
 - ❖ International credibility
 - ❖ Annual self evaluation
 - ❖ Confidence <-> competent authorities

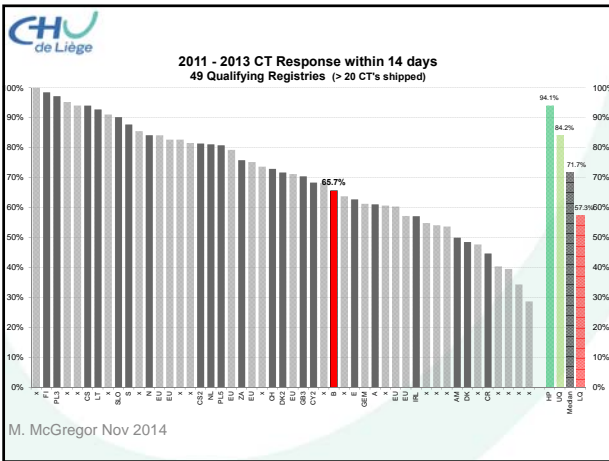
CHU de Liège

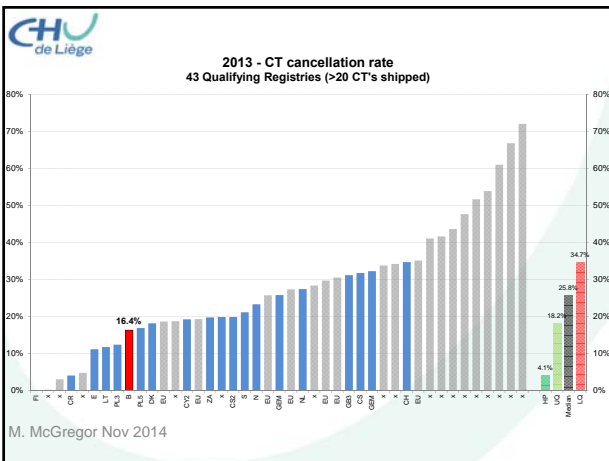
GEMS

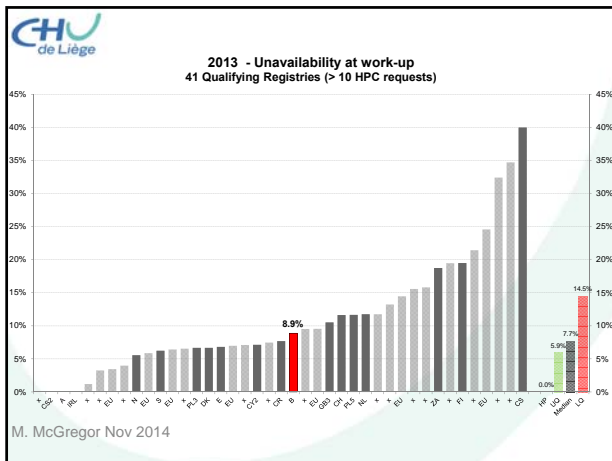
CHU de Liège

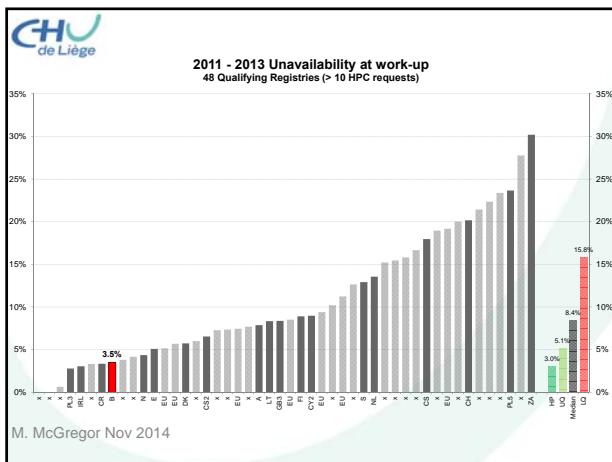
HLA typing

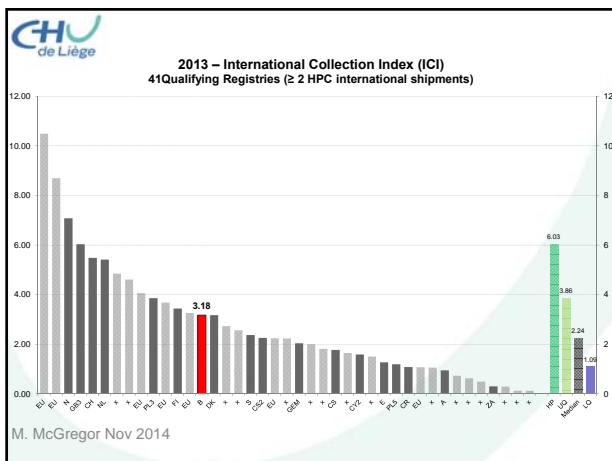
- Contract with Histogenetics ends March 2015
- New tender to start soon (expected applicants: DKMS, Histogenetics,...)
Proposals around 30€ (>10000 typings) for NGS HR 12 alleles ABORH and CCR5Delta 32 mutation

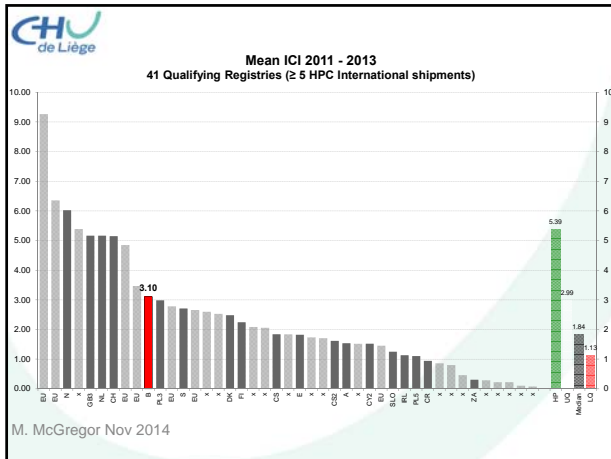


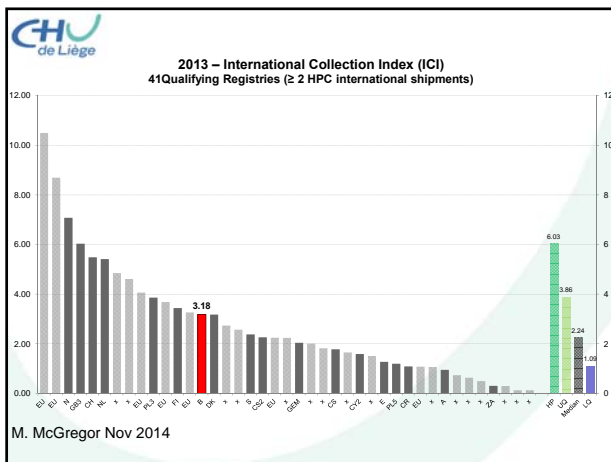


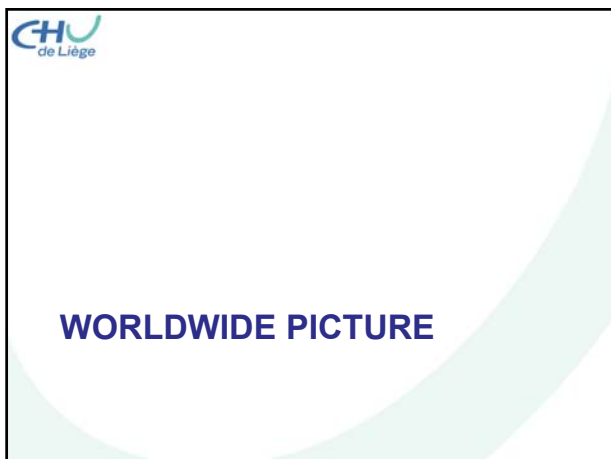


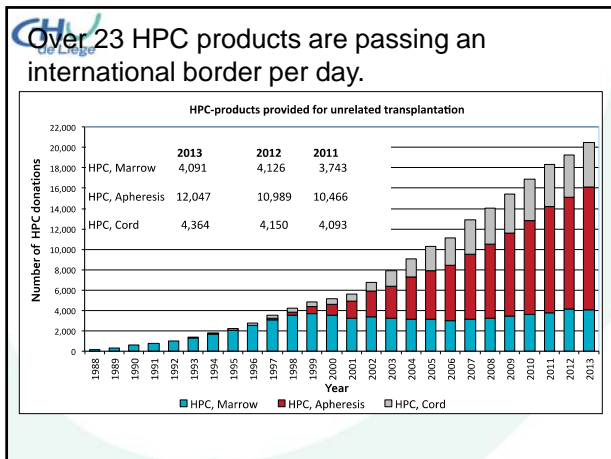






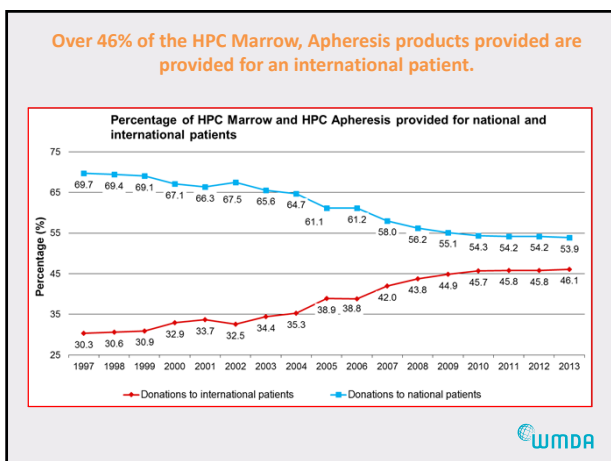






Which countries are the largest suppliers of HPC-products in 2013?

HPC-Marrow	No.	HPC-Apheresis	No.	HPC-Cord	No.
Japan-JMDP	1,338	Germany-ZKRD	5,254	USA-NMDP	1,324
Germany-ZKRD	1,117	USA-NMDP	2,729	Japan-JCBBN	1,158
USA-NMDP	911	China-CMDP	702	Spain-REDMO	320
Brazil-REDMO	152	Poland-DKMS	490	China-Shanghai	259
France-FGM	72	UK-Anthony Nolan	355	France-FGM	256
TOTAL	4,091	TOTAL	12,047	TOTAL	4,364



Import Only

(2006-2012)



Countries: Afghanistan, Belarus, Chile, Colombia, Cuba, Egypt, Estonia, Georgia, Jordan, Latvia, Lebanon, Malaysia, Philippines, Romania, Saudi Arabia, Uruguay.

- No fully operational registry in the period 2006-2012
- Starting up transplant programmes



Import and Internal Use Only

(2006-2012)

Countries: Bulgaria, Russia (526 imported donations)

- Percentage HLA-ABDR typed donors in BMDW
 - Russia Karelian Registry: 17%
 - Russia St. Petersburg: 10%
 - Russia HPC Registry: 100% (joined BMDW 03/2011)
- Small registry
 - Bulgaria: 729 donors are listed in BMDW



Import >> Export

Countries: Argentina, Australia, Austria, Belgium, Brazil, Canada, China, Croatia, Czech Republic, Denmark, Finland, France, Greece, China Hong Kong, Hungary, India, Iran, Ireland, Italy, Lithuania, Netherlands, New Zealand, Norway, Poland, Singapore, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Turkey.

* WMDA separates China, China Hong Kong and Taiwan in reports.



Import and Export Balanced

Countries: Israel, Mexico, Portugal, Taiwan, Thailand, United Kingdom, United States

Name country	Number of donors on January 1, 2014	% Unique phenotypes in BMDW*
Israel	825,707	4.31
Mexico	13,005	9.5
Portugal	338,614	4.2
Taiwan	360,923	4.14
Thailand	150,540	7
United Kingdom	903,858	4.38
United States	7,567,915	5.82


* Range 1.85 till 10.57



Export >> Import

Countries: Cyprus, Germany

- High number of donors
 - Germany: 5.9% of the population
 - Cyprus: 10.6% of the population

 United States: 2.1% of the population




Internal Use Only


Countries: Japan, Korea, Serbia

- Korea joined BMDW recently (August 2013);
- Serbia joined BMDW recently (January 2012);
- Japanese patients find in over 95% of the cases a donor in the national file.



 **Conclusions**

- The number of countries performing unrelated transplants is increasing (57 countries in 2013);
- Education is crucial to ensure high-quality products from all countries;
- Self sufficiency is a challenge; 51 countries import a high percentage products for their patients;
- Work towards self sufficiency by investing in your donor file:
 - Recruit donors
 - Quality of typing (at recruitment, prospective)
 - Donor availability
- Nearly 40% of the unrelated transplants come from Germany

 **Ongoing projects**

- CBWG technical survey on banking activities (International catalog of units)
- New book "Sharing Life" 50 stories on HSC donation
 - ✦ Release EBMT 2015 (ebook and print)
- Guidelines for HSC transport
- Guidelines for related donor care
