"Plasma donation: experience of the Marche Region"

Dr. Giovanna Salvoni



Responsabile Centro Regionale Sangue Regione Marche





Settimana nazionale della donazione di sangue 2018

The Italian blood donation week 2018



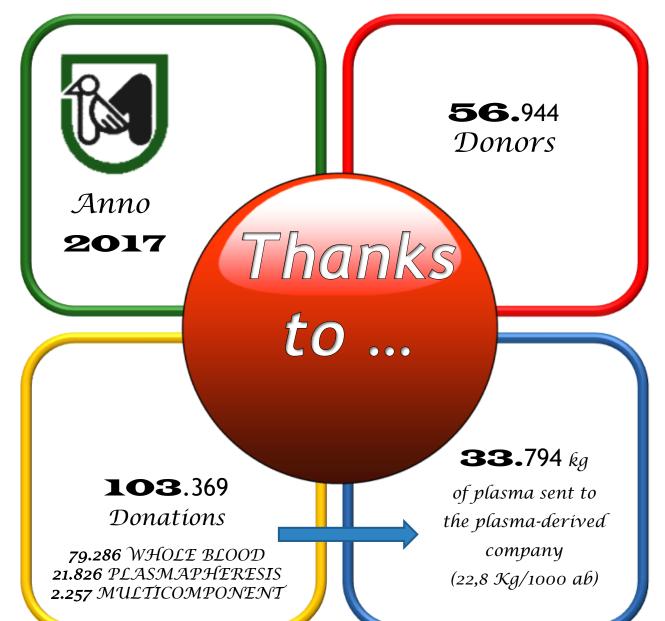
ESSERCI PER QUALCUN ALTRO. DONA IL PLASMA. CONDIVIDILA VITA.

BE THERE FOR SOMEONE ELSE. GNE PLASMA. SHARE LIFE.

Roma, 15 giugno 2018 - *Rome, June 15th 2018*

Istituto Superiore di Sanità Aula Pocchiari - Viale Regina Elena, 299





OUR REGIONAL SELF-SUFFICIENCY OF **BLOOD COMPONENTS** AND **PLASMA-DERIVED MEDICINAL PRODUCTS** (PDMP) ...

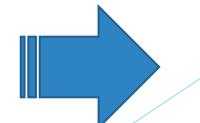
Dr. Giovanna Salvoni
"Plasma Donation: Experience of the
Marche Region"



From plasma collection to ...

DISTRIBUTION OF PDM PRODUCTS TO HOSPITAL PHARMACIES

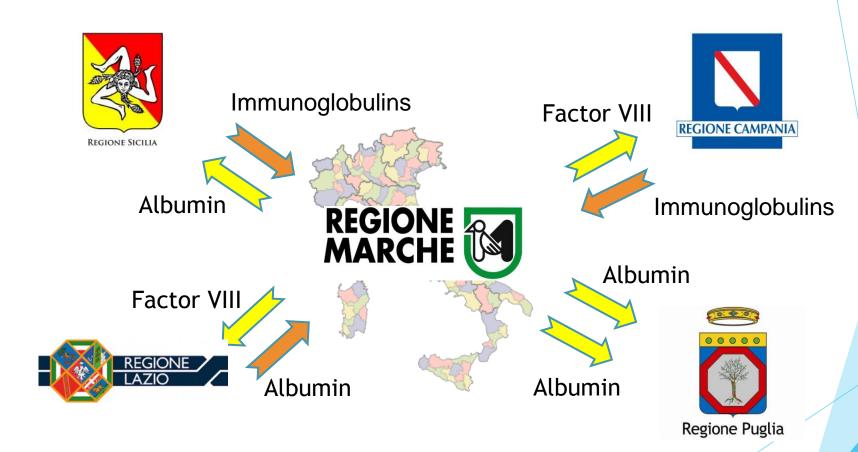
Marche Region	2015	2016	2017	Variation (three years)
Albumin (gr)	517.000	561.500	594.500	13,0%
Equivalent non-specific immunoglobulins (gr)	125.115	119.685	131.310	4,7%
Factor VIII (U.I.)	2.256.000	2.120.000	2.039.000	-10,6%
Factor IX (U.I.)	421.000	682.000	687.000	38,7%
Prothrombin complex (U.I.)	980.000	1.090.500	1.358.000	27,8%
Antithrombin III (U.I.)	2.504.000	2.059.000	2.227.000	-12,4%





From plasma collection to ...

INTER-REGIONAL COMPENSATION





From plasma collection to ...

INTER-REGIONAL COMPENSATION

(according to State-Regions Agreement 20-10-2015)

	Date	Product given	Quantity (bottles/vials)	Region (Customer)	Product received	Quantity (bottles/vials)
MARCHE	04/10/16	ALBUMIN	20.000	SICILIA	IMMUNOGLOBULINS	2.171
MARCHE	24/11/16	FACTOR VIII/ ANTITHROMBIN III	700/300	CAMPANIA	IMMUNOGLOBULINS	1.306
MARCHE	10/04/17	ALBUMIN	20.000	SICILIA	IMMUNOGLOBULINS	2.171
MARCHE	03/05/17	FACTOR VIII	826	REGIONE LAZIO	ALBUMIN	10.000
MARCHE	12/05/17	ALBUMIN	20.000	PUGLIA Regione Puglia	-	-
MARCHE	29/01/18	ALBUMIN	20.000	SICILIA	IMMUNOGLOBULINS	2.171



NAZIONALE SANGUE







Agenzia Italiana per la Cooperazione allo Sviluppo

From plasma collection to ...



INTERNATIONAL COOPERATION



INTERNATIONAL COOPERATION

2017





I.S.S. - C.N.S.

28/06/2017-0001467

00162 Roma Tel: 06 4990 4953 Fax: 06 4990 4975 E-mail: segreteriagenerale.cns@iss.it

Via Giano della Bella, 27

Al Direttore dell'Agenzia Regionale Sanitaria Prof. Francesco Di Stanislao

Al Direttore Dipartimento Interaziendale Regionale di Medicina Trasfusionale Dott.ssa Maria Antonietta Lupi

Al Responsabile del Centro Regionale Sangue Dott.ssa Giovanna Salvoni

Regione Marche

E, p.c.

Al Presidente regionale AVIS Dott. Massimo Lauri

Alla Kedrion SpA

Oggetto: Richiesta della Repubblica Islamica dell'Afghanistan di donazioni di medicinali plasmaderivati.

Con riferimento alla Vs. nota Prot. 5227/ARS/ARS/P del 5 giugno u.s., riscontriamo positivamente il Vs. interesse a partecipare al progetto di cooperazione con la Repubblica Islamica dell'Afghanistan e in particolare alla fornitura dei fattori della coagulazione per il trattamento dei pazienti affetti da emofilia.

Tenuto conto della richiesta pervenuta e delle disponibilità da Voi espresse, si ritiene opportuno programmare nell'arco dell'anno l'esportazione di 500.000 U.I. totali di fattore IX della coagulazione, verosimilmente attraverso due spedizioni, di cui la prima da realizzare nel corso delle prossime settimane, con 300 flaconi da 1000 U.I..

Sarà cura dello scrivente Centro prendere i necessari accordi operativi con il Centro Regionale Sangue, anche al fine di raccordare le disponibilità rappresentate da altre Regioni e in considerazione degli aspetti logistici del caso.

Cordiali saluti.

Il Direttore del Genfro Nazionale Sangue Dott. Giancarlo Maria Liumbruno

Referenti tecnici: Dott. Gabriele Calizzani Dott.ssa Samantha Profili Pagina I di I



REGIONE MARCHE

Servizio Sanità Il Dirigente



Al Direttore Dipartimento Interaziendale Regionale medicina Trasfusionale (DIRMT) Dr.ssa Maria Antonietta Lupi

Al Responsabile Centro regionale sangue DIRMT Dr.ssa Giovanna Salvoni

LORO SEDI

OGGETTO: Progetti Umanitari

Si fa riferimento alla comunicazione del 2 novembre u.s. inerente la possibile cessione, per fini umanitari, di fattore IX della coagulazione alla Repubblica Islamica dell'Afghanistan.

Al riguardo, preso atto delle disponibilità del prodotto e tenuto conto dell'alto valore umanitario, si comunica che nulla osta alla cessione in parola.

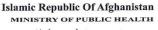
Cordiali saluti.

IL DIRIGENTE Dr.ssa Lucia Di Furia

7



د افغانستان اسلامی جمهوریت دعامی روغتیا وزارت



جمهوری اسلامی افغانستان وزارت صحت عامه

Ref: 678987

رياست روابط بين الملل

International Relations Directorate

INTERNATIONAL COOPERATION



2017

For Information Confidential Emergency Priority Routine

Date: 26-9-20/F

Mezzolani

Assessore Tutela della salute Regione Marche

Dr. Giovanna Salvoni

Direttore Centro Regionale Sangue, Regione Marche

Subject: Donation of factor IX by Regione Marche for the Hemophilia Center of Kabul

The Ministry of Public Health of the Islamic Republic of Afghanistan would like to thank Regione Marche and all local Blood Donor associations for their generous donation of plasma factor IX, highly needed for the care of our hemophilia patients.

The Ministry of Public Health hopes that this will be the beginning of a long-lasting collaboration and that through this partnership it will be possible to facilitate the access to factors and to a safe and effective treatment, guaranteeing a future for our patients.

Once again, we express our gratitude to the Regione March for the very efficient, effective and responsible support provided to our Country for many years.

I hope to have the opportunity to meet You in Rome next November

Sincerel

Dr. Ferozuddin Feroz Minister of Public Health

Islamic Republic of Afghanistan

Ministry of Public Health, Great Masoud Road Kabul-Afghanistan www.moph.gov.a IRD: moph.ird@gmail.com Phone: 020 2301529

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INTERNATIONAL COOPERATION



Islamic Republic of Afghanistan Ministry of Public Health

Date, Kabul 07 May 2018

9V/T/TT



2018



Following my previous letter to You requesting a donation of FVIII and FIX, I am writing again to take Your attention on the current situation of haemophilia care in our Country. With the institution of a new Paediatric Haemophilia Centre at the "Indira Ghandi" Hospital extending to the children the Adult Haemophilia Centre at Estiqal Hospital activities, the need for clotting factor concentrates has increased due to the growing number of patients Kabul area. In addition in Afghanistan there is lack of specialised expertise and adequate infrastructure for diagnosis, treatment and rehabilitation.

In consideration of the excellent relationship between our Countries and the precious support already provided in this sector by some Italian Regions in the past years, I would like to request any support aimed to donate at least 1,5 million IU of Factor VIII and 600.000 IU of Factor IX and to

10

H.E. Mrs Beatrice Lorenzin Minister of Health of the Italian Republic

Dr. Giuseppe Ruocco Secretary-General Ministry of Health of the Italian Republic.

Dr Sergio Venturi Health Care Councillor, Emilia-Romagna Region

Dr Luca Ceriscioli President Marche Region

Dr Giancarlo Liumbruno Director Italian National Blood Centre.

The Ministry of Public Health Afghanistan appreciates your support to health sector in Afghanistan regarding to donation of anti-hemophilic factors for Estiqlal Hospital and Indira Gandhi Hospital in Kabul .

Following my previous letter to You requesting a donation of FVIII and FIX, I am writing again to take Your attention on the current situation of haemophilia care in our Country. With the institution of a new Paediatric Haemophilia Centre at the "Indira Ghandi" Hospital extending to the children the Adult Haemophilia Centre at Estiqal Hospital activities, the need for clotting factor concentrates has increased due to the growing number of patients Kabul area. In addition in Afghanistan there is lack of specialised expertise and adequate infrastructure for diagnosis, treatment and rehabilitation.

In consideration of the excellent relationship between our Countries and the precious support already provided in this sector by some Italian Regions in the past years, I would like to request

develop a specific cooperation project with the objective of capacity building in the field of Haemophilia. This project and the related support to transfusion services and blood banks represent a main priority in our Ministry agenda.

Once again we express our gratitude to the Italian Government for the very efficient, effective and responsible support provided to our Country for many years.

Sincerely yours.

Dr.Ferozuden Feroz

Minister of Public Health



From plasma collection to ... INTERNATIONAL COOPERATION



2018

DEVELOPMENT OF TRANSFUSION AND DIAGNOSIS AND TREATMENT CENTERS OF HEMATOLOGICAL RARE DISEASES NETWORK IN PALESTINE

PALESTINA

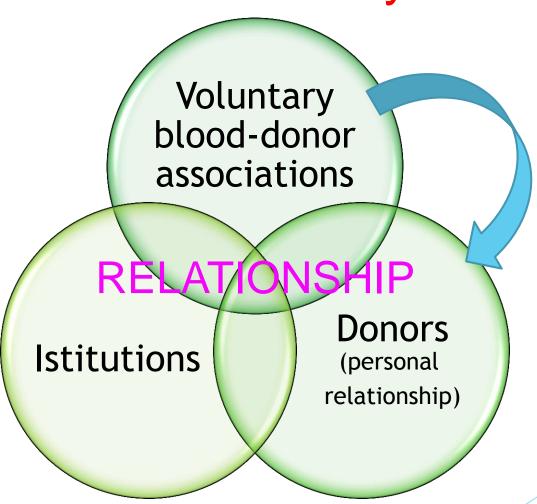
HAEMO_PAL

POTENZIAMENTO DELLA RETE TRASFUSIONALE E DEI CENTRI DI DIAGNOSI E TRATTAMENTO DELLE MALATTIE RARE EMATOLOGICHE IN PALESTINA

Concept Paper



Which strategies lead to regional self-sufficiency?





Which strategies lead to regional self-sufficiency? RELATIONSHIP WITH VOLUNTARY BLOOD-DONOR ASSOCIATIONS

Based on DGRM No. 873/2008 and Departmental Regulation (Resolution No. 1.731 of 29/11/2010) the tasks of blood donor associations and federations in the Marche Region are:





Which strategies lead to regional self-sufficiency? RELATIONSHIP WITH VOLUNTARY BLOOD-DONOR ASSOCIATIONS

Sharing regional (and national) objectives

Voluntary blood-donor associations are members of the Departmental Committee (decision-making and advisory body)



It expresses opinions:

- on the proposed <u>internal department rules</u> as well as on the <u>annual plan and the resource requirements</u>, proposed by the Director of the Department;
- on the distribution of the <u>departmental budget</u>;
- on relationships with other departments.

It exercises its advisory function on the structural changes of the department.

It <u>approves models for monitoring and assessing</u> the quality of blood transfusion services and for adopting diagnostictherapeutic guidelines and protocols.

Which strategies lead to regional self-sufficiency?

RELATIONSHIP WITH VOLUNTARY BLOOD-DONOR

ASSOCIATIONS

Sharing promotion campaigns

aimed to increase the number of regular donors





The greater the number of periodic donors, the more the Region's capacity to guarantee blood availability (also in emergency situations) for the citizens (also of other regions).







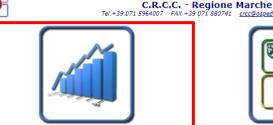
Which strategies lead to regional self-sufficiency?

RELATIONSHIP WITH VOLUNTARY BLOOD-DONOR

ASSOCIATIONS/DONORS

Sharing daily work-flow (collection)

ACTUAL AVAILABILITY OF HOSPITAL BLOOD BANKS



<u>Disponibilita' reale emoteche Marche</u>
Le disponbilita' sono relative alle unita' di emazie e
sono ricavate in tempo reale.



ERAZIENDALE REGIONALE di MEDICINA TRASFUSIONALE

<u>Area riservata DIRMT</u> Questa area e' riservata al personale del DIRMT WEB-SPACE
FOR
ASSOCIATIONS
(to view and to
download data
related to
donations made
by their donors)

Making available their test results and the agenda of their past donations

REGIONAL AGENDA OF THE DONORS



Agenda Regionale Donatori

Questa area e' riservata al personale addetto alla
prenotazione dei donatori sull'Agenda regionale.



Associazioni
Questa area e' riservata alle associazioni di
donatori e permette di visuionare ed
eventualmente scaricare i dati relativi alle
donazioni effettuate dai propri donatori.

PERSONAL AREA FOR DONORS



<u>Area donatori</u> Questa area e' riservata ai donatori della Regione Marche.



Inserimento richiesta esami donatore d'organo
Questa area e' utilizzata per le richieste di esami
per donatori d'organo, la sezione va utilizzata previ
accordi con il Laboratorio Regionale di Medicina
Trasfusionale e utilizzando le etichette prestampate
specifiche.

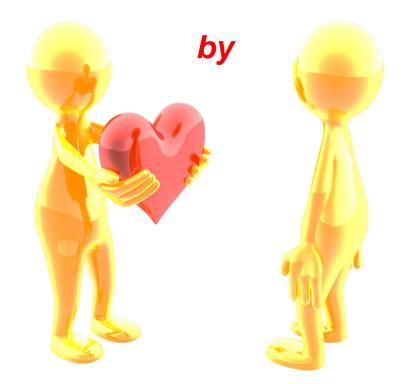
Dr. Giovanna Salvoni
"Plasma Donation: Experience of the
Marche Region"



Which strategies lead to regional self-sufficiency? RELATIONSHIP WITH VOLUNTARY BLOOD-DONORS

One-to-one dialogues aimed to engage them and to ... spread the message "Donate when necessary and what is necessary"

Blood-donor associations (for example during the periodic calls);



NHS (National Healthcare System) operators (during the medical examination pre-donation).

- 1



Which strategies lead to regional self-sufficiency? RELATIONSHIP WITH ISTITUTIONS

What are we trying to do? Constant cooperation with

THE NATIONAL BLOOD CENTRE

 Maintain a constant working partnership with the National Blood Center to contribute to achieving the annual national selfsufficiency, so that urgent needs can be addressed.

OTHER REGIONS

- Collaborate for inter-regional compensation of surplus bloodcomponents and plasma-derived products;
- share the best practices in managing transfusion activities;
- move toward cooperative arrangements between regions for obtaining plasma-derived medicinal products.

THE MARCHE REGION

- Engage regularly the Marche Region in identifying the strategic goals and the operative objectives;
- promote a continue dialogue on the importance of inter-regional cooperation;
- propose virtuous actions to increase the plasma collection without strong impact on the regional health resources.



But... all of this does not happen by accident

The road map of the Trasfusion Medicine System of the Marche Region

OUR MAIN STEPS



Dr. Giovanna Salvoni
"Plasma Donation: Experience of the
Marche Region"



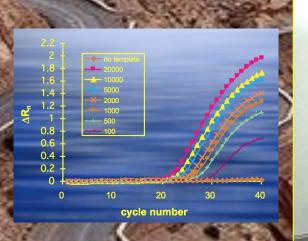
NAT testing Year 2001

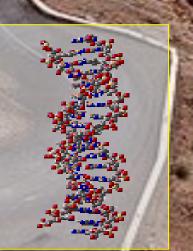
Fase Fase lineare

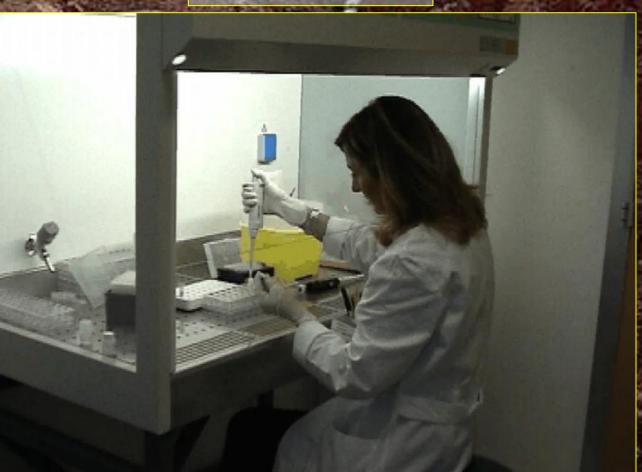
Plateau

Plateau

Fase sponenziale Fase lineare











Regional Law No 13/2003: Institution of the Regional Department

Indicators of activity

National Register of Blood 2004

Popolation=1.519.421

WholeBlood = 63.510

Donors/year = 35.470

Plasmapheresis = 11.832

Donors/populationIndex = 1/43

DonationIndex = 2.1





Donations 76.875

Sent plasma fractionation industry to: 19.759 litres









200

New technologies/systems

Laboratory Information Management System

- Modern laboratory automation
- Electronic Issue
- Blood Tracking
- Remote Issue
- Bedside systems
- Networked LIMS across sites
- New LIMS solutions
- Transportation systems

From 2004 to 2009
...updates until
today....

Information System

Single Information SystemTMM

Computerized Transfusion request Safe transfusion

Server WEB:

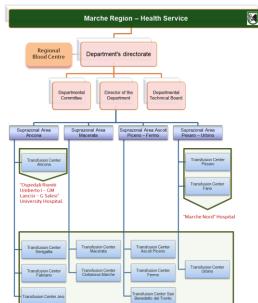
Centralized Laboratory of serum virology and molecular biology Regional Registry of Donors

Management of medical equipment, bags and reagents warehouse Management of medicines and industrial blood products warehouse Constitution of the regional blood bank of "real availabilities" Checking and compensation of blood components

Epidemiological Observatory Regional Register of HDN

Management of the "Quality System"

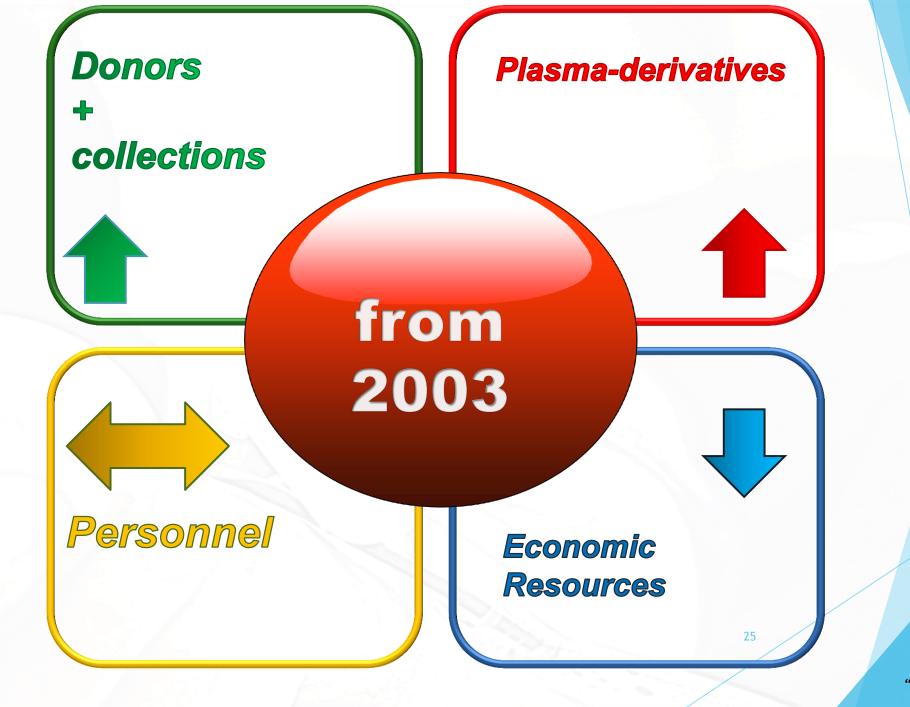












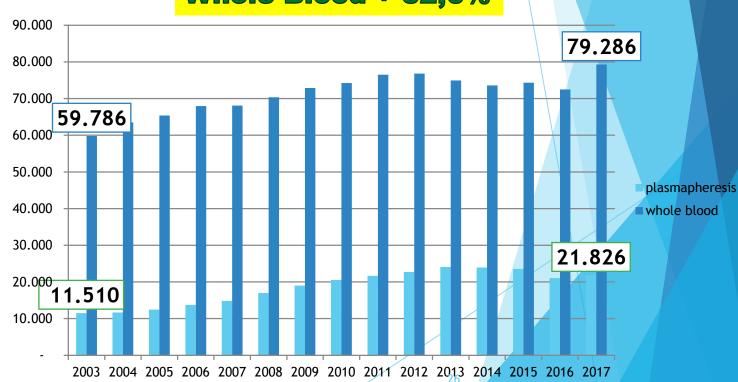
Dr. Giovanna Salvoni
"Plasma Donation: Experience of the
Marche Region"







Plasmapheresis + 89,6% Whole Blood + 32,6%





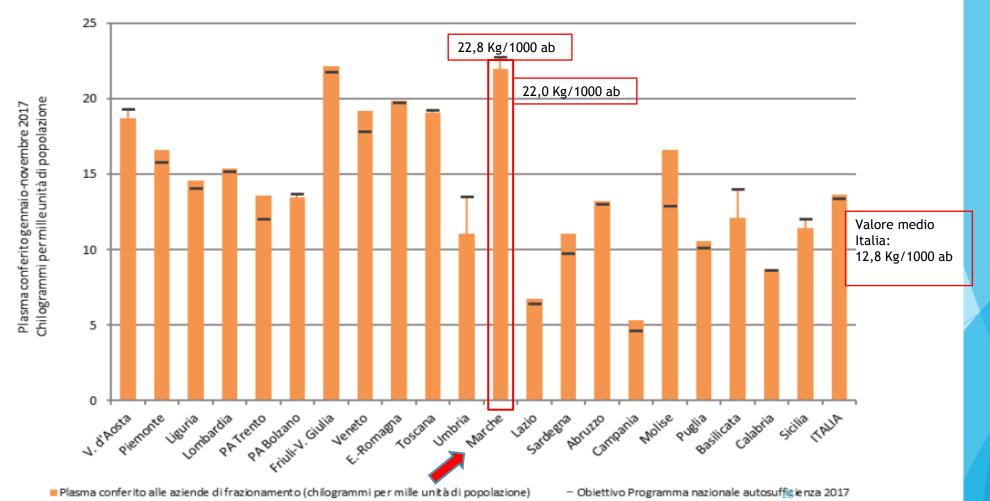
KG of plasma sent to the fractionation + 81,3%



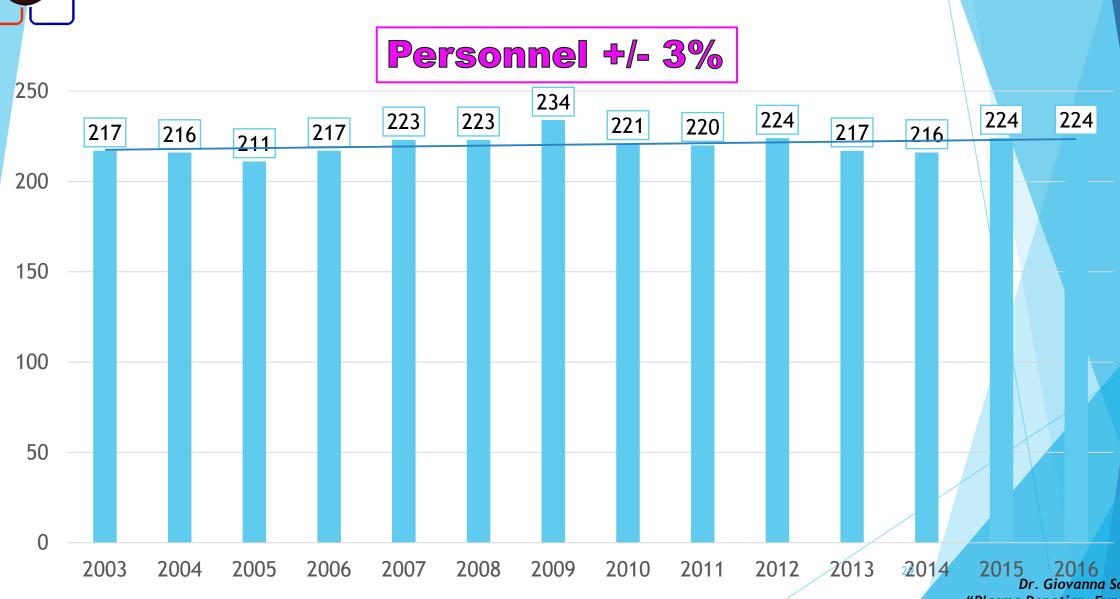




Figura 16. Plasma totale (chilogrammi per mille unità di popolazione) conferito dalle Regioni e PP AA nel periodo gennaio-dicembre 2017 e obiettivi di raccolta contenuti nel Programma nazionale autosufficienza 2017.





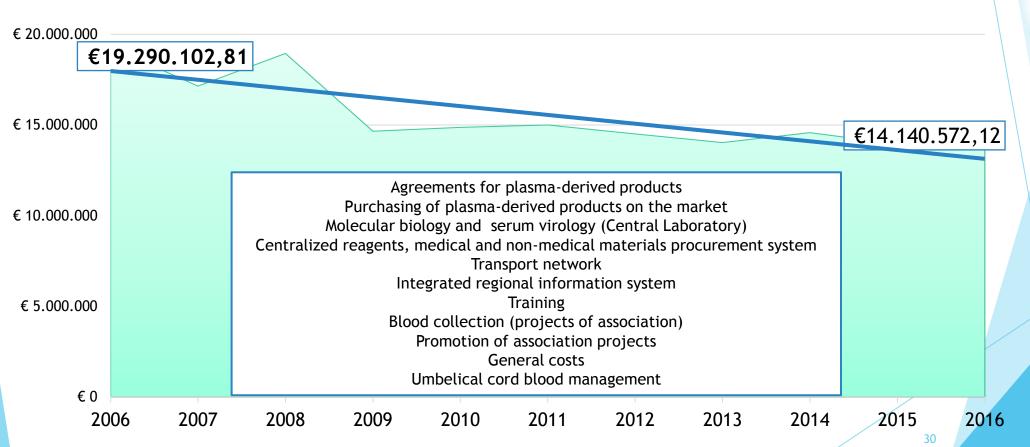


Dr. Giovanna Salvoni
"Plasma Donation: Experience of the
Marche Region"



Economic resources (managed by DIRMT) - 26,7%

€ 25.000.000



Last 10 vears

Dr. Giovanna Salvoni "Plasma Donation: Experience of the Marche Region"

Conclusion The origin





Tabella 4. Plasma totale (chilogrammi e chilogrammi per mille unità di popolazione) conferito dalle Regioni e PP AA nel periodo gennaio-dicembre 2017 e obiettivi di raccolta contenuti nel Programma nazionale autosufficienza 2017.

REGIONI, PP AA, Ministero Difesa	Plasma conferito nel periodo gennaio-maggio 2017 (kg)	Obiettivo Programma nazionale autosufficienza 2017 (kg)	Plasma necessario al raggiungimento dell'obiettivo 2017 (kg)	% sul totale obiettivo 2017	Plasma conferito alle aziende di frazionamento (kg per mille unità di popolazione)*	Obiettivo Programma nazionale autosufficienza 2017 (kg per mille unità di popolazione)*
V. d'Aosta	2.370	2.450	-80	97%	18,7	19,3
Piemonte	73.093	69.500	3.593	105%	16,6	15,8
Liguria	22.828	22.000	828	104%	14,6	14,1
Lombardia	153.786	152.000	1.786	101%	15,3	15,2
PA Trento	7.218	6.500	718	111%	13,4	12,1
PA Bolzano	7.155	7.200	-45	99%	13,6	13,7
Friuli-V. Giulia	26.778	26.500	278	101%	22,0	21,8
Veneto	86.191	87.604	-1.413	98%	17,6	17,9
ERomagna	88.354	88.000	354	100%	19,9	19,8
Toscana	71.356	72.000	-644	99%	19,1	19,2
Umbria	9.852	12.000	-2.148	82%	11,1	13,5
Marche	33.794	35.000	-1.206	97%	22,0	22,8
Lazio	39.745	38.000	1.745	105%	6,7	6,4
Sardegna	18.247	16.160	2.087	113%	11,0	9,8
Abruzzo	17.512	17.200	312	102%	13,2	13,0
Campania	31.083	27.000	4.083	115%	5,3	4,6
Molise	5.157	4.000	1.157	129%	16,6	12,9
Puglia	42.944	41.250	1.694	104%	10,6	10,2
Basilicata	6.481	8.000	-1.519	81%	11,4	14,0
Calabria	17.081	17.000	81	100%	8,7	8,7
Sicilia	57.688	61.000	-3.312	95%	11,4	12,1
M. Difesa	401	350	51	115%	-	-
ITALIA	819.114	810.714	8.400	101%	13,5	13,4

^{*} Popolazione residente all'1 gennaio 2017 (http://demo.istat.it – Ultima consultazione 15/11/2017).



What strategies lead to regional self-sufficiency? RELATIONSHIP WITH VOLUNTARY BLOOD-DONOR **ASSOCIATIONS**

Sharing daily work-flow (collection)

ACTUAL AVAILABILIT OF HOSPITAL **BLOOD BANKS**

REGIONAL

AGENDA

DONORS

OF THE

Disponibilita' reale emoteche Marche Le disponbilita' sono relative alle unita' di emazie e sono ricavate in tempo reale

Agenda Regionale Donatori Questa area e' riservata al personale addetto alla prenotazione dei donatori sull'Agenda regionale.



donatori e permette di visuionare ed



Ouesta area e' riservata al personale del DIRMT

DIPARTIMENTO INTERAZIENDALE REGIONALE di MEDICINA TRASFUSIONALE C.R.C.C. - Regione Marche Tel.+39 071 5964007 FAX +39 071 880741 crcc@ospedaliriuniti.marche.it

> <u>Associazioni</u> Ouesta area e' riservata alle associazioni di eventualmente scaricare i dati relativi alle donazioni effettuate dai propri donatori.



Inserimento richiesta esami donatore d'organo Ouesta area e' utilizzata per le richieste di esami per donatori d'organo, la sezione va utilizzata previ accordi con il Laboratorio Regionale di Medicina Trasfusionale e utilizzando le etichette prestampate

WEB-SPACE FOR **ASSOCIATIONS** (to view and to download data related to donations made by their donors)



Ouesta area e' riservata ai donatori della Regione

Dr. Giovanna Salvoni ma Donation: Experience of the Marche Region"



What strategies lead to regional self-sufficiency? RELATIONSHIP WITH VOLUNTARY BLOOD-DONORS

By making available their test results; agenda of their past donations

DIPARTIMENTO INTERAZIENDALE REGIONALE di MEDICINA TRASFUSIONALE C.R.C.C. - Regione Marche Tel.+39 071 5964007 FAX +39 071 880741 crc@ospedaliriuniti.marche.it



Disponibilita' reale emoteche Marche

Le disponbilita' sono relative alle unita' di emazie e sono ricavate in tempo reale.



Area riservata DIRM

Questa area e' riservata al personale del DIRMT



Agenda Regionale Donatori

Questa area e' riservata al personale addetto alla prenotazione dei donatori sull'Agenda regionale.



<u>Associazioni</u>

Questa area e' riservata alle associazioni di donatori e permette di visuionare ed eventualmente scaricare i dati relativi alle donazioni effettuate dai propri donatori.





<u>Area donatori</u>

Questa area e' riservata ai donatori della Regione
Marche.



Inserimento richiesta esami donatore d'organo

Questa area e' utilizzata per le richieste di esami per donatori d'organo, la sezione va utilizzata previ accordi con il Laboratorio Regionale di Medicina Trasfusionale e utilizzando le etichette prestampate Dr. Giovanna Salvoni ma Donation: Experience of the Marche Region"

Quantità totale di plasma da conferire al frazionamento industriale per l'anno 2018 (kg e kg/1000 pop)

Regioni e Province Autonome	Plasma da conferire al		
	frazionamento industriale		
Autonome	(chilogrammi)		
Valle d'Aosta	2.663		
Piemonte	72.000*		
Liguria	23.725		
Lombardia	153.786		
Prov. Auton. Trento	7.387		
Prov. Auton. Bolzano	7.061		
Friuli-V. Giulia	26.987		
Veneto	94.515*		
ERomagna	88.354		
Toscana	72.000		
Umbria	11.368		
Marche	35.000*		
Lazio	41.358		
Sardegna	18.730*		
Abruzzo	17.913*		
Campania	37.462*		
Molise	5.500		
Puglia	43.000*		
Basilicata	8.582		
Calabria	18.635		
Sicilia	61.500*		
S.T. Forze Armate	401		
Italia	847.927		

