





First meeting of the WP8 - Task 1

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The Italian Arthroplasty Registry Project

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National Centre for Epidemiology, Surveillance and Health Promotion Italian National Institute of Health What is an Arthroplasty Registry? Which are its objectives?

- Observational prospective study (~100% coverage) that collect a minimum set of information about the surgical procedure
- Endpoint: implant revision

Aims:

- To highlight in advance prostheses showing high failure/low performance
- To trace patients in case of recall









Studies funded by the DG medical devices and pharmaceutical service *HIP*

- 2006 2007 Preliminary study Definition of the model
- 2007 2009 Implementation of the model with the 3 existing regional registries
- 2009 2011 Extension of the model to other regions (8 new enrolled)
- 2012 2013 Data collection in the participating region and enrolment of new regions
- 2012 2013 Introduction of QoL at regional level (Puglia)

KNEE

- 2010 2012 Definition of the model; implementation in 3 of the existing regional registries
- 2013 2014 Extension of the model to other regions

SHOULDER

• 2014 – 2015 Definition of the model; implementation in selected regions

REGISTRY

• 2015 – 2017 Definition of local systems interoperability

MEDICAL DEVICES

- 2013 2014 Procedures for medical device identification and characterization
 - 2015 2016 Empowerment of RIAP-DM Dictionary. ICOR Collaboration





Italian Arthroplasty Registry: 3 main pillars

- **Structure:** federation of regional registries coordinated by a supranational public health institution (ISS). Close cooperation of all the stakeholders.
- Data collection: routinely collected data (HDR) integrated by an additional Minimum Data-set (MDS)
- Implanted devices: tracking and describing (identification, characterization)







2° pillar: HDR+MDS

- 1. Hospital code
- 2. Hospital sub-code
- 3. Year + N. of admission
- 1. Side
- 2. **Procedure (type)**
- 3. Diagnosis (primary/revision)
- 4. Previous procedure
- 5. Approach
- 6. Fixation
- 1. CND Code
- 2. Manufacturer
- 3. **Product code**
- 4. Lot number

SUPERIOR.



				2	16	DATIN3	Data intervento secondario		SDO
The second se	ACCIATO NECOT			2	7	INT3	3° Intervent	o secondario	SD0
_				2	18	DATIN4	Data interve	nto secondario	SD0
N	Variabile tracclato	Esplicitazione	Deducibile da	2	9	INT4	4° intervent	o secondario	SDO
	record			3	10	DATIN5	Data interve	nto secondario	SDO
		RICOVERO		3	н	INT5	5° Intervent	o secondario	SDO
1	COSP	Codice ospedale	SUUX tractato record	3:	12	MCDIM	Modalità di	dimissione	SDO
									SD0
								vza	SD0
	Inly	nan l		with					SD0
	IIIKa	1()H P	(HVS)	VVIIII		піл			SD0
			i o y o	VVICII				a	SD0
		U						sione	SD0
8	CODIND	Codice individuale	SDO	3	19	DRG	DRG		SD0
9	COMNAS	Comune di nascita	SDO	- 4	10	MDC	Major Diagn	ostic Category	SD0
10	COMRES	Comune di residenza	SDO					TERVENTO	
11	CITTAD	Cittadinanza.	SDO	- 4	11	LAT	Lato		Tr. Record aggiuntive
12	TIPRIC	Tipo di ricovero	SDO	- 4	12	TIPINT	Tipo di inter	vento	Tr. Record aggiuntive
13	DADIM	Data dimissione	SDO	4	13	CAU1	Causa inlen	vento primario	Tr. Record aggiuntic
14	DIAGN	diagnosi principale	SDO	4	и	CAU Inde	Altro - Caus	a intervento primario	Tr. Record aggiuntic
15	COND1	1º diagnosi secondaria	SD0	4	15	CAUR	Causa revis	ione/rimozione	Tr. Record aggiuntic
				4	16	CAURnole	Altro - Caus	a revisione/rimozione	Tr. Record aggiuntic
		141		4	17	INTPRE	intervento p	recedente	Tr. Record aggiuntic
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	4()()	() c	11 U.A.		19	VIAACC	Via di acces	190	Tr. Record aggiuntive
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22	DATIN1	Eata intervento secondario	SD0				D	ISPOSITIVO	
23	INT1	1º Intervenio secondario	SDO	5	2	DISPOSITIVO	Dispositivo		Tr. Record aggiuntive
24	DATIN2	Data intervento secondario	SDO						
	INT2	2º Intervenio secondario	SDO	_					
25				-					
25				1					

National Classification of medical devices (CND)									
DOOO	HIP PROSTHESES								
MD information	ACETABULAR CUPS								
	CUPS FOR PRIMARY IMPLANT								
1 000000101	CEMENTED CUPS FOR PRIMARY IMPLANT								
P090803010101	CEMENTED METAL CUPS FOR PRIMARY IMPLANT								
P090803010102	CEMENTED POLYETHYLENE CUPS FOR PRIMARY IMPLANT								
P090803010199	CEMENTED CUPS FOR PRIMARY IMPLANT - OTHER								
P0908030102	CEMENTLESS CUPS FOR PRIMARY IMPLANT								
P090803010201	CEMENTLESS METAL CUPS FOR PRIMARY IMPLANT								
P090803010299	CEMENTLESS CUPS FOR PRIMARY IMPLANT - OTHER								



RIAP Data collection



Medical devices identification and characterization

Data flow tested in 16 contexts

- 9 Regions
- 2 Provinces Autonomous
- «Livio Sciutto» Foundation

- Active data collection
- Studying integration in HDR
- Regional registry
- Enrolled in 2014
- Interested in participating
- Participating in a first phase
- ✤ Hip and knee
- ∧ Shoulder (to be implemented in 2015)







1) Coverage

2) Unique Personal Identification Number and Confidential Data





1) Coverage rate and participation rate

Coverage rate

Regional registries ~ 100% Other regions 1.7% ÷ 65.0%

Participation rate

Regional registries ~ 100% Other regions 3.3% ÷ 75.0%

- > 145,000 Hip
- > 75,000 Knee

To get coverage of over 90%, participation in the register must be mandatory!

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Ente	Articolazione	Data inizio	Data fine	Copertura (%)	Partecipazione (%)	Ricevuti	Utilizzati	
Valle d'Aosta	Anca	30/12/10	11/04/11	-	-	23	22	
Lombardia	Anca	01/01/07	31/12/12	≈100	100,0	103.267	97.611	
	Ginocchio	01/01/07	31/12/12	≈100	100,0	62.693	60.102	
PA Bolzano	Anca	01/01/10	31/12/13	97,3	100,0	4.904	4.880	
	Ginocchio	01/07/11	31/12/13	88,7	100,0	1.630	1.627	
PA Trento	Anca	01/01/10	31/12/13	65,0	75,0	2.368	2.215	
Veneto	Anca	09/09/10	31/12/10	-	-	90	90	
Emilia-Romagna	Anca	01/01/07	31/12/08	-	-	17.859	17.815	
Toscana	Anca	09/06/10	18/05/11	6,4	10,0	422	283	
Marche	Anca	28/12/10	19/06/13	-	-	922	-	
	Anca	27/11/13	31/12/13	15,0	10,0	22	18	
	Ginocchio	02/12/13	31/12/13	15,0	10,0	8	7	
Lazio	Anca	04/01/10	21/01/13	1,7	3,3	409	365	
Puglia	Anca	01/01/06	31/12/13	55,9(^)	63,2(^)	19.536	17.678	
	Ginocchio	01/01/06	31/12/13	49,7(^)	57,5(^)	12.149	11.537	
Basilicata	Anca	02/10/08	16/12/13	29,6	42,9	982	722	
	Ginocchio	09/01/13	16/12/13	17,2	42,9	84	84	
Sicilia	Anca	03/01/10	10/06/13	-	-	490	-	
	Anca	01/07/13	31/12/13	8,9	8,2	212	207	
	Ginocchio	01/07/13	31/12/13	6,7	7,4	150	143	
Fondazione Livio Sciutto	Anca	01/01/08	31/12/13	-	-	4.077	3.698	
ONLUS	Ginocchio	01/01/08	31/12/13	-	-	2.534	2.446	
Totale Anca					/	155.583	145.604	
Totale Ginocchio					(79.248	75.946	
Totale complessivo						234.831	221.550	

2013 – Riap database





2) Unique Identification of Patients and Confidential Data

a) High Interregional Mobility (patients having surgery outside their region are lost) b) No linkage to Mortality Registries (dead patients have the perfect prosthesis!)

D NO:

T NO:

Informed consent



Approved by the ISS Ethical Committee (21/6/2013)

L. Leone, V. Toccaceli, M. Torre e il Gruppo di Lavoro RIAP "Progetto RIAP e privacy: sviluppo di un modello di consenso informato per il paziente" Notiziario dell'ISS – Volume 25 (11), Novembre 2012:13-16





Possible Solution

DL 18/10/2012, n. 179 converted in L. 17.12.2012, n. 221 (Art. 12, Comma 10,11,12,13) *Further urgent measures for the country's growth*



"Registry (..., of implants, ...):

<u>a fundamental tool of prevention, diagnosis, treatment and</u> <u>rehabilitation, health planning, verification of the quality of care</u> in order to ensure an active system of <u>systematic collection of</u> <u>personal, sanitary and epidemiological data</u> in order to characterize all cases of health risk, cases of a particular disease or considerable health condition, in a defined population".









2000's:Switzerland; England and Wales; Catalonia (ES); Valdotra (SL); Czech Republic; Slovakia; Scotland; Netherlands; Croatia; Hungary; Portugal; Romania; Canada

90's: Denmark; New Zealand; Australia

Finland; Norway 80's:

Sweden

70's:

Arthroplasty Registries worldwide



Start of registries in Italy compared to the international context



2006 riap start 1975 Sweden (knee) 1979 Sweden (hip) 1980 Finland 1987 Norway 1995 Denmark 1998 New Zealand 1999 Australia 2000 Emilia-Romagna 2001 Canada 2001 Puglia (voluntary data collection) 2002 Valdotra (SL) 2002 England and Wales 2003 Lombardia 2004 Catalonia (ES) 2004 Czech Republic 2004 Slovakia 2006 Scotland **riap** start 2007 Netherlands 2007 Croatia 2007 Hungary 2009 Portugal 2010 Romania 2010 Puglia (mandatory data collection) 2011 Switzerland 2011 PA Bolzano 2013 Calabria





Joint arthroplasties trend in Italy Source: Hospital Discharge Records (2001-2013)



Cod.	Procedure	2001	2003	2005	2007	2008	2009	2010	2011	2012	2013	% (°)
Hip												
81.51	Total Hip Replacement	45.792	51.311	55.599	58.650	58.786	59.528	59.764	60.712	62.361	64.056	2,2
	" w/out fracture	39.144	43.419	46.561	49.104	49.289	49.915	50.371	51.410	52.930	54.135	
81.52	Partial Hip Repl.	20.768	21.020	22.402	22.326	23.069	22.542	23.953	24.177	24.324	24.998	1,6
	Resurfacing	-	-	-	-	-	303	476	157	94	96	-32,3
(*)	Revision	6.015	6.528	6.960	7.273	7.219	7.606	7.919	7.897	8.302	8.249	2,7
	Total Hip	72.575	78.859	84.961	88.249	89.074	89.979	92.112	92.943	95.081	97.399	2,1
Knee												
81.54	Total Knee Repl.	26.787	35.799	43.785	52.116	54.395	54.778	56.808	56.977	58.979	60.261	5,7
(**)	Revision	1.269	1.904	2.472	3.007	3.311	3.850	3.953	3.996	4.235	4.502	9,3
	Total Knee	28.056	37.703	46.257	55.123	57.706	58.628	60.761	60.973	63.214	64.763	5,9
Shoulde	r											
81.80	Total replacement	695	934	1.455	2.036	2.175	2.515	2.965	3.444	3.793	4.421	16,8
81.81	Partial replacement	844	917	1.051	1.203	1.234	1.242	1.333	1.211	1.352	1.432	4,4
	Total Shoulder	1.539	1.851	2.506	3.239	3.409	3.757	4.298	4.655	5.145	5.853	12,0
Other joints		871	1.062	1.940	1.915	1.696	1.665	1.623	1.739	1.674	1.720	5,4
	TOTAL	103.041	119.475	135.664	148.526	151.885	154.029	158.794	160.310	165.114	169.735	3,7

(°) % Average increase



(*) Hip: 81.53, 00.70, 00.71, 00.72, 00.73

(**) Knee: 81.55, 00.80, 00.81, 00.82, 00.83, 00.84

Other joints: 81.56, 81.57, 81.59, 81.73, 81.84, 81.97

> 750 hospitals



High burden of joint prostheses on public health expenditure



50% of the implantable MD, 10% of the total MD expenditure!



Report on the recognized expenditure from public health structures of the NHS for the purchase of medical devices (2013) (www.salute.gov.it)



The ASR e ASR XL (DePuy) story A paradigm of the registries role in MD vigilance RITIRATE DAL COMMERCIO NEL 2010

Anca: un tipo di protesi «richiamata» Ma non tutti gli interessati in Italia lo sanno

Il caso DePuy ASR. Non tutti sono stati avvisati. Il registro sugli interventi del ministero non è ancora partito





CORRIERE DELLA SERA

Reumatologia

25 gennaio 2012

93.000 prostheses implanted in the world since 2003 (4.500 in Italy since March 2004)

- 2005 higher revision rates (RR) notified by single surgeons
- 2007 Australian Registry: 2y RR 5.2% vs 2%
- 2009 recall from the Australian market
- 4/2010 NJR UK: notify MHRA, 7y RR 12% vs 3% (MDA 2010/033 All MoM: alert)
- 5/2010 MDA 2010/044 ASR: f-up management
- 8/2010 Voluntary recall of all ASR products. Actions for patients f-up.
- 9/2010 MDA 2010/069 ASR recall









Conclusions

Registries will be <u>a key element</u> not only for both the competent authority and manufacturers to monitor performance and incidents of medical devices, but also for clinicians to manage their patients on an informed basis.

Marcella Marletta, General Director DG medical devices and pharmaceutical service. Ministry of Health from the Preface to the 1° RIAP Report





Thank you!



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