The Susy Safe Project

Surveillance System on Suffocation Injuries Due to Foreign Bodies in European Children

Foreign bodies in children:

Safer products for preventing choking and injuries

Results of the Joint Program Italy-Argentina MAE-MINCYT

Dario Gregori Unit of Biostatistics, Epidemiology and Public Health Department of Cardiac, Thoracic and Vascular Sciences

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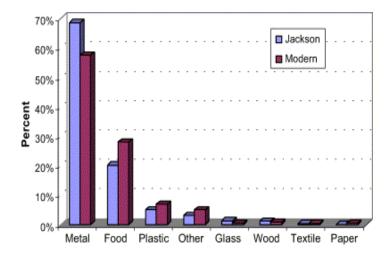


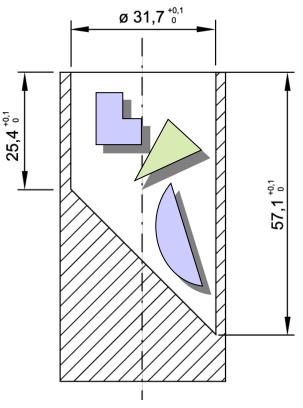
Statistics / history

Many attempts have been performed, to understand the relationship between shape and size of the object, obstruction location and injury severity.

- Chevalier Jackson (endoscopist) and colleagues removed 3200 objects between 1920 and 1932 (JC collection)
- Based on the JC collection, the small part cylinder was developed in the 1970s (by CPSC = Consumer Product Safety Comm., BPS = Bureau of Product

Safety)



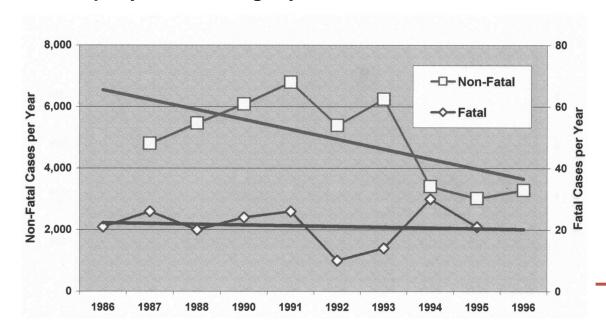






Epidemiological background

- Suffocation due to foreign bodies (FB) is a **leading cause of death in children aged 0-3** and it is common also in older ages, up to 14 years.
- Based on the RPA report (2003) the estimated number of incidents per year in children aged 0-14 is in EU of about **50.000**, **10% of which are fatal**
- In the RPA report (2003) About 10.000 accidents involve inorganic objects, in general industrial products, mostly plastic and metal parts, coins, and toys. Out of the estimated 2.000 incidents per year involving toys, the fatalities are 20.





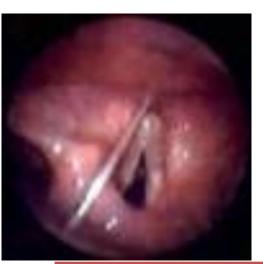
Foreign Bodies injuries: a multifactorial problem

The problem of choking risk from foreign bodies is a multifaceted problem since epidemiological. behavioural. medical. socioeconomic and legislatory aspects are involved and only a joint effort of all these components can achieve a significant result











Primary Endpoints of the project

- Aim of the project is to establish a registry for injuries due to non-food foreign bodies ingestion, gathering data on choking in all EU Countries and beyond, in order to:
 - provide a risk-analysis profile for each of the products causing the injury in terms of its characteristics with the aim at:
 - creating a surveillance systems for suffocation injuries caused to young consumers by inappropriate product design or packaging;
 - helping to guarantee the safety of consumers, indicating products whose risk profile is clearly not compatible with a safe fruition of the product itself;
 - providing the EU Commission with **comparative data on risk/benefit** of each of the products causing the injuries, in order to weight acceptable risks versus the foreseen economic impact of recalling the product involved from the market;



Susy Safe

ITALY

Ministero dello Sviluppo Economico - Direzione generale per l'Armonizzazione del Mercato e la Tutela del Consumatore. Ufficio D1 - Coordinamento Attività sicurezza e conformità dei prodotti Antonella D'ALESSANDRO



Department of Public Health and Microbiology, University of Torino

Dario GREGORI



Grosse schützen Kleine-Medical University of Graz Paola ZAUPA



AUSTRIA

Ministry od Commerce, Industry and Tourism-Competition and Cosumer protection service Constantinos DEMETRIADES





CZECH REPUBLIC Masaryk University Ivo SLAPAK





FRANCE

Commission de la Sécurité des Consommateurs Florence WEILL



Center for Research and Prevention of Injuries (CE.RE.PR.I.) -Medical school of University of Athens Eleni PETRIDOU



THE NETHERLANDS

Food and Cosumer Product safety Authority A.J. DE KONING



SLOVAK REPUBLIC



 Children's University Hospital, Bratislava Janka JAKUBIKOVA

PORTUGAL



 Hospital Sao Joao, Porto Manuel Antonio Caldeira PAIS CLEMENTE

GERMANY:



• Charite Universitätmedizin Berlin CHARITÉ Klaue SIEGFRIED

FINLAND:



· Ministry of Trade and Industry of Finland Kristian TAMMIVUORI



Participating Hospitals

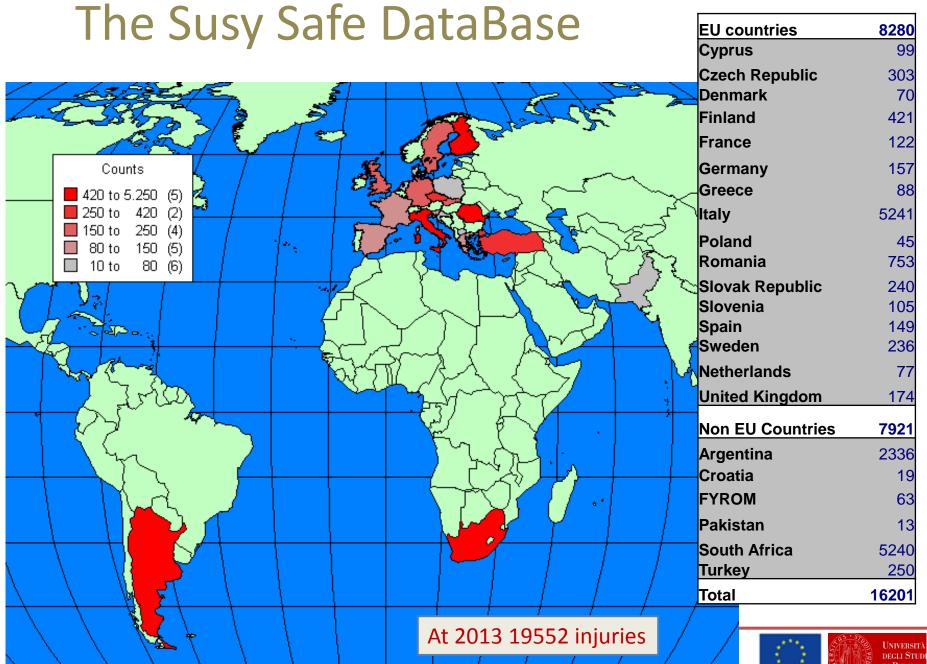
Medical Institutions involved in the project:

Institute for Respiratory Disaeses in Children	Skopje	Macedonia
Public health authority of the Slovak republic	Bratislava	Slovak Republic
Burlo - Garofolo	Trieste	Italy
/U Medical Center	Amsterdam	the Netherlands
Suez Canal University	Ismailia	Egypt
St. Joseph-Hospital	Berlin	Germany
Ramathibodi Hospital	Bangkok	Thailand
Helsinki University Central Hospital	Helsinki	Finland
Necker - Enfants Malades	Paris	France
Hopitâl Armand Trousseau	Paris	France
Baskent University Ankara Hospital	Ankara	Turkey
CHU A Michallon	Grenoble	France
A.O.R.N. Santobono Pausilipon	Napoli	Italy
Aretaeion Hospital	Nicosia	Cyprus
RNTNEH	London	UK
Azienda di Padova	Padova	Italy
Royal Manchester Children's Hospital	Manchester	UK
CHU Nancy	Vandoeuvre	France
Vall D'Hebron	Barcelona	Spain
Sf. Spiridon	lasi	Romania
Grigore Alexandrescu	Bucharest	Romania
Service Hospital, Paediatric ward	Lahore	Pakistan
Institute for Respiratory Disaeses in Children	Skopie	Macedonia
Medical and Public Health Services, Ministry of Health	Nicosia	Cyprus
Azienda Ospedaliera G. Rummo	Benevento	Italy
Azienda Ospedaliera G. Rummo	Benevento	Italy
Ospedale Pediatrico Bambino Gesù	Passoscuro (Roma)	Italy
Charite Campus Virchow	Berlin	Germany
Hacettepe University	Ankara	Turkey
Childrens University Hospital	Brno	Czech Republic
Children's University Hospital	Bratislava	Slovak Republic
University Medical Centre Ljubljana	Liubliana	Slovenia
Hopital S. Joao	Oporto	Portugal
The Medical University of Warsaw	Warsaw	Poland
Charité Campus Virchow	Berlin	Germany
Democritus University School of Medicine	Athens	Greece
Gentofte University Hospital of Copenhagen	Hellerup	Denmark
Hospital Ruber International	Madrid	Spain
Huddinge University Hospital	Stockholm	Sweden
University Hospital Salata - KBC	Zagreb	Croatia
Sf. Maria Hospital	Bucharest	Romania
Maria Sklodowska Curie	Bucharest	Romania
Praxis	Bergisch Gladbach	Germany
Sos Benjamin - Observaoire National d\\'Etudes des conduites à risques	Sens	France
Policlinico Universitario Le Scotte	Siena	Italy
Azienda Ospedaliera OIRM-Sant'Anna	Torino	Italy
Azienda Ospedaliera Complesso Ospedaliero San Giovanni - Addolorata	Roma	Italy

Overall 68 Institutions from 36 countries

University clinical center	Tuzla	Bosnia And Herzegowina	
Behcet Uz Children Hospital	Bornova Izmir	Turkey	
General Hospital of Volos	Volos	Greece	
Siriraj Hospital	Bangkok	Thailand	
Menoufiya university hospital	Shibin Elkom	Egypt	
Robert Debr Hospital	Paris	France	
VU medisch centrum	Amsterdam	Netherlands	
University of Ilorin Teaching Hospital	llorin	Nigeria	
Santobono Hospital	Napoli	Italia	







Susy Safe Data Base summary

Reference	Number of FB observed
SUSY SAFE Total	16201
SUSY SAFE EU	8280
Mikovic:2003	6953
Reilly:2003	5528
Ciftci:2003	563
Oguzkaya:1998	500
Black:1994	440
Emir:2001	403
Rothmann:1980	225
Black:1984	224
Blazer:1980	200
Jimenez:2000	189
Shinar:2003	182
Lau:2001	181
Karakoc:2002	174
Rimell:1995	165
Benjamin:1974	162
Cohen:1980	143
Brkic:2001	136
Tan:2000	135
Wolach:1994	127
WaiPak:2001	115

International Journal of Pediatric Otorhinolaryngology (2006) 70, 1663-1664



International Journal of **Pediatric**Otorhinolaryngology

www.elsevier.com/locate/ijporl

LETTER TO THE EDITOR

The Susy Safe Project
A web-based registry of foreign bodies injuries in children

KEYWORDS Foreign bodies; Choking; Children injuries; Removal techniques cooperative effort with the Italian Ministry of Industry. The project is scientifically leaded by the Department of Public Health and Microbiology at the University of Torino, with the cooperation of the Competition and Consumers Protection Service, Ministry of Commerce, Industry and Tourism, Cyprus, the Charité Universitätmedizin, Bertin, Germany, the Ministry of Trade and Industry of Finland, jointly with the Helsinki University Central Hospital and the Commission de la Sécurité des Consommateurs. France.

Situation at the end of Phase I

Prospective cases: **1010** (14%) Retrospective cases: **6269** (76%)

Situation at the end of Phase II

Prospective cases: **5041** (29.7%)

Retrospective cases: **11910** (70.01%)

Data available from 1987





12/11/2013 Slide 10

SS Activities

Research Activities

- SS maintenance and enlargement
- SS Risk Profiling System development
- Consumer data
- Unconventional data sources evaluation and implementation
- Literature review and synthesis

Scientific Activities

- Scientific dissemination (papers & congresses)
- Institutional cooperation (CEN, DGSANCO, MAE, ...)
- International Societies Support
- Dissemination to public (PUBCHILD, I2C)
- Cooperation with other no-profit institutions (PROCHILD,SAFEKIDS)



Publication & Privacy Policies

•Publication:

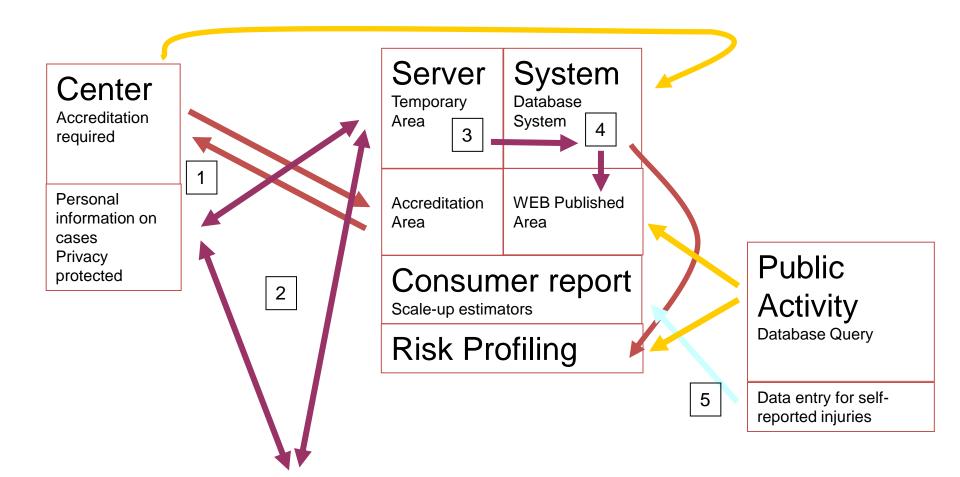
•Main scientific papers using the overall data will be published using the formula "**The SUSY SAFE Investigators**", with a list of all enrolling centres, recognizing in this way the contribution of each investigator as a co-author.



Privacy:

All the cases will be anonymously reported, no personal information of the patients being send nor stored in the Susysafe Registry. All the personal information will be stored **exclusively** on the physician's computer.





Quality Control

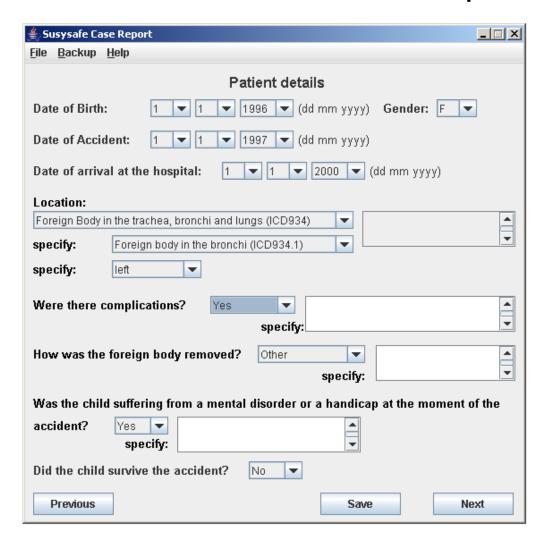
Verification of data completeness and correctness





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General details about the patient and the injury



Location (ICD9 code)
Presence of complications
Basic characteristics of the child



Details about the extracted Foreign Body

Type
Shape
Consistency
Axis' length (diameter)
FB association
with other objects

∯ Susysafe Case Report X
<u>F</u> ile <u>B</u> ackup <u>H</u> elp
Foreign Body Typology Type of foreign body:
Brand of foreign body:
Shape: 3D (pen cap, toys,) dimension (mm):
Consistency: Conforming (balloon, elastic,) ▼
Was the foreign body purchased or a part of an object purchased? Yes ▼
If yes, when purchased, was the FB packed with another object(s)?
If yes, of what type? Toy specify:
At the time of the accident was the FB associated with another object(s)?
If yes, of what type? Food specify:
Previous Save Next



Susysafe Case Report software (SCR)

- → circumstances of the accident
 - Adult presence
 - Child's activity at the moment of the accident
- → hospitalization details
 - The department that initially look for the child
 - Hospitalization period
- → FB physical details
 - Picture of the FB
 - Cylinder test data
 - Actual volume of the FB

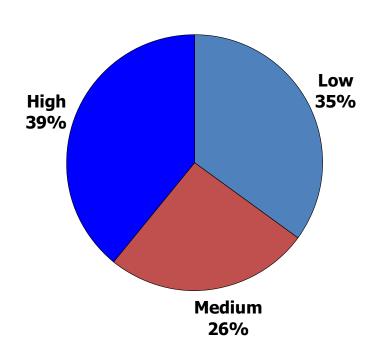




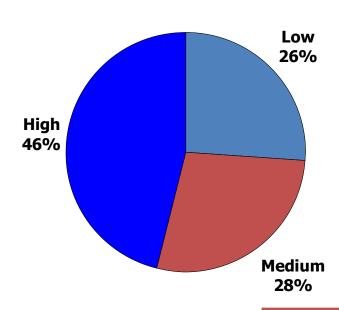
Quality Control Procedure

- Low Quality: few basic data available (e.g.: gender, age, ...)
- Medium quality: basic data on FB characteristics and procedures are available (FB type, type of procedure, ...)
- High quality: detailed data on at least one FB characteristic are available (shape, size, circumstances of the accident, ...)

Retrospective Cases



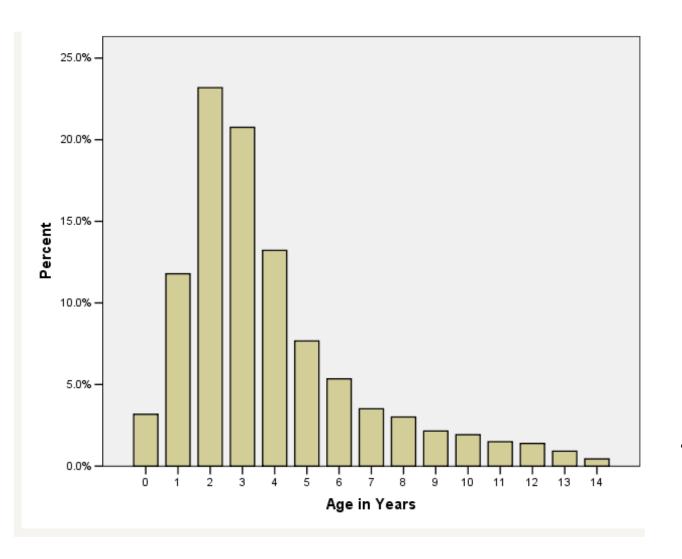
Prospective Cases

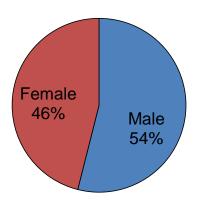






The Injured Children

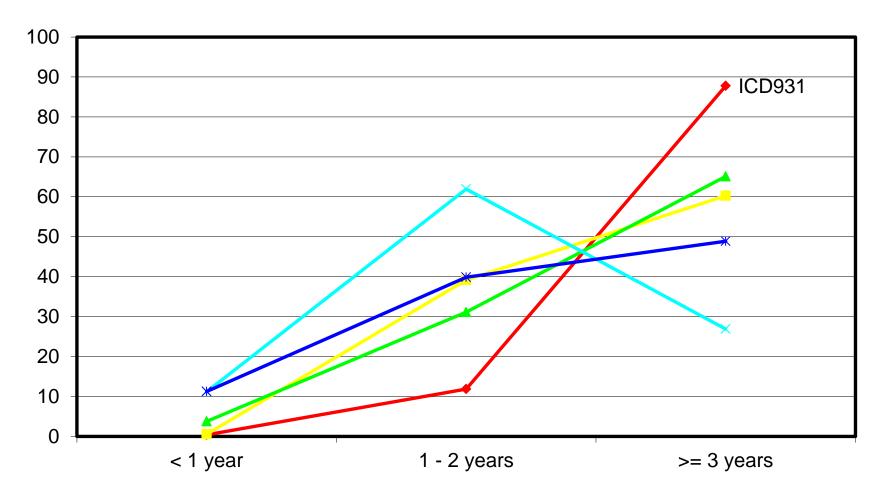




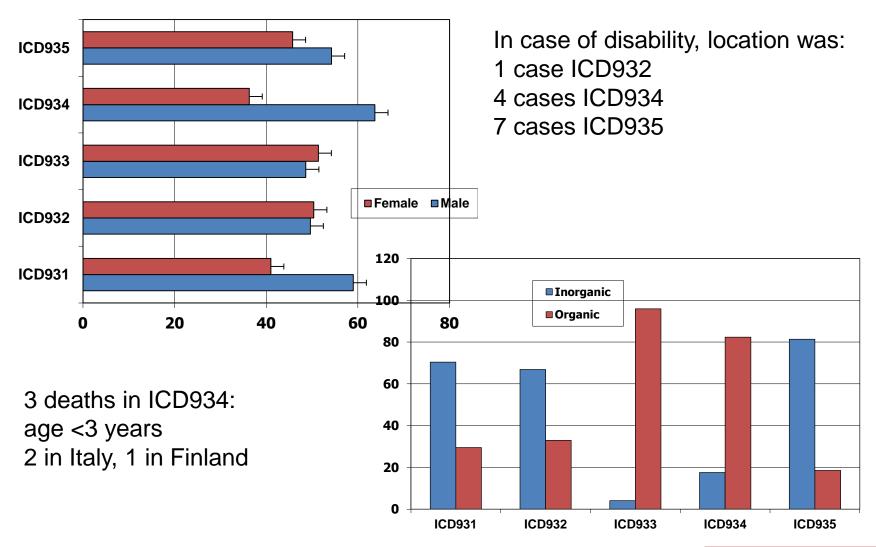
12 children were disable



Location of Foreign Body



Location, FB Type and Gender

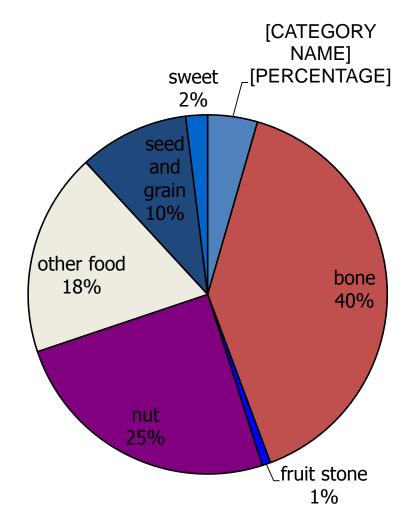






Food objects

•Food Objects 51.3%







Non-food objects

Non-food objects 48.7%

	%
accessorize	0.92
arthropod	1.60
battery	2.84
bone	0.06
button	2.34
сар	0.37
coin	10.97
cotton	2.10
earplug	0.92
FPCI	0.68
jewellery	3.02
metal	1.17
paper	4.13
pearl, ball and marble	29.78
pebble	7.89
pin and needle	4.56
plastic	4.69
polystyrene	1.91
sponge	0.62
stationery	5.98
other stationery	0.37
stick	0.74
tinfoil and cellophane	1.36
toy	10.97
other inorganics	4.81
other organics	0.80

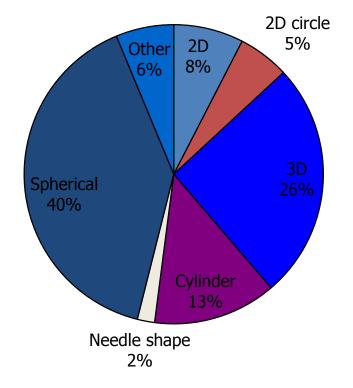






	2D	3D+Cyl	Sphere
accessorize	25.0	58.3	0.0
arthropod	5.9	58.8	35.3
battery	0.0	97.1	0.0
button	0.0	71.4	21.4
cap	25.0	75.0	0.0
coin	0.0	100.0	0.0
cotton	22.2	29.6	37.0
earplug	0.0	18.2	81.8
FPCI	42.9	57.1	0.0
jewellery	19.0	31.0	40.5
metal	13.3	6.7	13.3
other inorganics	44.2	42.3	9.6
other organics	20.0	60.0	20.0
other stationery	20.0	60.0	0.0
paper	55.6	11.1	2.2
pearl, ball and marble	7.6	9.6	81.4
pebble	4.8	21.0	59.0
pin and needle	0.0	54.4	0.0
plastic	23.6	49.1	5.5
polystyrene	3.8	23.1	57.7
sponge	0.0	71.4	28.6
stationery	5.3	84.2	5.3
stick	20.0	50.0	0.0
tinfoil and cellophane	82.4	5.9	11.8
toy	24.6	42.0	31.2

Shape (non food objects)

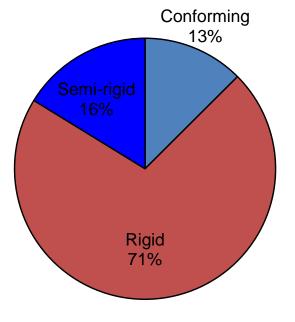




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Consistency (non food objects)

	Conforming	Rigid	Semi-rigid
accessorize	13.3	66.7	13.3
arthropod	19.2	0.0	42.3
battery	0.0	90.7	0.0
button	0.0	73.0	2.7
cap	0.0	66.7	0.0
coin	0.0	100.0	0.0
cotton	76.5	0.0	5.9
earplug	20.0	0.0	80.0
FPCI	11.1	33.3	22.2
jewellery	0.0	81.3	4.2
metal	0.0	94.7	0.0
other inorganics	27.3	40.9	15.2
other organics	23.1	30.8	38.5
other stationery	0.0	50.0	33.3
paper	50.7	4.5	10.4
pearl, ball and marble	6.0	71.9	11.9
pebble	1.6	90.6	1.6
pin and needle	2.9	89.9	0.0
plastic	15.1	43.8	26.0
polystyrene	41.9	0.0	41.9
sponge	60.0	0.0	10.0
stationery	4.3	46.8	34.0
stick	0.0	75.0	8.3
tinfoil and cellophane	40.9	4.5	40.9
toy	6.2	50.8	23.7

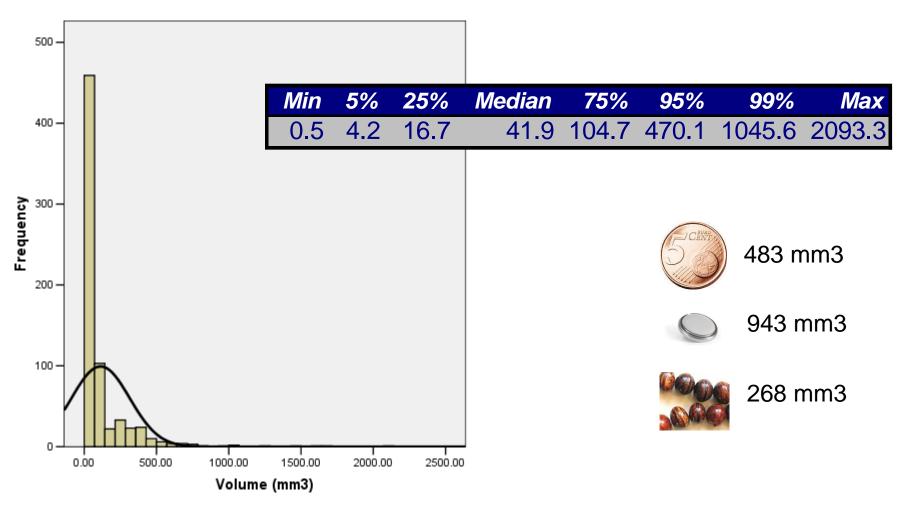






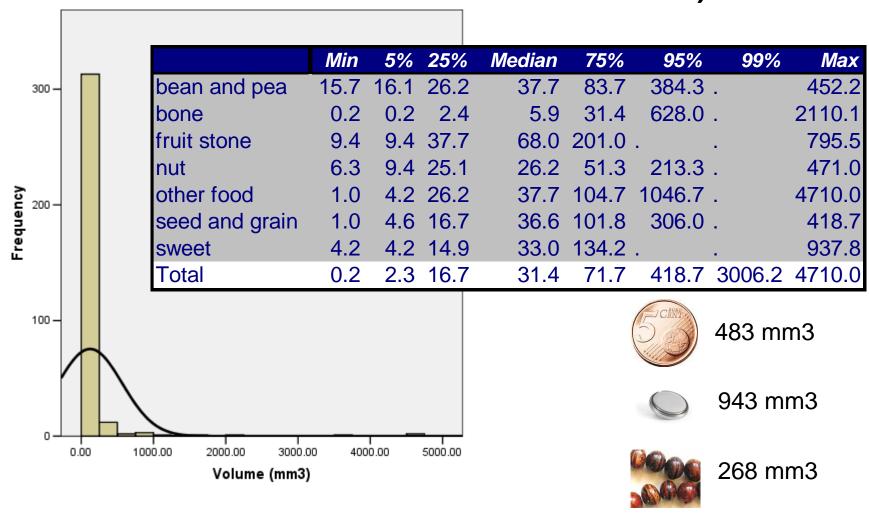
Slide 25

Volume (non-food objects)





Volumes (food objects)



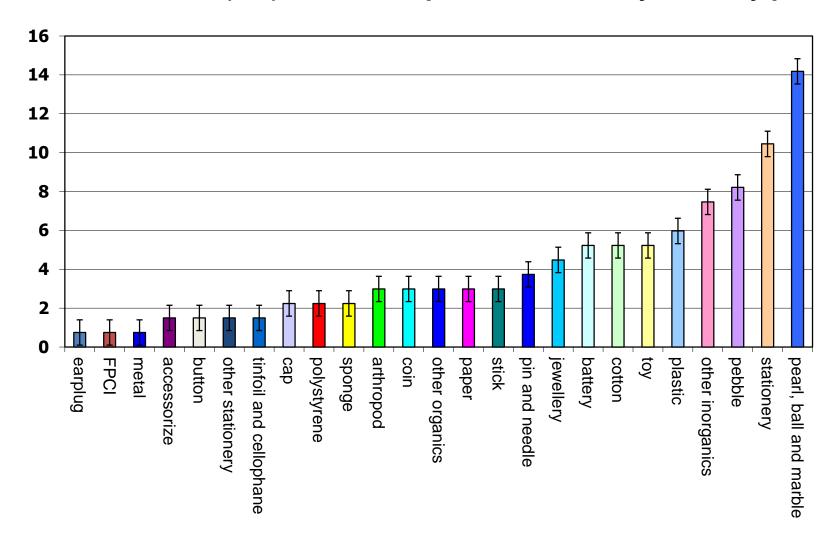


Outcome definitions

- Severe injury: FB injury requiring at least one day of hospitalization (DTI, 1999)
- Complications: occurrence of at least one complication, as reported by the physician, requiring or not hospitalization



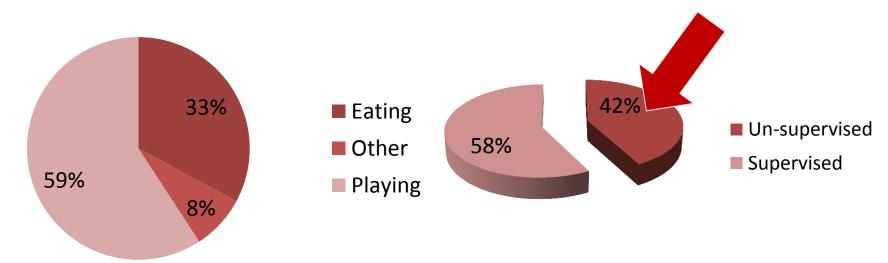
Incidence (%) of complications by FB type







Activity and supervision



	Eating	Other	Playing
Un-supervised	14.10%	51.90%	56.40%
Supervised	85.90%	48.10%	43.60%

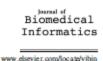


The risk engine: Bayesian Model





Journal of Biomedical Informatics xxx (2008) xxx-xxx



V = object characteristics (volume, shape, ...)

C = child characteristics (age, gender, ...)

Web-based tool for injury risk assessment of foreign body injuries in children

P. Berchialla a, A. Stancu b, C. Scarinzi b, S. Snidero b, R. Corradetti b, D. Gregori a,*

* Department of Public Health and Microbiology, University of Torino, Via Santena 5bis, 10126 Torino, Italy
Department of Statistics and Applied Mathematics 'Diego de Castro', University of Torino, Italy
Received 11 April 2007

 $P(I|V,C) = P(V|I_{SS},C) \times P(I_{SS}|I,C) \times P(I|C) \times P(V)^{-1}$

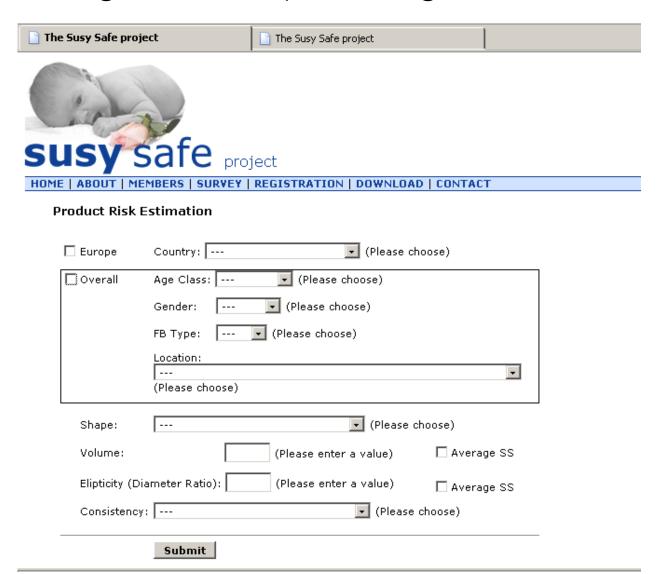
Susy Safe

Registration coverage

ICD records



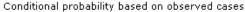
Estimating the risks (Risk Engine Web Interface)

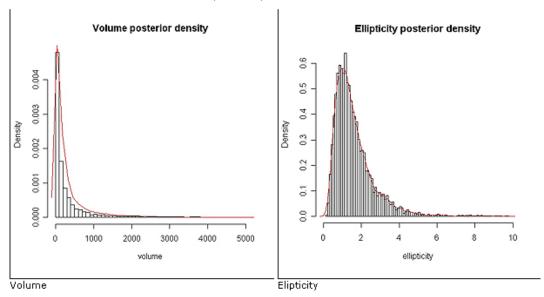




Probability of injury in trachea, bronchi and lungs, due to 2D circle object < 39.47 mm3 (approx coin)



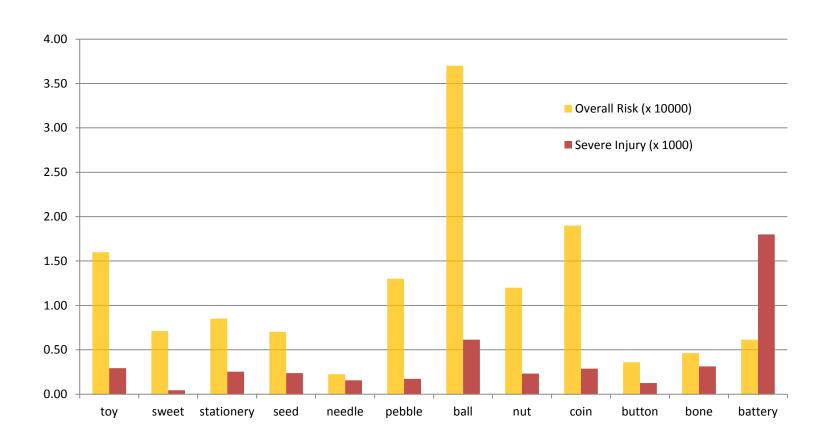




¹SS data ²Papadopoulos 2004



Risk of Injury vs. Risk of Severe Injuries





"Alta rilevanza Scientifica e Tecnologica Italia-Argentina" Projects

The projects starts with a framework agreement between the Italiand and Argentina Governments, signed in Bologna on the 3° of December 1977 and

Direzione Generale per la
Promozione del Sistema
Paese, Unità per la
Cooperazione Scientifica e
Tecnologica del Ministero
degli Affari Esteri Italiano

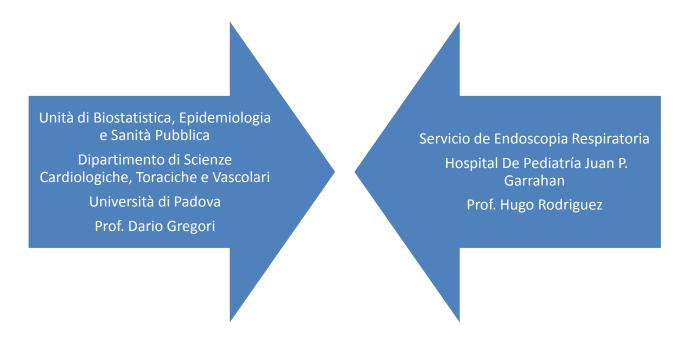
Ministerio de Ciencia,
Tecnología e Innovación
Productiva (MINCyT)
Argentino

Goal of promoting High-Quality Scientific and research Cooperative Projects between highly qualified partners in both countries



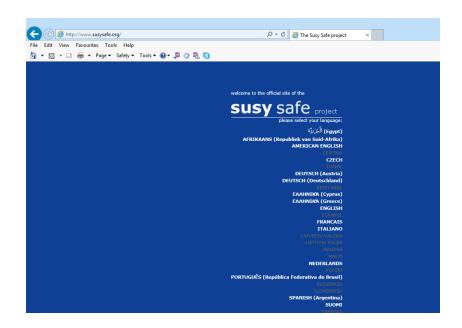
The Italy-Argentina Project 2011-2013

Development of a common risk –assessment tool for Risk-Assessment of Foreign Bodies Injuries in children





3059 Injuries recorded in Argentina



A dedicated web server Italian/Spanish

http://www.susysafe.org/granderilevanzalT-AR/

Home Partecipanti Risultati Incidenti da CE Susy Safe Download

I Progetti di Grande Rilevanza MAE

I progetti di **ricerca scientifica e tecnologica bilaterale di "Grande Rilevanza"** nascono grazie all'accordo culturale tra il Governo della Repubblica Italiana ed il Governo Argentino, firmato a Bologna il 3 dicembre 1997, ed entrato in vigore il 13 aprile 2001.

La Direzione Generale per la Promozione del Sistema Paese, Unità per la Cooperazione Scientifica e Tecnologica del Ministero degli Affari Esteri italiano e il Ministerio de Ciencia, Tecnologia e Innovación Productiva (MINCyT) argentino hanno collaborato nella delineazione di questo importante strumento il cui fine è quello di incoraggiare la cooperazione scientifica e tecnologica fra Italia e Argentina.

Il supporto offerto è destinato ai **progetti di mobilità dei ricercatori**, riguardanti collaborazioni di tipo Culturale, Scientifica e Tecnologica, che appartengono alle seguenti aree di ricerca: Ambiente ed energia; Nanotecnologie; Medicina e salute; Scienze di base (matematica, fisica, chimica, biologia e geologia); Tecnologia spaziale; Tecnologie applicate ai Beni Culturali.







3-years Scientific Activity



Pediatric Pulmonology 48:344-351 (2013)

Inhaled Foreign Bodies in Children:

A Global Perspective on Their Epidemiological, Clinical, and Preventive Aspects

Francesca Foltran, MD, PhD, ¹ Simonetta Ballali, BS, ¹ Hugo Rodriguez, MD, ² Arjan B. (Sebastian) van As, MD, PhD, ³ Desiderio Passali, MD, ⁴ Achal Gulati, MD, ⁵ and Dario Gregori, MA, PhD ^{1*}



Editorial

Preventing Foreign Bodies Injuries in Children: the Italy-Argentina Joint Research Programme 2011-2013

Ambassador Guido La Tella*

Ambasciata d' Italia in Buenos Aires, Capital Federal, Argentina

Volume 6

Open Access

Quality Control Techniques and Standards Implemented in the WEB-Based "Susy Safe" Registry

Paola Berchialla^{1,8}, Arber Haxhiaj², Desiderio Passali³, Hugo Rodriguez^{4,8} and Dario Gregori^{*,5,8}

Foreign Bodies Injuries in Children in Argentina: A Countrywide Program Connecting Evidence with Prevention

Hugo Rodriguez^{1,§}, Giselle Cuestas¹, Simonetta Ballali², Graciela Sica³, Walter Widmann⁴, Silvina Carca⁴, Susana Tortosa⁴ and Dario Gregori^{*,5,§}

Foreign Bodies in Non-Life Threatening Locations: A Risk Analysis of Nose and Ears Foreign Bodies in European Children

Dario Gregori^{*,1,8}, Francesca Foltran¹, Giselle Cuestas², Hugo Rodriguez^{2,8}, Desiderio Passali³ and Paola Berchialla^{4,8}



Preventing Foreign Bodies Injuries in Children: The Italy-Argentina Joint Research Programme 2011-2013

Guest Editors: Dario Gregori, Hugo Rodriguez & Paola Berchialla

The Open Pediatric Medicine Journal, 2010, 6, 15-37



Public awareness campaign: >300 newspaper and TV clippings







Beyond Argentina: Mexico and Ecuador



Contents lists available at ScienceDirect

International Journal of Pediatric Otorhinolaryngology



journal homepage: www.elsevier.com/locate/ijporl

Epidemiology of foreign bodies injuries in Ecuador: A first look based on a single centre experience

Fernando Silva Chacon ^a, Simonetta Ballali ^b, Desiderio Passali ^c, Giselle Cuestas ^d, Gustavo Burbano ^a, Rodolfo Perez ^a, Mario Quintero ^a, Giulio Cesare Passali ^e, Francesco Maria Passali ^f, Francesca Foltran ^b, Luisa Bellussi ^c, Hugo Rodriguez ^d, Dario Gregori ^{b,*}

^a Francisco De Icaza Bustamante Children Hospital, Guayaquil, Ecuador

b Labs of Epidemiological Methods and Biostatistics, Department of Environmental Medicine and Public Health, University of Padova, Via Loredan 18 35131 Padova, Italy

ENT Respiratory Endoscopy, Hospital Garrahan, CABA, Argentina

d ENT Department, Catholic University of Sacred Heart, Rome, Italy

^e ENT Department, Medical school, University of Siena, Italy ^f ENT Department, "Tor Vergata" University, Rome, Italy

La prevención de eventos asfícticos por aspiración de cuerpos extraños en niños

Dr. Ricardo de Hoyos Parra*

Dr. Dario Gregori, MA, PhD**

Simonetta Ballali**

Dr. Javier Dibildox M.***

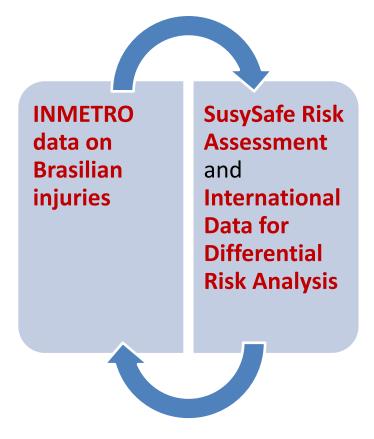
- * Otorrinolaringologo Pediatra, Monterrey, NL.
- **Unidad de Bioestadística, Epidemiología y Salud Pública. Universidad de Padova, Italia.
- *** Otominolaringòlogo, San Luis Potosi, S.L.P.



The SusySafe-INMETRO joint Agreement

On September 2013, a Memorandum of Understanding has been signed between INMETRO and SUSYSAFF









Project plan proposal 2014-2016

Progetti di Alta Rilevanza MAE (Italy) and MINCYT (Argentina)

Addressing vulnerabilities in children: a pilot project for the development of a surveillance and prevention system

Extending the notion of injuries to that of "<u>vulnerability</u>" of children, including "any situation exposing the child to future chronic or immediate acute illness or disability" like obesity, violence...

Establishing in selected Health Care facilities a common platform from data recording, alerting and information sharing, based on the experience of the susysafe web platform and risk assessment engine

Studying the relationships among adverse outcomes and their determinants (e.g.: obesity and injuries w.r.t. socio-economic status)



the susy safe project

Aim of the project is to establish a surveillance registry for injuries due to non-food foreign bodies ingestion:

- provide a risk-analysis profile for each of the products causing the injury
- provide an evaluation of how socio-economic disparities among EU citizens may affect the likelihood of being injured by FB ingestion, with the aim of implementing specific educational activities on safe behavior and active parental guard with regards to the specific products causing the injury
- involve, as appropriate, Consumer Associations and/or National Market Surveillance Authorities in data collection and proper education of consumers



www.susysafe.org



Funded by the European Commission, DGSANCO, Consumer Affairs Directorate

Permanently endorsed as a Key-Relevance project for **European Union**





