Contents lists available at SciVerse ScienceDirect



International Journal of Pediatric Otorhinolaryngology

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



The Susy Safe project overview after the first four years of activity

The Susy Safe Working Group^{1,*}

ARTICLE INFO

Article history: Available online 16 February 2012

Keywords: Susy Safe registry Risk assessment

ABSTRACT

Objectives: to collect relevant, up-to-date, representative, accurate, systematic information, related to foreign bodies (FB) injuries. *Methods*: The "Susy Safe" registry, a DG SANCO co-funded project gathering data on choking in all EU Countries and beyond, was established in order to create surveillance systems for suffocation injuries able to provide a risk-analysis profile for each of the products causing the injury. Main findings after 4

years of activities are resumed here. *Results:* 16,878 FB injuries occurred in children aged 0–14 years have been recorded in the SUSY SAFE databases; 8046 cases have been reported from countries outside EU. Almost one quart of the cases involving very young children (less than one year of age) presented a FB located in bronchial tract, thus representing a major threat to their health. Esophageal foreign bodies are still characterizing injuries occurred to children younger than one year, in older children the most common locations are the ears and the nose. FB type was specified in 10,564 cases. Food objects represented the 26% of the cases, whereas non-food objects were the remaining 74%. Among food objects, the most common were bones, nuts and seed, whereas for the non-food objects pearls, balls and marbles were observed most commonly (29%). Coins were involved in 15% of the non-food injuries and toys represented the 4% of the cases. *Conclusions:* this data collection system should be been taken into consideration for the calculation of the risk of injuries in order to provide the EU Commission with all the relevant estimates on FB injuries.

1. Introduction

Suffocation due to foreign bodies (FBs) is a leading cause of death in children aged 0–3 and it is common also in older ages, up to 14 years old. Based on the RPA report [1] the estimated number of incidents per year in children aged 0–14 is in European Union (EU) of about 50,000, 10% of which are fatal. In the RPA report [1] about 10,000 accidents are estimated to involve inorganic objects, in general industrial products, mostly plastic and metal parts, coins, and toys [2]. Out of the estimated 2000 incidents per year involving toys, the fatalities are around 20. Based on official records, the cost in terms of life loss due to suffocation in general has been estimated, for the EU community, as about 5 billion euros per year, only because of injuries due to industrial products [3].

The need for a multinational pan-European study derived by the lack of comparable data on the choking risk prevalence in European countries has been recently pointed out in few papers [4–6]. In fact, most of the epidemiologic evidence on foreign bodies (FBs) in children comes from single-center retrospective studies, covering a time range of about 3-10 years [7-13] in the past. Very recently, attempts have been made to start a systematic collection of FBs in view of using them to characterize the risk of chocking in terms of size, shape and consistency of the FB [14]. Also several review papers discussed more clinical aspects of the FB injuries, like clinical diagnosis and management of the injured child [15]. Country specific experiences have also been presented in the literature, with a wide although not systematic spread and geographical coverage [16–19]. In particular, very small attention has been paid to this subject in Europe, which was, till few years ago, lagging behind the North-American experience, often based on large databases and data collection repositories. Even if not too many papers have been published on the argument based on European data [4,20–22], still very few attempts have been made to synthesize the epidemiological data as arising from the literature.

Difficulties are arising from the relative rarity of the phenomenon, in particular in EU and USA, after the adoption of severe rules for toy packaging and distribution. Actually the effect of regulatory acts had the effect of step-down the trend in choking injuries. Actual estimates are indicating mortality for suffocation (all causes) in EU exceeding nearly a death per 100,000 children. The heterogeneity among countries is very high, making the comparison among countries very difficult.

^{*} Corresponding author. Dario Gregori, Laboratory of Epidemiological Methods and Biostatistics, Department of Environmental Medicine and Public Health, University of Padova, 35121 Padova, Italy. Tel.: +39 049 8215384; fax: +39 02 700445089.

¹ Authors listed in Appendix.

^{0165-5876/\$ -} see front matter © 2012 Elsevier Ireland Ltd. All rights reserved. doi:10.1016/j.ijporl.2012.02.003

From the methodological point of view, basically three approaches were actually adopted for these purposes: (i) official data re-analysis, mostly based on discharge records of official death certificates, and published official statistical data, (ii) clinical registries, most often single center-based [15,23], and (iii) foreign body collections, with the specific aim of describing the shape and the material of the object causing the injury [14]. Unfortunately, all these methods are revealing as largely inadequate to address the epidemiological characterization of the phenomenon in the sense described above, because of the relatively scarce and geographically limited area of the clinical registry, the poor clinical information of the official data and the limited spectrum of perspectives of the object collections.

In addition to this scientific scenario, also from the political point of view things changed in EU. Indeed, over the last years, the focus in the European Commission has moved toward what is sometimes called "science-based policy making" and better regulation. As a consequence, increasing pressure has been put on the scientific community, not necessarily because it is essential to justify decisions, legislations, or activities, but because in order to do so it is extremely important to have a sound knowledge, a sound basis in terms of information for every area that needs to be investigated, in terms of Commission work but naturally also in terms of Consumer Safety. Now that more formal recognition has been given in the new Consumer Policy Strategy for the years 2007-2013, it is important to remark the importance of data collection at an EU level. So, it is considered as an absolute priority the creation of a harmonized system for collecting such data to improve the evidence base for the assessment of risks related to Product and Service Safety [24]. Therefore, the key objective of the European Commission is to ensure that relevant, up-to-date, representative, accurate, systematic information, related to accidents and injuries for consumer products or related to consumer products and any provision of consumer service are available to the Commission and other relevant bodies when decisions need to be taken.

To overcome such scientific issues and to address such political needs with respect to foreign bodies' injuries in children, a large, multi-center registry has been established in Europe: the Susy Safe project.

2. The Susy Safe registry

The surveillance registry for injuries due to non-food foreign bodies' ingestion, the "Susy Safe" registry, gathering data on choking in all EU Countries and beyond, was established in order to:

- 1. provide a risk-analysis profile for each of the products causing the injury with the aim at:
 - a. creating a surveillance systems for suffocation injuries caused to young consumers by inappropriate product design or packaging;
 - b. helping guaranteeing the safety of consumers, indicating products whose risk profile is clearly not compatible with a safe fruition of the product itself;
 - c. 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;
- providing 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;
- 3. involving, as appropriate, Consumer Associations and/or National Market Surveillance Authorities in data collection and

proper education of consumers, allowing a precise estimate of the risk profiles for those products which are actually causing the injury, but, because of the low impact in terms of child health (self resolved FB ingestions) are usually under reported and not known in the official clinical discharge data.

Thus, the project used the previous experience gained with the European Survey of Foreign Body Injuries (ESFBI) [25] as a starting point, with the aim of applying that methodology to creation of a surveillance registry in EU and EFTA countries, with the joint effort of statisticians, public health expert, otorhynolaryngologists, consumers and educational professionals.

The objectives envisaged by the project were planned to be met in particular by:

- 1. establishing an ad-hoc WEB server for collection of data in a centralized manner, in order to allow:
 - a. constant quality control on data collection and completeness;
 - b. easy and cost-effective access (via low-band internet connection) to data collection activities for public and private institutions willing to share their data with the project, with the aim of lowering as much as possible any barriers to participation to the project;
- setting up an ad-hoc risk analysis engine (running on the WEB server) with the aim of obtaining an updated estimate of risk profiles for each of the objects causing the injuries, effectively as new data become available;
- 3. translating risk-analysis and statistical concepts into accessible information for EU citizens, involving EU consumer's associations in the process of safe product consumption, also in the view of lowering the effects of the possible socio-economic disparities involved in the injuries.

3. Data collection

16,878 FB injuries occurred in children aged 0–14 years have been recorded in the SUSY SAFE databases; 8046 cases have been reported from countries outside EU. Details regarding the patients' distribution by country are reported in Table 1.

Table 1

Patients enrolled by country in the Susy Safe registry.

Countries	Ν
EU Countries	8832
Austria	12
Czech Republic	607
Cyprus	99
Denmark	70
Finland	421
France	122
Germany	157
Greece	88
Italy	5241
Poland	45
Romania	753
Slovak Republic	241
Slovenia	105
Spain	149
Sweden	236
The Netherlands	77
UK	409
Non EU Countries	8046
Argentina	2461
Croatia	19
FYROM	63
Pakistan	13
South Africa	5240
Turkey	250
Total	16,878

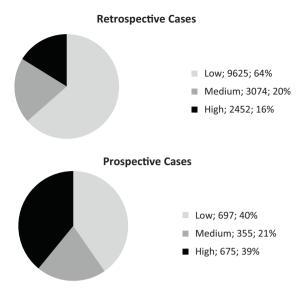


Fig. 1. Distribution of cases according to their quality.

The registry collected 1727 prospective cases and 15,151 retrospective cases. Retrospective cases are past consecutive cases available in each center registry and shared with Susy Safe. Data collection for retrospective cases followed the same procedure as for the prospective cases. All cases, in fact, irrespectively from their retrospective or prospective nature have been entered in the registry using the Susy Safe Case Report Form (CRF), thus ensuring the same quality, at least from the data entry point of view, for all cases reported in the system. For the purposes of providing a picture of the overall data quality, three definitions have been adopted: (i) *low quality data*: few basic data available (e.g. gender and age), (ii) *medium quality data*: basic data on FB characteristics and procedures are available (FB type, type of procedure) and (iii) *high quality*: detailed data on at least one FB characteristic are available (shape, size, circumstances of the injury).

Sixty percent of the prospective cases have a level of quality high enough (medium or high) to meet the requirements of the risk analyses system (see below), and, although this percentage lowers down to 36% for retrospective cases, still this remains a very good achievement (Fig. 1).

4. Main findings

The children age distribution is shown in Fig. 2: 55% of the cases are males, and about 38% of them are younger than three years.

Table 2

Age distribution of cases in classes by gender.

	Female		Male		Total		
	Ν	%	Ν	%	Ν	%	
<1 year 1−2 years ≥years	229 1555 2373	5.5 37.4 57.1	261 1632 3074	5.3 32.9 61.9	490 3218 5479	5.3 35.0 59.6	
Total	4157	100.0	4967	100.0	9187	100.0	

Table 3

Distribution of FB location by age, according to ICD9-CM code: ears (ICD931), nose
(ICD932), pharynx and larynx (ICD933), trachea, bronchi and lungs (ICD934),
mouth, esophagus and stomach (ICD935).

FB location	<1 year		1-2 years		\geq 3 years		Total
	Ν	%	Ν	%	Ν	%	
ICD931	24	4.9	277	8.6	1921	35.2	2222
ICD932	27	5.6	1131	35.2	1194	21.9	2352
ICD933	40	8.2	82	2.6	248	4.5	370
ICD934	120	24.7	683	21.3	298	5.5	1101
ICD935	254	52.4	927	28.9	1367	25.0	2548
Other	20	4.1	111	3.5	430	7.9	561

This percentage rises to 43% for females (Table 2). Forty-seven children were reported with mental of physical impairment.

FB location was reported according to ICD9-CM code: ears (ICD931), nose (ICD932), pharynx and larynx (ICD933) trachea, bronchi and lungs (ICD934), mouth, esophagus and stomach (ICD935). Almost one quart of the cases involving very young children (less than one year of age) presented a FB located in bronchial tract, thus representing a major threat to their health. Moreover, esophageal foreign bodies are still characterizing injuries occurred to children younger than one year. Notice that for older children the most common locations are the ears and the nose (Table 3).

Distribution of cases by location and by gender is shown in Fig. 3: while FBs in the ears were more common in females, all other sites were more common for males than for females.

FB type was specified in 10,564 cases; the retrieved FB description is given in Table 4. Food objects represented the 26% of the cases, whereas non-food objects were the remaining 74%. Among food objects, the most common were bones, nuts and seed, whereas for the non-food objects pearls, balls and marbles were observed most commonly (29%). Coins were involved in 15% of the non-food injuries and toys represented the 4% of the cases.

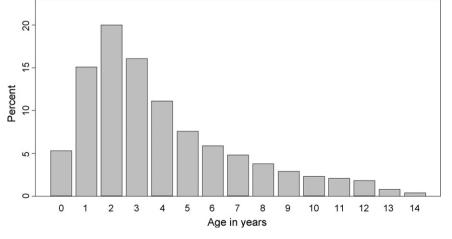


Fig. 2. Age distribution of foreign body injuries observed.

Tables 5 and 6 show the distribution of the cases according to the shape and consistency stratified by foreign body type. Spherical objects represent the 36% of the cases; the 76% of the retrieved FBs were rigid.

Looking to FB volume, food objects had a median volume of 31.4 mm³, with a maximum observed volume of 4710 mm³: bones tended to have higher volumes than nuts and beans. Non food objects had a median volume of 41.9 mm³, with an upper 95th percentile of 470.1 and 99th percentile of 1045 mm³ (Table 7). The maximum volume observed was of 2093 mm³. To allow a comparison with commonly used objects, a 5 eurocent coin has a volume of 483 mm³, a flat battery of 943 mm³. Accessorize had a greater volume among various foreign body types (Table 8).

An important tool has been introduced both in USA and in Europe to foster safety of toys avoiding the contact of small parts with children [26]. Indeed, toys with small parts cannot be sold to children younger than three years old without specific warnings. Small parts are defined as those object components fitting in the so-called "small part cylinder" (Fig. 4). Regarding the "small-part cylinder", overall 617 objects collected in the Susy Safe registry and looking at the longer axis' length, did not fit in the cylinder: out of them, 85 were spherical and none were non food objects. Looking at the overall volume, no one object had a volume greater than volume A.

In order to understand the impact of spherical objects to the risk of injuries, the "ellipticity" measure has been computed, which is nothing but the ratio of the longer and the shorter axis of the object, thus being equal to one for spherical objects. Toys were mostly spherical, at most with a very small ellipticity ratio of 2. The description of FB ellipticity by age of the child is given in Table 9.

Looking at the consequences of the injury, the Susy Safe registry adopted the DTI definition [27] of severe injury, as that requiring at least one day of hospitalization. In addition, we considered also the occurrence of complications, as reported by the physician,

Table 4

Description o	f the	FB	which	caused	the	incident
---------------	-------	----	-------	--------	-----	----------

FB description	Ν	Percentage
Pearl, ball and marble	1698	16%
Coin	1534	15%
Bone	885	8%
Other non-food	639	6%
Nut	613	6%
Other food	563	5%
Pin and needle	506	5%
Тоу	441	4%
Seed and grain	430	4%
Pebble	424	4%
Stationery	422	4%
Paper	365	3%
Plastic	304	3%
Jewellery	215	2%
Metal	183	2%
Battery	170	2%
Cotton	162	2%
Button	152	1%
Stick	150	1%
Bean and pea	142	1%
Sponge	95	1%
Sweet	91	1%
Arthropod	80	1%
Сар	70	1%
Other stationery	56	1%
Polystyrene	53	1%
Tinfoil and cellophane	42	0%
accessorize	26	0%
Fruit stone	20	0%
Earplug	20	0%
Medicine	13	0%
Total	10,564	

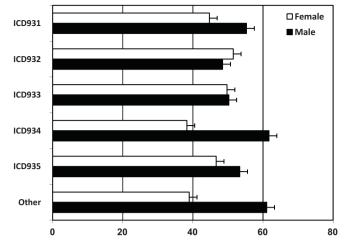


Fig. 3. Distribution of cases by injury location and by gender.

requiring or not hospitalization. The vast majority of the cases have been managed by the Emergency Department (5986 cases) followed by the ENT department (5812), mostly with endoscopic techniques; only 160 cases (1.4%) needed a surgical intervention. Data regarding the need of hospitalization was at disposal in 5840 cases: among them 36% of children (2106) were hospitalized; particularly, 806 were discharged after 24 h whereas 248 required hospitalization more than 3 days.

Most commonly observed complications were infections other than pneumonia (6.7%) and pneumonia (6.4%), followed by asthma (3.1%) and by perforation (2.9%). Complications requiring hospitalization occurred in 7.1% of children younger than 1 year while, they seem to be less frequent in older (Fig. 5).

Complication distribution according to FB characteristics is shown in Tables 10 and 11. Conforming consistency showed a higher incidence of complications; consisting with this result, sponges seem to be the FB most often related with complications' occurrence, while pearls, balls and marbles, which are the most frequently retrieved FB, are rarely involved in complicated cases (Fig. 6).

Table 5

Distribution of non-food objects by shape (numbers are percentages).

FB description	2D/circle	3D/cylinder	Spherical	Other
Accessorize	21.7	52.2		26.1
Arthropod	4.5	63.6	27.3	4.5
Battery	73.8	16.9	4.6	4.6
Button	68.4	10.5	15.8	5.3
Cap	3.6	92.9		3.6
Coin	97.9	0.3	1.7	
Cotton	24.2	33.3	30.3	12.1
Earplug		18.8	56.3	25.0
Jewellery	24.1	35.4	26.6	13.9
Medicine	66.7		33.3	
Metal	12.5	31.3	9.4	46.9
Other non-food	32.3	36.0	11.8	19.9
Other stationery	18.2	63.6		18.2
Paper	60.7	10.7	1.8	26.8
Pearl, ball and marble	5.5	7.5	85.8	1.1
Pebble	4.9	33.1	50.0	12.0
Pin and needle	16.1	59.8	2.3	21.8
Plastic	25.6	52.3	7.0	15.1
Polystyrene	4.2	33.3	45.8	16.7
Sponge		60.0	20.0	20.0
Stationery	7.6	75.9	8.9	7.6
Stick	14.3	57.1		28.6
Tinfoil and cellophane	81.3	12.5	6.3	
Тоу	22.4	52.1	22.8	2.7
Total	29.6	26.7	35.7	8.0

Table 6

Distribution of non-food	l objects by consistency	(numbers are percentages).
--------------------------	--------------------------	----------------------------

FB description	Conforming	Rigid	Semi-rigid
Accessorize	12.0	72.0	16.0
Arthropod	20.6	41.2	38.2
Battery		100.0	
Button		95.8	4.2
Cap	2.7	64.9	32.4
Coin		100.0	
Cotton	92.6		7.4
Earplug	16.7	5.6	77.8
Jewellery		97.8	2.2
Medicine	77.8	11.1	11.1
Metal		100.0	
Other non-food	26.6	62.4	11.0
Other stationery	4.7	90.7	4.7
Paper	86.5	5.9	7.6
Pearl, ball and marble	3.4	89.6	7.0
Pebble	1.1	98.1	0.7
Pin and needle	2.7	97.3	
Plastic	13.3	63.6	23.1
Polystyrene	34.9	41.9	23.3
Sponge	95.1		4.9
Stationery	18.7	64.0	17.3
Stick		92.9	7.1
Tinfoil and cellophane	44.1	2.9	52.9
Тоу	13.7	71.1	15.2
Total	14.6	76.4	9.1

Some injuries occurred for what is called the "unexpected usage" or "mis-usage" of the object: this includes packaging and association with food and non food object when combined without the necessary attention to safety issues. In the Susy Safe registry, 5 different categories of objects have been considered in view of providing the EU Commission with useful information:

a. not an industrial component;

- b. a piece of an object: the FB was a broken part of the product (e.g. a broken part of a pen and the wheel of a toy car);
- c. in co-presence with another object: when the objects were sold together like the cap with the pen, the marble with a board game, etc.;
- d. a package or a part of a package of a product (e.g. the tinfoil containing a chocolate, a polystyrene ball, and a piece of cardboard);
- e. the inedible part of food products containing inedibles (FPCI): stickers in crisps, toys in chocolate eggs, etc. Moreover we divided this category in two subcategories: the proper FPCI and the improper FPCI.

Where the association was not specified we considered the product like a single object and not an industrial component. Obviously, food and the other organics objects were treated as non industrial components. In the RPA report [28] the food products containing inedibles (FPCI) were defined as the combination of edible and inedible components, such as toys, used by food

Distribution of volume	by food object (mm ³).

Table 7

manufacturers to promote a wide range of products including sweets, crisps, yoghurt, ice cream and cereal. Several studies [29– 33] were published on the risk that a child may face placing the inedible object contained in the product in or near their mouth, causing potentially ingestion, choking or suffocation. For such injuries we used the definition of "proper FPCI". We defined the "improper FPCI" as the objects sold with food but not for a strict promoting purpose, like the candles on a cake, the drinking-straw with a juice or other non-organic decorations on the food. Overall, nine FPCI only have been observed in the Susy Safe registry, all without neither hospitalizations nor complications.

What is lacking is really proper adult supervision: according to Susy Safe data, an adult was present in 25% of the injuries, and in 40% of those involving a child younger than one year. In 87.9% of the cases the child was playing. This evidence suggests the need of fostering the attention of families toward a proper surveillance of children, in particular of younger ages.

5. Providing evidence to the EU Commission

The final aim of this data collection system was the construction of a system able to provide the EU Commission with all the relevant estimates on FB injuries. This has been accomplished via a fairly complex statistical system being developed for the purposes of the project: the so-called "Susy Safe risk engine".

A risk engine can be thought of as a table in which one could look up the potential threat associated with any given consumer product. To perform a risk analysis, key factors affecting risk need to be identified. Factors impacting hazards usually include product design and consumer exposure [6,34–36]. Thus through the use of injury data, consideration of product characteristics and statistical tools it is possible to provide a numerical assessment of the threat of a product in terms of the probability of injury occurrence. At the end, the analysis results can be used both by consumers and manufacturers to make informed risk management decisions, in accordance with the "knowledge-based" action demanded by the EU Consumer Policy Strategy 2002–2006 (2.2.2. 3rd Comma) [37].

A risk engine is expected to produce the probability of occurrence of an injury given hazardous factors – e.g. an object that has a volume lower than a threshold value and a spherical shape – and it is expected to give insights of how the risk of injury occurrence changes when new data becomes available since product safety design, which depends also on the object dimension, shape and consistency, is subject to change over time in order to reduce or preclude further injuries.

Inside the Susy Safe project the object features taken into consideration for the calculation of the risk of injuries were size and shape of the foreign body which caused the injury [38].

Such a choice allows for evaluating the impact of dimension and shape as hazardous product characteristics in the spirit of European standard BSEN 71-1 of 1998 (Safety of Toys – Specifications for Mechanical and Physical Properties) which introduced the cylinder test to reduce the risk of choking in children. In fact, the cylinder test consists of a cylinder with an

Scholadol of Volume by food object (mm).									
FB description	Min	5%	25%	Median	75%	95%	99%	Max	
Bean and pea	15.7	16.3	26.2	37.7	94.2	350.4	_	452.2	
Bone	0.2	0.2	2.7	14.4	31.4	628.0	-	2110.1	
Fruit stone	9.4	9.4	37.7	84.8	352.7	-	-	795.5	
Nut	6.3	9.4	25.1	26.2	51.3	229.0	-	471.0	
Other food	1.0	3.8	26.2	42.9	104.7	1177.5	-	4710.0	
Seed and grain	1.0	7.3	19.4	37.7	104.7	246.4	-	418.7	
Sweet	4.2	4.2	14.9	33.0	134.2	-	-	937.8	
Overall	0.2	2.5	16.7	33.5	83.7	418.7	2565.3	4710.0	
Overall	0.2	2.5	16.7	33.5	83.7	418.7	2565.3		

Table 8

Distribution of volume by non-food object (mm³).

FB description	Min	5%	25%	Median	75%	95%	99%	Max
Accessorize	20.9	20.9	38.9	400.1	1478.9	-	-	1657.9
Arthropod	8.4	8.4	15.2	26.2	37.7	-	-	37.7
Battery	3.1	7.9	19.6	50.2	78.5	418.7	-	418.7
Button	7.1	7.1	24.3	72.7	158.6	-	-	314.0
Cap	33.5	33.5	67.4	82.2	176.6	-	-	261.7
Coin	3.1	78.5	86.7	314.0	435.4	669.9	-	1256.0
Cotton	16.7	16.7	16.7	26.2	34.0	-	-	51.3
Earplug	18.8	18.8	67.0	104.7	104.7	-	-	104.7
Jewellery	1.6	1.7	29.0	52.3	268.9	754.9	-	785.0
Medicine	4.2	4.2	4.2	6.8	-	-	-	9.4
Metal	1.0	1.0	30.1	52.3	52.3	-	-	117.8
Other non-food	6.3	8.6	16.7	39.8	149.5	850.4	-	1046.7
Other stationery	37.7	37.7	37.7	84.3	-	-	-	130.8
Paper	14.1	14.1	14.1	33.5	-	-	-	94.2
Pearl, ball and marble	0.5	4.2	9.4	26.2	67.0	235.5	434.6	1496.7
Pebble	6.3	9.4	26.2	37.7	67.0	139.2	-	235.5
Pin and needle	1.6	1.6	3.5	12.6	51.8	-	-	314.0
Plastic	2.1	2.1	18.3	62.8	240.3	-	-	1046.7
Polystyrene	1.0	1.0	4.2	9.4	37.7	-	-	837.3
Sponge	4.2	4.2	19.9	85.8	141.6	-	-	153.9
Stationery	1.6	3.5	23.6	55.0	94.2	355.9	-	418.7
Stick	31.4	31.4	31.4	172.7	-	-	-	314.0
Tinfoil and cellophane	16.7	16.7	19.1	60.2	94.2	-	-	94.2
Тоу	1.0	6.3	26.2	67.0	104.7	671.6	2093.3	2093.3
Overall	0.5	4.2	16.7	47.1	104.7	486.7	1046.7	2093.3

Table 9

FB ellipticity stratified by child age (numbers are percentages).

Age class	Min	5%	25%	Median	75%	95%	99%	Max
<1 year	1.0	1.0	1.3	2.5	8.5	28.3		30.0
1–2 years	1.0	1.0	1.0	1.5	3.7	22.0	40.0	63.5
\geq 3 years	1.0	1.0	1.0	1.0	3.0	25.0	40.0	60.0
Total	1.0	1.0	1.0	1.2	3.6	24.0	40.0	63.5

inner diameter of 31.7 mm and truncated askew with an upper dimension of 51.7 mm and a lower dimension of 25.4 mm. Any toy entering the cylinder without pressure is considered unsuitable for children younger than 3 and is legally banned.

In order to calculate this probability we need to know the distribution of such characteristics, the coverage of the surveillance system and finally the probability of occurrence of an injury. In fact, let us consider the following equation:

$$\mathsf{P}(I, I_{SS}|C) = \frac{\mathsf{P}(C|I, I_{SS})}{\mathsf{P}(C)} \times \mathsf{P}(I_{SS}|I) \times \mathsf{P}(I)$$

where I_{SS} stands for an injury covered by the surveillance system, I stands for an occurred injury and C stays for the object

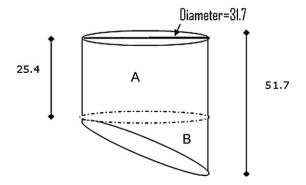


Fig. 4. Characteristics of the "small parts" cylinder (measures in mm).

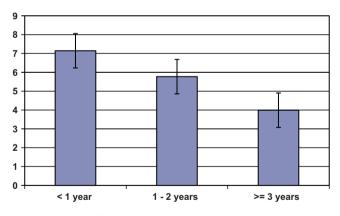


Fig. 5. Distribution of complications (%) requiring hospitalization by age class.

Table 10

FB volume and ellipticity in complicated and non complicated cases.

	Complication		
	No	Yes	
Volume (mm ³)			
25%	16.7	25.1	
Median	37.7	37.7	
75%	98.9	78.5	
Ellipticity			
25%	1.0	1.0	
Median	1.0	1.5	
75%	3.5	2.3	

Table 11

Percentage of complication according to shape and consistency.

	Complications (%)		
	No	Yes	
Shape			
2D	91.4	8.6	
2D circle	94.1	5.9	
3D	89.1	10.9	
Other	91.3	8.7	
Spherical	91.2	8.8	
Consistency			
Conforming	84.8	15.2	
Rigid	93.4	6.6	
Semi-rigid	87.9	12.1	

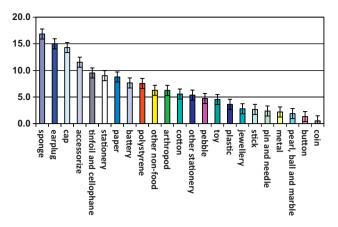


Fig. 6. Distribution of incidence (%) of complications by FB type (only non-food).

safer, so that these injuries no longer occur to such an extent. The Commission however needs secure data about injuries in order to adopt administrative or legislative measures. We

will not be able to immediately adopt strict measures based only on a few injuries that occur in all large communities. The

quality of legislative or administrative measures depends

precisely on the amount and the reliability of data. We should

always consider this when we discuss any preventive or

characteristics. Thus with $P(I, I_{SS}|C)$ at the first member of equation we indicated the probability that a foreign body injury occurred and it was detected by the surveillance system given foreign body characteristics *C*. An example of the risk estimates is shown in Tables 12 and 13.

6. Final remarks

Every infant injury, every dead child, is something utterly intolerable. We should bear in mind the objective to avoid as many of these infant injuries as possible. The European Commission devotes a lot of time and work within its activities minimizing infant injuries and making objects and environments

Table 12

Risk of injury

Foreign body type	Median volume (mm ³)	Median ellipticity (spherical shape=1)	Risk estimate	95% credibility interval
Non food				
Battery	33.36	6	6.14E-05	1.58E-06; 6.18E-05
Coin	314	10	0.00019	5.62E-06; 0.00022
Тоу	66.99	1	0.00016	5.55E-06; 0.00022
Pearl, ball and marble	16.75	1	0.00037	1.07E-06; 0.00041
Paper, tinfoil and cellophane	33.49	2	2.29E-06	1.43E-08; 2.36E-05
Button	67	5	3.60E-05	1.08E-06; 6.78E-05
Pin and needle	9.03	4.5	2.25E-05	1.01E-06; 3.56E-05
Stationery (pen cap, pencil lead)	6.28E+01	2	8.51E-05	2.23E-06; 8.71E-05
Pebble	37.68	1	0.00013	3.75E-06; 0.00017
Food				
Nut	26.17	1	0.00012	8.03E-05; 0.00017
Bone	5.88	16	4.63E-05	1E-06; 6.83E-05
Seed and grain	36.63	2.5	7.02E-05	4.73E-05; 8.46E-05
Sweet	32.97	1	7.12E-05	6.20E-05; 8.32E-05

legislative measure.

Table 13

Risk of severe injury (injury which required at least one day of hospitalization).

Foreign body type	Median volume (mm ³)	Median ellipticity (spherical shape=1)	Risk estimate	95% credibility interval
No Food				
Battery	33.36	6	6.14E-05	1.58E-06; 6.18E-05
Coin	314	20	2.87E-05	2.15E-05; 3.52E-05
Тоу	69.86	1.66	2.93E-05	2.88E-05; 2.99E-05
Pearl, ball and marble	9.42	1	0.00018	1.04E-05; 0.00023
Paper, tinfoil and cellophane	25.12	.1	5.07E-07	5.04E-07; 3.2E-06
Button	50.24	4	1.26E-05	1.22E-05; 1.28E-05
Pin and needle	20.02	5	1.56E-05	1.38E-05; 1.63E-05
Stationery (pen cap, pencil lead)	28.78	2.33	2.53E-05	2.20E-05; 2.59E-05
Pebble	28.78	1	1.72E-05	1.53E-05; 1.77E-05
Food				
Nut	27.17	1	2.32E-05	1.45E-05; 3.32E-05
Bone	26.17	6.67	3.12E-05	4.20E-06; 3.87E-05
Seed and grain	33.68	3.33	2.38E-05	1.1E-05; 3.35E-05
Sweet	16.75	1	4.43E-06	4.25E-06; 4.57E-06

Appendix. The Susy Safe Working Group

Coordination Group

Prof. Dario Gregori, University of Padova, Italy, Principal Investigator, e-mail: dario.gregori@unipd.it

Dr. Francesca Foltran, University of Padova, Italy Mrs. Simonetta Ballali, PROCHILD ONLUS, Italy Dr. Paola Berchialla, University of Torino, Italy

Governing Board

Dr. Hugo Rodriguez, Hospital De Pediatría Juan P. Garrahan, Argentina

Dr. Paola Zaupa, Grosse schützen Kleine, Austria

Dr. Peter Spitzer, Grosse schützen Kleine, Austria

Dr. Costantinos Demetriades, Ministry of Commerce, Industry and Tourism, Cyprus Prof. Ivo Šlapák, Masaryk University, Czech Republic

Prof. Ljiljana Sokolova, Institute for Respiratory Diseases in Children, FYROM

Prof. Eleni Petridou, Athens University - Medical School - Department of Hygiene and Epidemiology, Greece

Dr. Antonella D'Alessandro, Ministero dello Sviluppo Economico, Italy Prof. Manuel Antonio Caldeira Pais Clemente, Instituto Portugues de Tabacologia, Portugal

Prof. Jana Jakubíková, Children's University Hospital, Slovak Republic Prof. Sebastian Van As, Red Cross War Memorial Children's Hospital, South Africa Eng. Ton De Koning, Voedsel en Waren Autoriteit, The Netherlands

Prof. Sebastian Van As, Red Cross War Memorial Children's Hospital, South Africa Quality Control

Prof. Desiderio Passali, University of Siena, Italy

Argentina

Prof. Alberto Chinsky, Children's Hospital Gutierrez, Argentina Dr. Hugo Rodriguez, Children's Hospital Juan P. Garrahan, Argentina

Bosnia and Herzegowina

Dr. Fuad Brkic, University Clinical Center, Bosnia and Herzegowina

Croatia

Dr. Ranko Mladina, University Hospital Salata, Croatia

Cyprus

Dr. Olga Kalakouta, Medical and Public Health Services, Ministry of Health, Cyprus Dr. Andreas Melis, Aretaeion Hospital, Cyprus

Czech Republic

Dr. Michaela Máchalová, Childrens University Hospital, Czech Republic

Denmark

Dr. Per Caye-Thomasen, Gentofte University Hospital of Copenhagen, Denmark

Egypt

Dr. Enas Elsheikh, Suez Canal University, Egypt Dr. Ahmed Ragab, Menoufiya University Hospital, Egypt

Finland

Dr. Anne Pitkäranta, Helsinki University Central Hospital, Finland

France

Dr. Philippe Contencin Necker, Enfants Malades Hospital, France

Dr. Jocelyne Derelle, CHU Nancy, France

Dr. Magali Duwelz, SOS Benjamin - Observaoire National d'Etudes des Conduites à **Risques**, France

Dr. Martine Francois, Robert Debré Hospital, France

Dr. Stephane Pezzettigotta, Armand Trousseau Hospital, France

Dr. Christian Righini, CHU A. Michallon, France

Dr. Pezzettigotta Stephane, Armand Trousseau, Hospital France

FYROM

Dr. Jane Buzarov, Institute for Respiratory Diseases in Children, FYROM

Germany

Dr. Roehrich Bernhard, St. Joseph Hospital, Germany

Dr. Volker Jahnke, Charité Campus Virchow, Germany

Dr. Goktas Onder.Charité Campus Virchow, Germany

Dr. Petra Zieriacks, Kinderheilkunde und Jugendmedizin, Naturheilverfahren und Akupunktur,Germany

Greece

Dr. Vicky Kalampoki, Athens University, Department of Hygiene and Epidemiology, Greece

Dr. Nikola Simasko, Democritus University School of Medicine, Greece Dr. Charalampos Skoulakis, General Hospital of Volos, Greece

Italy

- Dr. Angelo Camaioni, San Giovanni Addolorata Calvary Hospital, Italy
- Dr. Cesare Cutrone, University Hospital of Padova, Italy

Dr. Elisa Gaudini, Ear-Nose-Throat Department, Policlinico Le Scotte, Italy

- Dr. Domenico Grasso, Burlo Garofolo Pediatric Institute, Italy
- Dr. Nicola Mansi, Santobono Pausilipon Pediatric Hospital, Italy
- Dr. Gianni Messi, Burlo Garofolo Pediatric Institute, Italy
- Dr. Claudio Orlando, Santobono Pausilipon Pediatric Hospital, Italy
- Dr. Sabino Preziosi, Elisoccorso ospedale Ravenna, Italy
- Dr. Italo Sorrentini, G. Rummo Hospital, Italy

Dr. Marilena Trozzi, Bambino Gesù Pediatric Hospital, Italy

- Dr. Alessandro Vigo, Sant'Anna Pediatric Hospital, Italy
- Dr. Giuseppe Villari, G. Rummo Hospital, Italy

Dr. Giulio Cesare Passali, Ear, Nose, and Throat Clinic, University "Tor Vergata", Rome. Italy

Dr. Francesco Maria Passali, ENT Department, Catholic University "The Sacred Heart" of Rome, Italy

Japan

Eng. Yoshifumi Nishida. National Institute of Advanced Industrial Science and Technology (AIST), Japan

Kazakhstan

Dr. Gainel Ussatayeva, Kazakhstan School of Public Health, Kazakhstan

Mexico

Dr. Ricardo De Hoyos, San Jose-Tec de Monterrrey Hospital, Mexico

Nigeria

Dr. Foluwasayo Emmanuel Ologe, University of Ilorin Teaching Hospital, Nigeria

Pakistan

Dr. Muazzam Nasrullah, Services Hospital, Paediatric Ward, Pakistan

Panama

Dr. Amarilis Melendez, Santo Tomas Hospital, Panama

Poland

Dr. Mieckzyslaw Chmielik, Medical University of Warsaw, Poland

Portugal

Dr. Teresa Belchior, Deco Proteste, Portugal

Romania

- Dr. Mihail Dan Cobzeanu, Sf. Spiridon Hospital, Romania
- Dr. Dan Cristian Gheorghe, Maria Sklodowska Curie Hospital, Romania
- Dr. Adelaida Iorgulescu, Grigore Alexandrescu Pediatric Hospital, Romania Dr. Caius-Codrut, Sarafoleanu Sf. Maria Hospital, Romania
- Dr. Miorita Toader, Grigore Alexandrescu Pediatric Hospital, Romania

Slovak Republic

Dr. Jana Barkociová, Children University Hospital, Slovak Republic Dr. Beata Havelkova, Public Health Authority of the Slovak Republic, Slovak Republic

Slovenia

Dr. Miha Zargi, University Medical Centre, Slovenia

Spain

Dr. Felix Pumarola, Vall d'Hebron University Hospital, Spain

Dr. Lorenzo Rubio, Ruber International Hospital, Spain

Sweden

Dr. Pontus Stierna, Huddinge University Hospital, Sweden

Dr. Sakda Arj-Ong, Ramathibodi Hospital, Thailand Dr. Chulathida Chomchai, Siriraj Hospital, Thailand

Dr. Lennaert Hoep, VU Medical Center, The Netherlands

Dr. Erdinc Aydin Baskent, University Ankara Hospital, Turkey

Dr. Volkan Sarper Erikci, Behcet Uz Children Hospital, Turkey

Dr. John Graham, Royal Free Hampstead NHS Trust, United Kingdom

Dr. Christopher Raine, Bradford Royal Innfirmary, United Kingdom

Dr. Sadie Khwaja, Royal Manchester Children's Hospital, United Kingdom

[1] RPA, Inedibles in Food Product Packaging Prepared for STOA, European Parlia-

Dr. Rico Rinkel, VU Medical Center, The Netherlands

Dr. Metin Onerci, Hacettepe University, Turkey

Taiwan

Dr. Wei-chung Hsu, National Taiwan University Hospital, Taiwan

Thailand

Turkey

The Netherlands

United Kingdom

References

ment. 2003.

- [2] F. Foltran, D. Gregori, D. Passali, L. Bellussi, G. Caruso, F.M. Passali, et al., Toys in the upper aerodigestive tract: evidence on their risk as emerging from the ESFBI study, Auris Nasus Larynx 38 (October (5)) (2011) 612–617.
- [3] G. Zigon, D. Gregori, R. Corradetti, B. Morra, L. Salerni, F.M. Passali, et al., Child mortality due to suffocation in Europe (1980–1995): a review of official data, Acta Otorhinolaryngol. Ital. 26 (June (3)) (2006) 154–161.
- [4] D. Gregori, L. Salerni, C. Scarinzi, B. Morra, P. Berchialla, S. Snidero, et al., Foreign bodies in the upper airways causing complications and requiring hospitalization in children aged 0–14 years: results from the ESFBI study, Eur. Arch. Otorhinolaryngol. 265 (August (8)) (2008) 971–978.
- [5] F. Foltran, D. Gregori, D. Passali, Foreign bodies inhalation as a research field: what can we learn from a bibliometric perspective over 30 years of literature? Int. J. Pediatr. Otorhinolaryngol. 75 (2011) 721–724.
- [6] P. Berchialla, S. Snidero, A. Stancu, C. Scarinzi, R. Corradetti, D. Gregori, et al., Predicting severity of foreign body injuries in children in upper airways: an approach based on regression trees, Risk Anal. 27 (5) (2007) 1255–1263.
- [7] H.K. Tan, K. Brown, T. McGill, M.A. Kenna, D.P. Lund, G.B. Healy, Airway foreign bodies (FB): a 10-year review, Int. J. Pediatr. Otorhinolaryngol. 56 (December (2)) (2000) 91–99.
- [8] O. Goktas, S. Snidero, V. Jahnke, D. Passali, D. Gregori, Foreign body aspiration in children: field report of a German hospital, Pediatr. Int. 52 (February (1)) (2010) 100–103.
- [9] F.S. Chacon, S. Ballali, D. Passali, G. Cuestas, G. Burbano, R. Perez, et al., Epidemiology of foreign bodies injuries in Ecuador: a first look based on a single centre experience, Int. J. Pediatr. Otorhinolaryngol. 75 (June (6)) (2010) 854–857.
- [10] A. Chinski, F. Foltran, D. Gregori, S. Ballali, D. Passali, L. Bellussi, Foreign bodies in the oesophagus: the experience of the Buenos Aires Paediatric ORL Clinic, Int. J. Pediatr. (2010).
- [11] A. Chinski, F. Foltran, D. Gregori, D. Passali, L. Bellussi, Nasal foreign bodies: the experience of the Buenos Aires Paediatric ORL Clinic, Pediatr. Int. May (2011).
- [12] A. Chinski, F. Foltran, D. Gregori, D. Passali, L. Bellussi, Foreign bodies causing asphyxiation in children: the experience of the Buenos Aires paediatric ORL clinic, J. Int. Med. Res. 38 (March-April (2)) (2010) 655-660.
- [13] A. Chinski, F. Foltran, D. Gregori, D. Passali, L. Bellussi, Foreign bodies in the ears in children: the experience of the Buenos Aires pediatric ORL clinic, Turk. J. Pediatr. 53 (July–August (4)) (2011) 425–429.
- [14] B.K. Reilly, D. Stool, X. Chen, G. Rider, S.E. Stool, J.S. Reilly, Foreign body injury in children in the twentieth century: a modern comparison to the Jackson collection, Int. J. Pediatr. Otorhinolaryngol. 67 (December (Suppl. 1)) (2003) S171–S174.
- [15] V. Erikci, S. Karacay, A. Arikan, Foreign body aspiration: a four-years experience, Ulus. Travma Acil Cerrahi Derg. 9 (January (1)) (2003) 45-49.
- [16] T. Mahafza, A. Batieha, M. Suboh, T. Khrais, Esophageal foreign bodies: a Jordanian experience, Int. J. Pediatr. Otorhinolaryngol. 64 (July (3)) (2002) 225–227.
- [17] A.O. Ogunleye, O.G. Nwaorgu, O.A. Sogebi, Upper airway obstruction in Nigeria: an aetiological profile and review of the literature, Trop. Doct. 31 (October (4)) (2001) 195–197.
- [18] B.C. Becker, T.G. Nielsen, Foreign bodies in the airways and esophagus in children, Ugeskr. Laeger 156 (July (30)) (1994) 4336-4339.
- [19] R. al-Hilou, Inhalation of foreign bodies by children: review of experience with 74 cases from Dubai, J. Laryngol. Otol. 105 (June (6)) (1991) 466–470.
- [20] D. Gregori, C. Scarinzi, B. Morra, L. Salerni, P. Berchialla, S. Snidero, et al., Ingested foreign bodies causing complications and requiring hospitalization in european

children: results from the ESFBI study, Pediatr. Int. 52 (February (1)) (2010) 26-32.

- [21] D. Gregori, B. Morra, P. Berchialla, L. Salerni, C. Scarinzi, S. Snidero, et al., Foreign bodies in the ears causing complications and requiring hospitalization in children 0–14 age: results from the ESFBI study, Auris Nasus Larynx 36 (February (1)) (2009) 7–14.
- [22] D. Gregori, L. Salerni, C. Scarinzi, B. Morra, P. Berchialla, S. Snidero, et al., Foreign bodies in the nose causing complications and requiring hospitalization in children 0–14 age: results from the European survey of foreign bodies injuries study, Rhinology 46 (March (1)) (2008) 28–33.
- [23] M. Wai Pak, W. Chung Lee, H. Kwok Fung, C.A. van Hasselt, A prospective study of foreign-body ingestion in 311 children, Int. J. Pediatr. Otorhinolaryngol. 58 (April (1)) (2001) 37–45.
- [24] D. Gregori, F. Foltran, D. Passali, Foreign body injuries in children: need for a step forward against an old yet neglected epidemic, Paediatr. Perinat. Epidemiol. 25 (March (2)) (2011) 98–99.
- [25] D. Gregori, B. Morra, S. Snidero, R. Corradetti, D. Passali, The ESFBI Study. Final Report, Franco Angeli, Milano, Italy, 2005.
- [26] S.M. Milkovich, R. Altkorn, X. Chen, J.S. Reilly, D. Stool, L. Tao, et al., Development of the small parts cylinder: lessons learned, Laryngoscope 118 (11) (2008) 2082– 2086.
- [27] DTI, Choking Risk to Children Under Four from Toys and Other Objects, DTI, London, 1999.
- [28] RPA, Inedibles in Food Product Packaging Final Report: STOA, 2003.
- [29] Y.L. Chan, S.S. Chang, K.L. Kao, H.C. Liao, S.J. Liaw, T.F. Chiu, et al., Button battery ingestion: an analysis of 25 cases, Chang Gung Med. J. 25 (March (3)) (2002) 169– 174.
- [30] Y.J. Chang, H.C. Chao, M.S. Kong, M.W. Lai, Clinical analysis of disc battery ingestion in children, Chang Gung Med. J. 27 (September (9)) (2004) 673– 677.
- [31] S.A. Cowan, P. Jacobsen, Ingestion of button batteries. Epidemiology, clinical signs and therapeutic recommendations, Ugeskr. Laeger 164 (February (9)) (2002) 1204–1207.
- [32] S. Dane, A.J. Smally, T.R. Peredy, A truly emergent problem: button battery in the nose, Acad. Emerg. Med. 7 (February (2)) (2000) 204–206.
- [33] C.C. Gomes, E. Sakano, M.C. Lucchezi, P.R. Porto, Button battery as a foreign body in the nasal cavities. Special aspects, Rhinology 32 (June (2)) (1994) 98– 100.
- [34] P. Deheuvels, Development of a Method Allowing to Define Security Rules for Particular Classes of Products, to be Enforced through Technical Standards by European Bodies under Mandate of the European Commission – Final Report, 2003.
- [35] G. Rider, S. Milkovich, D. Stool, T. Wiseman, C. Doran, X. Chen, Quantitative risk analysis, Inj. Control Saf. Promot. 7 (2) (2000) 115–133.
- [36] P. Berchialla, A. Stancu, C. Scarinzi, S. Snidero, R. Corradetti, D. Gregori, Web-based tool for injury risk assessment of foreign body injuries in children, J. Biomed. Inform. 41 (August (4)) (2008) 544–556.
- [37] Commission of the European Communities, Consumer Policy Strategy 2002– 2006, COM (2002), 208, Off. J. Eur. Communities (2002).
- [38] F.L. Rimell, A. Thome Jr., S. Stool, J.S. Reilly, G. Rider, D. Stool, et al., Characteristics of objects that cause choking in children, JAMA 274 (December (22)) (1995) 1763–1766.