IAPO-Interamerican Association of
Pediatric Otorhinolaryngology

Public Health and Prevention of Foreign Bodies Injuries: the Experience of the European Registry "Susy Safe"

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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 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**. Out of the estimated 2.000 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 € per year, only because of injuries due to industrial products [2].

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 [3]. In fact, most of the epidemiologic evidence on foreign bodies (FB) in children comes from single-center retrospective studies, covering a time range of about 3-10 years [4] in the past. Very recently, attempts have been made to start a systematic collection of FB in view of using them to characterize the risk of chocking in terms of size, shape and consistency of the FB [5]. Also several review papers discussed more clinical aspects of the FB injuries, like clinical diagnosis and management of the injured child [6]. Country specific experiences have also been presented in the literature, with a wide although not systematic spread and geographical coverage [7-10]. 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 to European data [3, 11-13], 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 toys 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 (**Table 1**).

Table 1. Metanalysis of published papers on choking injuries (30 years review 1973-2003).

		Pooled proportion (SE)	*Confidence Interval (95%)*	*Q- Cochrane*	*Homogeneity p-value*
Type	Organic	0.732 (0.045)	0.645-0.819	4168.24	< 0.001
	Inorganic	0.206 (0.033)	0.142- 0.271	2345.66	< 0.001
	Toys	0.041 (0.010)	0.021- 0.062	98.62	< 0.001
	Nuts	0.478 (0.048)	0.385- 0.571	1042.05	< 0.001
Gender	Male	0.597 (0.016)	0.566-0.628	199.12	< 0.001
Age	<=3 years	0.765 (0.014)	0.739- 0.792	90.58	< 0.001

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 [6,14], and (iii) foreign bodies collections, with the specific aim of describing the shape and the material of the object causing the injury [5]. 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 relative 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 towards 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. 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.

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;
2. 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;
3. involve, 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) [15] 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;

2. **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.

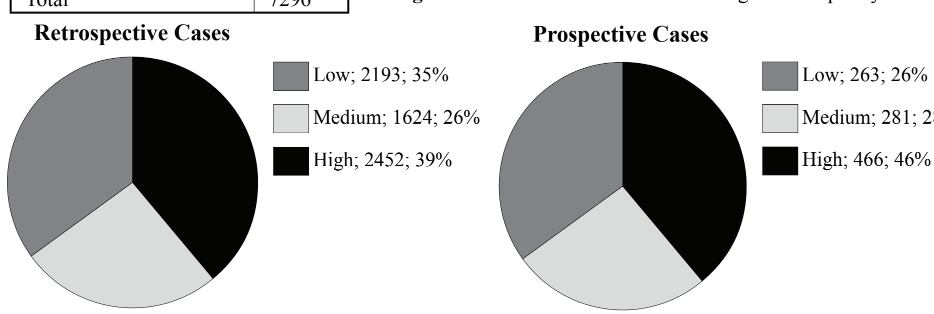
The registry collected 1010 prospective cases and 6286 retrospective cases, which constitute the 76% of the registry **Table 2.** Retrospective cases are past consecutive cases available in each center registry and shared with Susy Safe. Data collection for retrospective cases followed the same procedure as for the prospective cases.

Table 2. Patients enrolled by country in the Susy Safe registry.

EU countries	6994
Cyprus	9
Czech Republic	303
Denmark	70
Finland	367
France	116
Germany	33
Greece	88
Italy	4718
Poland	45
Romania	328
Slovak Republic	240
Slovenia	105
Spain	139
Sweden	236
the Netherlands	35
UK	162
Non EU Countries	302
FYROM	58
Pakistan	7
Croatia	19
Turkey	218
Total	7296

Three-hundred and two cases have been reported from countries outside EU. All cases, 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, 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, …) (**Figure 1**).

Figure 1. Distribution of cases according to their quality.



Seventy-four 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 65% for retrospective cases, still this remains a very good achievement. The children age distribution is shown in **Figure 2**: 54% of the cases are male, and about 41% of them are younger than three years. This percentage drops down to 36% for females **(Table 3**). Twelve children were reported with mental of physical impairment.

Figure 2. Age distribution of foreign body injuries observed.

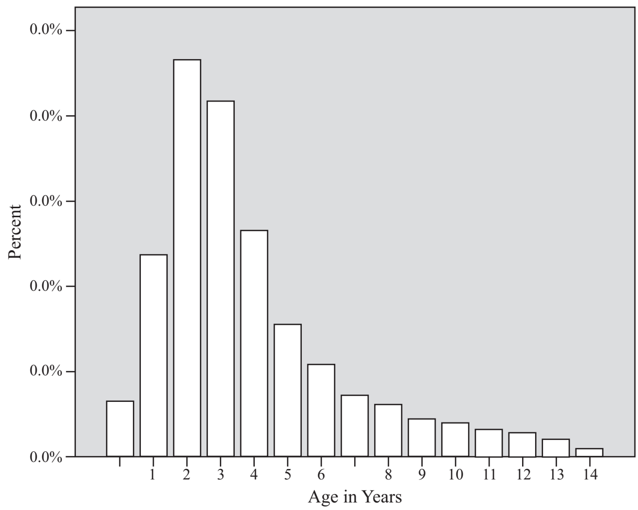


Table 3. Age distribution of cases in classes by gender.

	Female		Male		Total	
	N	%	N	%	N	%
< 1 year	87	3.0	119	3.6	206	3.3
1 - 2	1095	38.3	1084	32.4	2179	35.1
>= 3 years	1675	58.6	2143	64.0	3818	61.6
Total	2857	100.0	3346	100.0	6203	100.0

The vast majority of the cases have been managed by the ENT department (83%), mostly with endoscopic techniques; only 159 cases (2.3%) needed a surgical intervention.

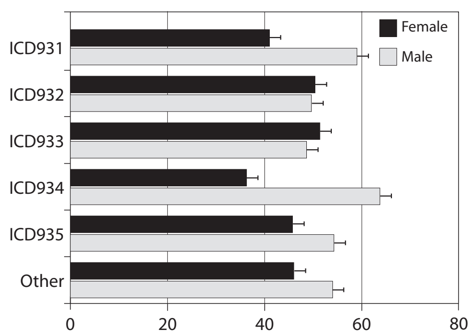
Forty-six percent of the cases involving very young children (**less than one year of age**) involved the **aero-laryngeal and bronchial tract**, thus representing a major threat to their health. Notice that **for older children the most common location (about 45% on average) is the nose.** Esophageal foreign bodies are still characterizing injuries occurred to children younger than one year. **Foreign bodies in the ears are a characteristic of older ages** (**Figure 2** and **Table 4**).

Table 4. Distribution of location of Foreign Body by age

	< 1 year	%	1 - 2 years	%	>= 3 years	%	Total
ICD931	6	2.9	177	7.7	1311	32.4	**1494**
ICD932	16	7.7	1084	47.4	1666	41.2	**2766**
ICD933	35	16.8	290	12.7	606	15.0	**931**
ICD934	96	46.2	532	23.3	231	5.7	**859**
ICD935	50	24.0	177	7.7	217	5.4	**444**
Other	5	2.4	28	1.2	16	0.4	**49**

Irrespectively from age, aero-laryngeal and bronchial injuries were **more common for males than for females** (**Figure 3**). In this location, three deaths have been observed, two in Italy and one in Finland. Children with disability had one foreign body in the nose, four in the bronchi's and seven in the oesophagus.

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



Food objects represented the **51.3% of the cases**, whereas non-food objects were the remaining **48.7%** (**Figure 4 and Table 5**). **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%).

Figure 4. Distribution of injuries by food types.

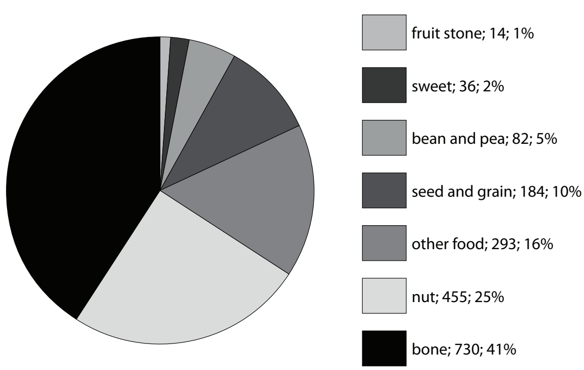


Table 5. Distribution of injuries by non-food type (N=absolute number, % = percentage).

	N	%
accessorize	18	1.0
arthropod	26	1.4
battery	49	2.7
button	38	2.1
cap	34	1.9
coin	188	10.5
cotton	34	1.9
earplug	15	.8
jewellery	50	2.8
medicine	4	.2
metal	27	1.5
other non-food	129	7.2
other stationery	6	.3
paper	68	3.8
pearl, ball and marble	489	27.2
pebble	129	7.2
pin and needle	75	4.2
plastic	80	4.5
polystyrene	27	1.5
sponge	10	.6
stationery	71	4.0
stick	12	.7
tinfoil and cellophane	24	1.3
toy	192	10.7
Total	1795	100.0

Coins were involved in 11% of the non-food injuries and toys represented the 11% of the cases. Spherical objects represent the 39% of the cases. Needle-shaped objects are representing the 2% of the cases, but still related **with an increased risk of complications, mostly due to bleeding.** According with this numbers, the **71% of the cases were rigid**. **Table 6** and **Table 7** are showing the distribution of the cases according to the shape and consistency stratified by foreign body type.

Table 6. Distribution of non-food objects by shape (numbers are percentages).

	2D/circle	3D/cylinder	Spherical	Other
accessorize	20.0	53.3		26.7
arthropod	5.9	58.8		35.3
battery	7.3	82.9	4.9	4.9
button	3.4	69.0		27.6
cap	4.0	92.0		4.0
coin	9.0	75.0	16.0	
cotton	22.2	29.6		48.1
earplug		18.2		81.8
jewellery	18.2	29.5	2.3	50.0
medicine	66.7			33.3
metal	13.0	21.7	4.3	60.9
other non-food	31.1	30.1	4.9	34.0
other stationery	20.0	60.0		20.0
paper	55.6	11.1		33.3
pearl, ball and marble	7.5	9.7	.2	82.6
pebble	4.7	21.7		73.6
pin and needle		50.8	47.6	1.6
plastic	22.6	48.4	4.8	24.2
polystyrene	4.5	27.3		68.2
sponge		71.4		28.6
stationery	6.7	75.0	5.0	13.3
stick	20.0	50.0		30.0
tinfoil and cellophane	84.2	5.3		10.5
toy	25.0	42.8	2.0	30.3
Total	14.2	36.5	5.2	44.2

Table 7. Distribution of non-food objects by consistency (numbers are percentages).

	Conforming	Rigid	Semi-rigid
accessorize	11.8	76.5	11.8
arthropod	31.3		68.8
battery		100.0	
button		96.6	3.4
cap	3.8	61.5	34.6
coin		100.0	
cotton	92.9		7.1
earplug	20.0		80.0
jewellery		95.3	4.7
medicine		50.0	50.0
metal		100.0	
other non-food	37.0	36.1	26.9
other stationery		60.0	40.0
paper	77.3	6.8	15.9
pearl, ball and marble	6.6	79.5	13.9
pebble	1.7	96.7	1.7
pin and needle	2.9	97.1	
plastic	15.9	50.7	33.3
polystyrene	59.1		40.9
sponge	85.7		14.3
stationery	6.3	55.6	38.1
stick		90.0	10.0
tinfoil and cellophane	52.4	4.8	42.9
toy	7.7	62.8	29.5
Total	12.8	71.0	16.2

Non food objects had a median volume of 41.9 mm^3, with an upper 95-th percentile of 470.1 and 99-th percentile of 1045 mm^3. The maximum volume observed was of 2093 mm^3. To allow a comparison with commonly used objects, a 5 euro-cent coin has a volume of 483 mm^3, a flat battery of 943 mm^3. Accessorize had a greater volume among various foreign body types (**Table 8**).

Table 8. Distribution of volume by non-food object (mm^3).

	Min	5%	25%	Median	75%	95%	99%	Max
accessorize	20.9	20.9	28.3	381.5	942.0	.	.	1657.9
arthropod	8.4	8.4	15.2	26.2	37.7	.	.	37.7
battery	3.1	6.0	19.6	50.2	78.5	418.7	.	418.7
button	7.1	7.1	19.6	67.0	176.6	.	.	314.0
cap	33.5	33.5	67.4	82.2	176.6	.	.	261.7
coin	3.1	78.5	82.6	314.0	459.2	683.0	.	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	31.9	67.0	263.0	748.9	.	785.0
medicine	4.2	4.2	4.2	6.8	.	.	.	9.4
metal	1.0	1.0	1.6	41.9	104.7	.	.	117.8
other non-food	6.3	8.8	16.7	41.9	149.2	837.3	.	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	4.1	9.4	26.2	67.0	235.5	473.0	1496.7
pebble	6.3	9.4	26.2	37.7	67.0	159.2	.	235.5
pin and needle	1.6	1.6	4.2	24.3	170.1	.	.	890.2
plastic	2.1	2.1	19.9	67.0	420.0	.	.	3532.5
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	3.7	20.0	48.4	90.3	348.0	.	418.7
stick	31.4	31.4	31.4	172.7	.	.	.	314.0
tinfoil and cellophane	16.7	16.7	16.7	26.2	.	.	.	94.2
toy	1.0	6.3	26.7	67.0	104.7	628.0	2789.4	2826.0
Total	0.5	4.2	16.7	50.8	104.7	490.6	1161.8	3532.5

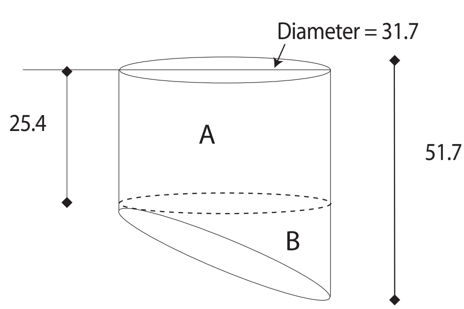
Food objects had a median volume of 31.4 mm^3, with a maximum observed volume of 4710 mm^3: bones tended to have higher volumes than nuts and beans (**Table 9**).

Table 9. Distribution of volume by food object (mm^3).

	Min	5%	25%	Median	75%	95%	99%	Max
bean and pecans	15.7	16.1	26.2	37.7	83.7	384.3	.	452.2
bone	0.2	0.2	2.4	5.9	31.4	628.0	.	2110.1
fruit stone	9.4	9.4	37.7	68.0	201.0	.	.	795.5
nut	6.3	9.4	25.1	26.2	51.3	212.0	.	471.0
other food	1.0	3.4	26.2	41.9	104.7	1308.3	.	4710.0
seed and grain	1.0	4.7	16.7	37.2	104.7	302.1	.	418.7
sweet	4.2	4.2	14.9	33.0	134.2	.	.	937.8
Total	0.2	2.2	16.7	31.4	74.8	418.7	3120.0	4710.0

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 [16]. 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"** (**Figure 5**). Regarding the "small-part cylinder", overall 617 objects collected in the Susy Safe registry and looking at the longer axis's 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.

Figure 5 Characteristics of the "small parts" cylinder (measures in mm).



Spherical objects are more common in younger ages, who also tend to be injured by relatively bigger objects (**Table 10**).

Table 10. Age of the child by FB ellipticity (numbers are percentages).

	Min	5%	25%	Median	75%	95%	99%	Max
< 1 year	1.0	1.0	1.2	2.5	7.0	25.0	.	30.0
1 - 2 years	1.0	1.0	1.0	1.5	3.3	22.0	40.0	63.5
>= 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	3.3	23.0	40.0	63.5

Looking at the consequences of the injury, the **Susy Safe registry adopted the DTI definition [17] 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, requiring or not hospitalization. Most commonly observed **complications were bleeding, asthma, hypoacusia, infections, with a higher incidence rates in the younger age class** (**Figure 6**) and in **correspondence with foreign bodies like pearls, stationery, cotton, toys and batteries** (**Figure 7**).

Figure 6. Distribution of incidence (%) of severe FB injuries by age class.

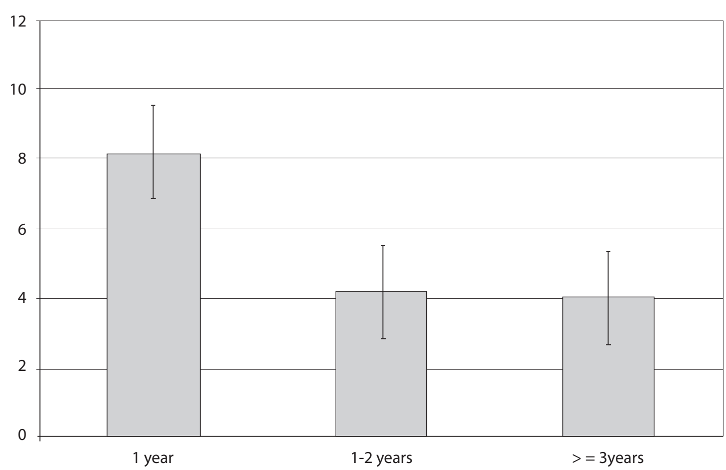
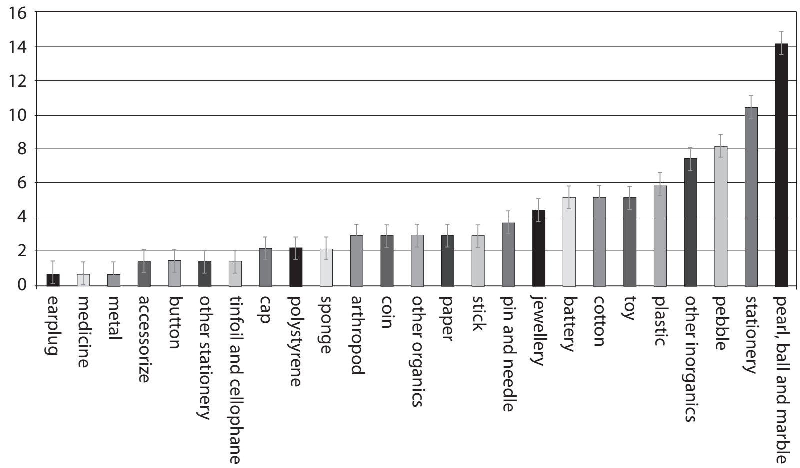


Figure 7. Distribution of incidence (%) of complications by FB type.



Bigger foreign bodies with conforming consistency showed a higher incidence of complications (**Table 11**).

Severe injuries occurred more commonly in injuries involving non spherical objects (median ellipticity of severe injuries equal to 4 versus 2 for non severe injuries) and involved non spherical objects of rigid consistency (**Table 11**).

Table 11. Distribution of incidence (%) of complications according to FB characteristics.

			No	Yes
Volume (mm^3)		25%	16.7	24.7
		Median	37.7	48.7
		75%	104.7	79.8
Ellipticity		25%	1.0	1.0
		Median	1.0	1.5
		75%	3.0	2.3
Shape	Incidence (%)	2D		13.3
		2D circle		7.8
		3D		12.9
		Cylinder		6.5
		Spherical		6.1
Consistency		Conforming		17.4
		Rigid		8.5
		Semi-rigid		14.4

Sixty-five of the hospitalized children had a hospital stay of one day, longer for those in younger ages (**Table 12**).

Table 12. Distribution of hospital stay by age (numbers are percentages).

	1 day	2 days	3 days	more than 3 days
< 1 year	59.6	19.9	7.4	13.2
1 - 2 years	50.5	23.2	10.6	15.7
>= 3 years	57.3	21.3	9.2	12.3
Total	54.1	22.1	9.7	14.1

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:

1. not an industrial component;
2. a piece of an object: the FB was a broken part of the product (e.g. a broken part of a pen, the wheel of a toy car, etc);
3. 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;
4. a package or a part of a package of a product (e.g. the tinfoil containing a chocolate, a polystyrene ball, a piece of cardboard, etc);
5. the inedible part of a FPCI (food product containing inedibles): 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 [18] the Food Products Containing Inedibles (FPCI) were defined as the combination of edible and inedible components, such as toys, used by food manufacturers to promote a wide range of products including sweets, crisps, yoghurt, ice cream and cereal. Several studies [19-23] 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 (**Table 13**).

Table 13. Distribution of cases by injury location and type of packaging (first row are absolute numbers, second row are percentages, for each category).

	ICD931	ICD932	ICD933	ICD934	ICD935	Other	Total
not industrial component	174	310	746	710	58	9	2007
	29.5	35.7	95.4	81.1	15.0	30.0	56.8
whole object-copresence	56	108	6	46	42		258
	9.5	12.4	.8	5.3	10.9		7.3
whole object-no copresence	278	342	19	76	260	9	984
	47.1	39.4	2.4	8.7	67.2	30.0	27.9
piece of object-copresence	8	20	2	2	3		35
	1.4	2.3	0.3	0.2	0.8		1.0
piece of object-no copresence	50	55	3	13	6	1	128
	8.5	6.3	0.4	1.5	1.6	3.3	3.6
package	12	14	2	2	5	2	37
	2.0	1.6	0.3	0.2	1.3	6.7	1.0
inedible of FPCI-whole		1			4		5
		0.1			1.0		0.1
inedible of FPCI-part	1	2	1	2			6
	0.2	0.2	0.1	0.2			0.2
unknown	11	16	3	24	9	9	72
	1.9	1.8	0.4	2.7	2.3	30.0	2.0
Total	590	868	782	875	387	30	3532
	100.0	100.0	100.0	100.0	100.0	100.0	100.0

But 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 is evidence suggesting the **need of fostering the attention of families toward a proper surveillance of children, in particular of younger ages.**

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 [24-25]. 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 2002-06 (2.2.2. 3rd Comma) [26].

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 become available since product safety design, which depends also on the objects 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 [27].
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 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:

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

where I_{SS} stands for an injury covered by the surveillance system, I stands for an occurred injury and C stays for the object 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 are shown in **Table 14** and **Table 15**.

Table 14. Risk of injury.

Foreign body type	Median volume (mm³)	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	10	0.00019	5.62E-06; 0.00022
toy	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

Table 15. Risk of severe injury (injury which required at least one day of hospitalization).

Foreign body type	Median volume (mm³)	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
toy	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

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 spends a lot of time and work within its activities minimizing infant injuries and making objects and environments 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 legislative measure.

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