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

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Abstract: The "Susy Safe" project is a European, WEB-based Registry (www.susysafe.org) aimed at collecting data regarding injuries caused by foreign bodies in the upper aero-digestive tract, occurred to children between 0 and 14 years of age. In most of the situations, injury registries are lacking an appropriate mechanism to control the data quality, mostly due to the low incidence of such events and to the corresponding high variability in the doctors reporting about the injury. In the Susy Safe registry, quality is a priority. Therefore, in order to monitor quality both automated and manual data inspections are used. There are automated checks which are based on classical data-entry controls and innovative statistical techniques mimicked from the industrial quality control. The manual inspections are conducted by dedicated medical doctors who check all cases that have an insufficient quality score obtained in the automated control. Having a centralized database and a Web access system, the quality control (QC) process becomes more flexible, improving its accuracy and reducing both the number of persons involved and the necessary time for its accomplishment.

Keywords. Quality Assurance, Quality Control, Foreign body injury.

INTRODUCTION

The inhalation, aspiration, insertion or ingestion of foreign bodies (FB) by children is one of the most important causes of sometimes fatal accidents. FB injuries' effects are dependent on the lodgment's site; in particular, airways FBs are often fatal. Particularly, children's airways differ from those of adults in several aspects and these differences contribute to the ease by which the child's airways can become obstructed. Even a small reduction in the size of airways can cause a significant increase in airway resistance; therefore, the consequences of foreign bodies' inhalation could be dramatic [1].

Foreign bodies injuries are therefore posing a great threat not only with regards to the clinical aspects but also from the public health perspective, their treatment being associated with high costs, in particular when surgery is needed [2].

Commonly aspirated objects include food, coins, small toys, small pieces of jewelry; organic material, mainly nuts, seem to represent the majority of the findings, particularly in 0-3 year age group [3].

Unfortunately, FB injuries are a neglected epidemic [4] and there's a lack of sensibility in terms of recognition and acknowledgement of the FB injury risk: the greater part of the published work around Europe and beyond regarding this issue in fact is usually based on single center reports or general injury registries that do not cover all the specific details needed to study its mechanisms. reviews and meta-analysis of the scientific literature are means commonly used to integrate and synthesize knowledge about a topic; however, these instruments often suffer from the heterogeneity in coding objects, clinical presentation, complications. Therefore, the adoption of national or supra-national surveillance systems able to collect the information in a standardized way and leading to identify which objects, products and behaviors could be dangerous for children seems to be necessary.

In this paper we will describe the "Susy Safe" Registry, a Web based registry whose purpose is to collect data regarding injuries caused by the aspiration of foreign bodies in the upper airways occurred to children between 0 and 14 years of age across the European Union and beyond. Particularly, we will focus on methods, implementation and management of quality assurance and control procedures.

THE SUSY SAFE PROJECT

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:

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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. 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) [5] as a starting point, with the aim of applying that methodology to the creation and development of a surveillance registry in EU and EFTA countries, with the joint effort of statisticians, public health expert, otorhyno-laryngologists, 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 QUALITY CONTROL PROCESS

The Case Report Form (CRF)

Foreign body injuries cases were collected using a Case Report Form (CRF). The CRF was designedby the coordinating center in collaboration with the other members of the Susy Safe project, taking into consideration specific needs and requirements. In order to achieve the established aims of the project and make data collection of a large amount of details easier, the CRF was split into four distinctsections: (i) the first one to fill in with the child's personal information (patient ID, Discharge Card number), exclusively stored by the area referent; (ii) the second section to fill in with the patient's information (date of birth, gender, accident date, localization of the foreign body (ICD code), the presence of complications, the FB removal technique, the necessity of hospitalization and its lasting, and the regime of hospitalization); (iii) the third part containing information on the foreign body typology (the FB description, shape, size and consistency, association with other objects at the time of the injury and the details of the other object, association with other objects at the moment of purchasing); (i) the fourth part containing information about the typology of assistance in hospital (how the hospital was reached, which was the department that first looked at the child, and the department that discharged the child).

Data Reporting Software

To ensurea fast and reliable data entry process, a web-based interface was the chosen solution. Due to privacy issues and quality control procedures, a stand-alone client software solution called Susysafe Case Report Software was preferred. The Susysafe Case Report was developed in Java because of its hardware/software independenceundera complex System Architecture (Fig. **1**).

The Susysafe Case Report Software interacts with a MySQL database server, used for the data storage, using Internet as a mean of transportation through the TCP/IP protocol. Locally, the application saves in the XML (Extensible Markup Language) format two files for each case. One of them contains the private meta-data of the patient, while the other one encapsulate the meta-data regarding the case itself.

Quality Assurance and Control Procedures

The usage of Web technologies allows a secure reporting of cases, also ensuring an automated and flexible Quality Control process, as well as a flexible access to data. According to Knatterud [6], the quality assurance of a data collection web-based system should be parted in three major modules: prevention, detection and actions. In order to ensure collection of high quality data, several aspects were taken in considerationfor the development of the data entry application [6]: (*i*) the "netting" of the patients, which is– the inclusion and exclusion criteria for the population under study is set; (*ii*) the patient data management, which is the identification of the relevant factors for the study; (*iii*) the
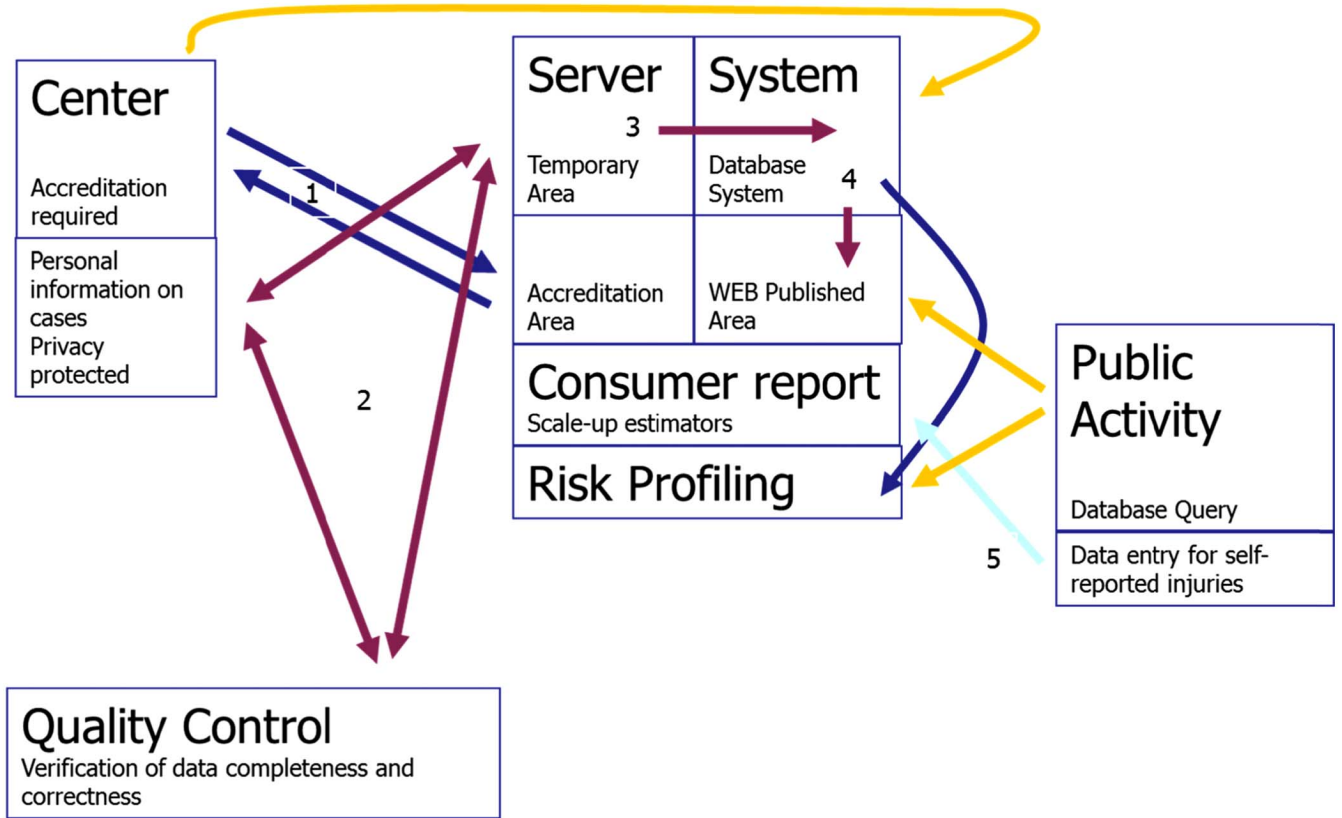
Fig. (1). The Susysafe Registry Informatics Architecture.

incident in a wider context, which is geographical details and co-morbidity.

The quality control is done into two phases (Fig. **2**). In the first phase, the control process is automated, based on logic checks performed by the data entry application. At this level, the integrity of the inserted data and the completion of the fields are checked. The controls are built within the software application and they regard matters such as date validation, completion of mandatory fields and others. The

date validation rules determine if a patient's age is within the project's range and they do not allow discrepancies such as accident's date to be prior to the birth date. Furthermore, they give the physician the possibility to choose from a given range of predefined standardized variables, this way ensuring the homogeneity of the data.

To alert the doctor if any errors occur during the process, a transmission monitoring protocol was furthermore implemented.
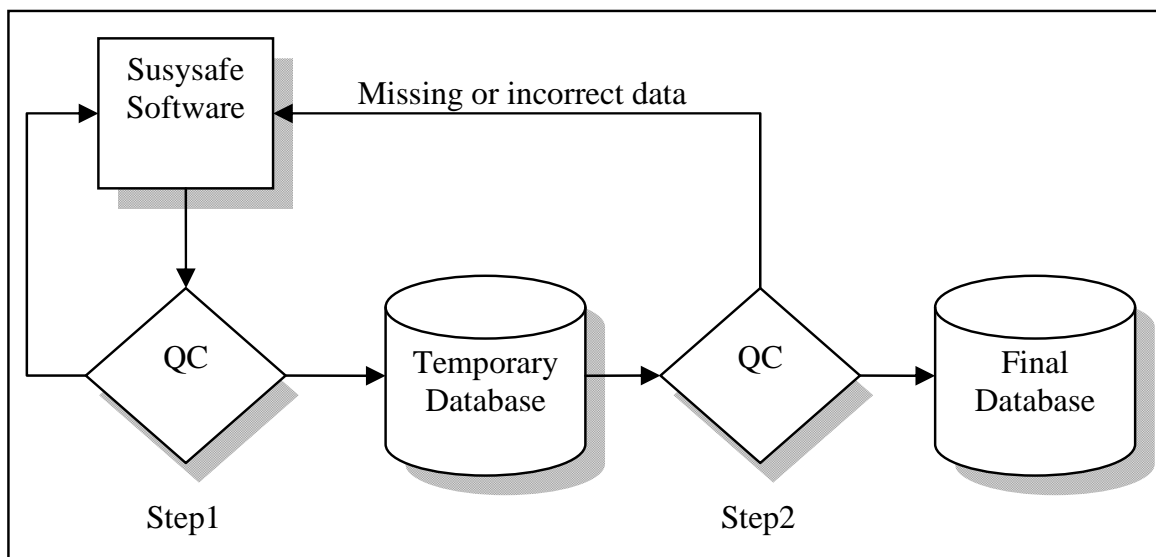

Fig. (2). Quality Control phases of the Susysafe Data Collection System.

The second phase consists inthe manual control, where dedicated doctors check for all cases that obtained an insufficient quality score during the phase 1. This process is done online, *via* a web-based interface. The procedure is very flexible, giving the controller the tools and means to interact with the database. It also gives the possibility to return the case to the physician that submitted it, whether necessary.

The protocol of the Susy Safe project along with a model of the CRFand the instructions for completion of data collection forms are contained in the Susy Safe Manual, which is the source document and training guide.

DATA COLLECTION

Sixteen-thousand-eight-hundred-seventy-eight FB injuries occurred in children aged 0-14 years have been recorded in the SUSY SAFE databases; 8075 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	N
EU Countries	8803
Austria	273
Czech Republic	607
Belgium	5
Bulgaria	124
Cyprus	99
Denmark	70
Finland	421
France	122
Germany	33
Greece	88
Italy	5236
Poland	45
Romania	702
Slovak Republic	241
Slovenia	105
Spain	149
Sweden	236
Switzerland	51
the Netherlands	77
UK	119
Non EU Countries	*8075*
Argentina	2461
Croatia	19
FYROM	63
Pakistan	68
South Africa	5240
Turkey	224
Total	*16878*

The registry collected 1727 prospective cases and 15151 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, 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, and, although this percentage lowers down to 36% for retrospective cases, still this remains a very good achievement (Fig. **3**).

RESULTS

The children age distribution is shown in Table **2**: 55% of the cases are male, and about 38% of them are younger than three years. 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, oesophagus and stomach (ICD935). Almost one quarter 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, oesophageal 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. While FBs in the ears were more common in females, all other sites were more common for males than for females.

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 [7]. 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. **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. A comparative description of the observed volumes is provided in Fig. (**4**). 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 **3**.
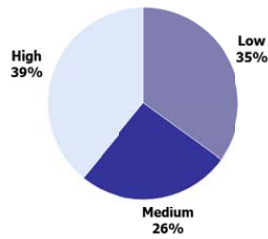
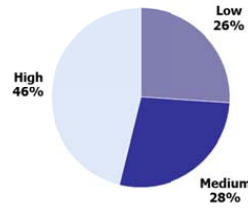**Fig. (3).** Distribution of cases according to their quality.

Table 2.   Age Distribution of Cases in Classes by Gender

	Female		Male		Total	
	N	**%**	**N**	**%**	**N**	**%**
< 1 year	229	5.5	261	5.3	490	5.3
1 - 2 years	1555	37.4	1632	32.9	3218	35.0
>= 3 years	2373	57.1	3074	61.9	5479	59.6
Total	4157	100.0	4967	100.0	9187	100.0

Fig. (4). Volume distribution (mm^3) for non-food objects. Figures provide an example of the volumes for three very common objects: a 5€cent coin, a small battery, a pearl chain.

Looking at the consequences of the injury, the Susy Safe registry adopted the DTI definition [8] 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. 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 hours whereas 248 required hospitalization more than 3 days.
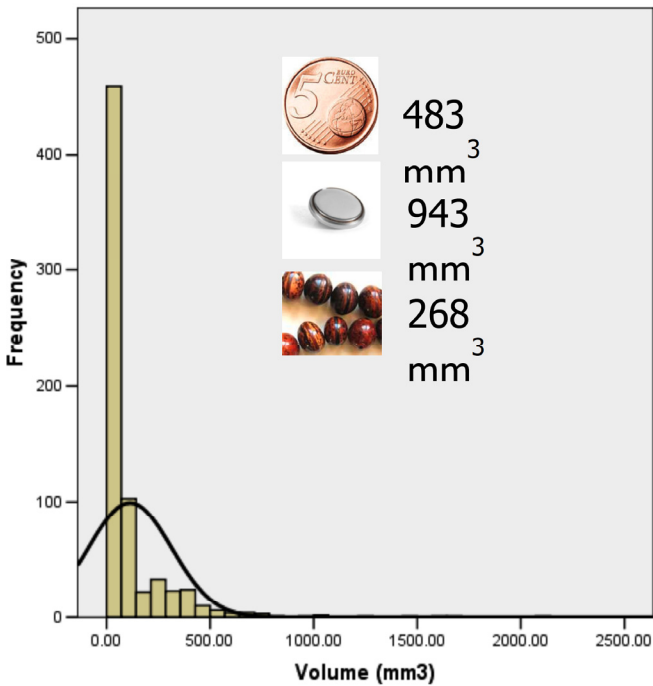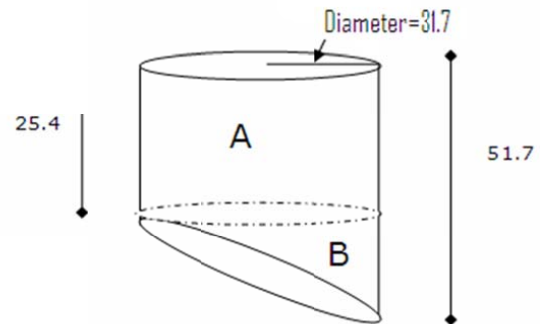

Fig. (5). Characteristics of the "small parts" cylinder (measures in mm).

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.

Complication distribution according to FB characteristics is shown in Tables **2** and **3**. 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.

Some injuries occurred for what is called the "unexpected usage" or "misuse" 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;

Table 3.   FB Ellipticity Stratified by Child Age (Numbers are Percentages)

	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
>= 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

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 inedible): stickers in crisps, toys in chocolate snacks, 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 [9] the Food Products Containing Inedible (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 [10-14] 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.

The Risk Engine

The aim of the risk engine is to provide a quantitative risk assessment for the identification of the features of the products that cause a foreign body injury. The goal is the construction of a model for the evaluation of the risks and harms associated to the characteristics of objects.

In general, probabilistic methods enable the characterization of uncertainty associated with the dimensions and the shape of the objects involved in the injuries. Using these methods the safety design of products can be assessed on a quantitative basis, furthermore allowing the evaluation of the risk associated to the characteristic of an object such as its volume, shape and consistency.

One of the most challenging aspects of applying any probabilistic methodology to this problem is the determination of the appropriate distribution of the actual features of the products. Furthermore one of the benefits of utilizing a probabilistic approach is that Bayesian statistical tools can be used to update probability distributions as soon as new data become available.

With regard to the substantive issue motivating the paper, available data come from official discharge records, thus any foreign body characteristics data represent a random sample from the detected injuries while self-resolved injuries are lost at observation. So that the risk engine provides a risk evaluation of the characteristics associated to the ICD931 to ICD935 which refer respectively to foreign bodies localized in the ears (ICD931), in the nose (ICD932), in the pharynx and larynx (ICD933), in the mouth, oesophagus and stomach (ICD934) and finally in the bronchi, trachea and lungs (ICD935).

The risk engine can be thought of as a table in which one could look up the contributions of item features to foreign body injuries stated in terms of probability.

The aim consists in modeling the joint distribution of volume, shape and consistency of foreign bodies which causes injuries. We assume that the probability distributions are conditionally independent. Thus the goal can be achieved through the conditional probability rule, by which:

$$P(V_1, V_2, V_3) = P(V_1 \mid V_2, V_3) \times P(V_2 \mid V_3) \times P(V_3) \qquad (1)$$

where V_1 indicates the volume of the *i*-th item, V_2 its shape and V_3 the consistency.

In order to learn from ESFBI data, a simple model was implemented. Categorical distributions were fitted about the shape and the consistency while volume measurements were fitted about a log-normal distribution since they are highly skewed to the right. Priors on parameter models were chosen as non-informative.

The WinBUGS software package can be used for Bayesian analysis of complex statistical models using MCMC technique. The program is given some consistent initial state and then it progresses sampling from each of the conditional distributions given the current values of all other variables. When this process is repeated, the distributions produced converge to the true marginal probability distributions.

Finally, sampling from the targeted densities allows us to produce summary statistics on conditional probabilities in equation (1).

Bayesian statistics provides a very plain approach to a "learning from experience" process which allows new data to be used in order to revise baseline probability distributions. Suppose to observe a new data point. The model can be updated through the classical Bayesian approach:

Posterior distribution $\propto$ likelihood $\times$ prior distribution

where the new prior distributions are now the posterior ones estimated on the old data.

The learning process is done by entering the observations and performing iterations of the sampling algorithm until convergence occurs. In fact Markov chain Monte Carlo methods can be used to produce an approximation to the target distribution. As the number of samples taken is increased this approximation converges.

Results show how the distributions of the characteristics of foreign bodies conditional on the place they were located differs. Since in the data available for the parameters estimation were absent three-dimensional objects like pen cap and two-circle objects like coin, from probability distributions 3D and 2D-circle shaped objects were not sampled. In particular it can be observe that the probability of extracting a spherical object or a two-dimensional object is the same for ICD933 (foreign bodies localized in the pharynx and larynx).

With regard to the volume, foreign bodies localized in the ears are the smallest objects, with a median equal to 55.35 mm^3, while foreign bodies localized in the bronchi, trachea and lung are the bigger objects with median equal to 1242 mm^3 and with a spherical shape.

DISCUSSION

Foreign body injuries are very common in children being still an important cause of childhood morbidity and mortality, in fact, through play, experimentation and daily activities, children are likely to place foreign bodies into their ears, nose or mouth. While the placement or presence of foreign bodies in the ear canal and their subsequent removal can be a source of significant morbidity but rarely constitutes a life-threatening event, the inhalation/aspiration of foreign bodies (FB) into the upper airways or in the aero-digestive tract can be a very serious event, sometimes resulting in fatal outcome [2, 3, 15-17].

Shared databases, conceived as supranational institutions could be able to identify at a local level which objects and products are dangerous for children, but also to guide the production and commercialization processes by means of a framework of actions aging at a national level as well as at international ones.

The central database makes the data to be easily accessible for a central review of quality and completeness using the online reporting system. The quality control monitoring was expanded to occur, as much as possible, in "real time".

Furthermore, as data become available, several statistical quality control procedures will be implemented.

The quality control activity is a sophisticated but necessary process in "Susy Safe" registry that ensures the homogeneity of the submitted data.

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ACKNOWLEDGEMENT

CONFLICT OF INTEREST

None declared.

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