

SURveillance SYstem on SuffocAtion injuries due to Foreign bodies in European children

Susy Safe Project Phase II: from Data to Consumers

Introduction

The Susy Safe Project, started in February 2005, was aimed at establishing a registry of cases of Foreign Bodies (FB) injuries in children aged 0-14 years. The final goal of the project was to provide the EU commission and the participating countries with a system able to implement quantitative risk estimates of the product causing the injuries, on the basis of the collected data.

The project ended in the first months of 2007. Seven-thousand-two-hundred-ninety-six injuries were registered in the database (which is now perhaps the biggest in the world with regards to such events). Additionally, an interactive WEB site has been set for the production of the risk estimates at product level (the so-called “Susy Safe Risk Engine”), and it has been made available to the DGSANCO and the participating countries representatives (www.susysafe.org).

General analyses on the cases collected have highlighted some major aspects:

1. the very high percentage of injuries that occur to very young children without the supervision of adults (about 75% as concerns non-food products)
2. a close connection between volume and shape of the object and characteristics of the child, particularly his/her age
3. a close connection between shape, volume and consistency of the objects and gravity of the injury, both in terms of complications and of days of hospitalization.

Objectives

With respect to the phase of the project that has just ended, two major aspects, that do need further analyses, form the basis for a request for a further financing, together with the need to continue the injury surveillance by means of a more complete data collection:

1. the need to use collected data for operative indications both in terms of design and use of non-food products.
2. the need to involve consumers both as playing an active role in collecting data (“*near-missing*” injuries, i.e. not referred to hospitals, since self-resolved) and as beneficiary of targeted educational and prevention programs

With respect to the first point, the projects is aimed at:

1. defining a shared protocol among participating countries, aimed at using and interpreting evidence, as it emerge from statistical analyses and from the “risk engine” estimate, to product indications and guide-lines to promote safety both in terms of design and better use of the products.

2. determining, by means of a detailed case and risk estimate analysis, the risk heterogeneity among participating countries, with respect to product characteristics and inadequate behaviour of both children and adults.

With respect to the second point, the involvement of the consumers in the Susy Safe project has been limited to the setup within the Susy Safe web site of some basic tools for collecting data directly from the consumers. The main goal of the second phase of the Susy Safe is thus to focus the attention on the consumers:

1. Establishing a self reporting system of injuries, WEB based, in a way that the consumer will be able to report injuries timely as they occur
2. Estimating, both using the self-reporting system above and setting up some web-based survey systems, the number of injuries which are at the time being not known, as they are not referred to the hospital or not entering the official data collection systems. Such injuries are mostly self-resolved cases, and no data, beside some pilot studies, have been produced so far on this subject.
3. Setting up a EU-wide, web based system for the production of the information about the FB injuries. This implies the construction of a web portal, containing information both on the medical aspects, like on the first emergency care in case of injuries, and on the general information on the initiatives taken from DGs in EU and in each participating countries to foster the consumer safety in this field, like the recall of specific products or the production of some regulatory acts. A specific part of this portal will be devoted to the setup of a system for communicating the basic risk estimates of the “Susy Safe Risk Engine” to the general public, in a way to provide unbiased and conscious information.

Obviously, the third goal of the Susy Safe Project – Phase II is to foster the data collection in hospitals and emergency care systems in EU, with the aim of improving the number of cases in the database and the geographical coverage of the Susy Safe Registry

Relationship of the Project with the General Product Safety Directive

Consumer policy strategy (CPS) 2002-06 is based on (2.2.2. 3rd Comma) a “knowledge-based” action, on information and data on both consumers and the market. This would be based on “internet based mechanisms” to make things effective.

A detailed knowledge of each aspect of FB injury will have the following feedbacks in terms of the CPS:

1. object identification: a detailed definition of the object causing suffocation will help in promoting rules on safer product design;
2. risk analysis based on actual data, detailed in terms of geographical distribution, characteristics of the FB and of the child and his/her family will help in promoting knowledge-based initiatives aimed at strengthening the safety of non-food product consumption; involvement of the consumer in the data collection activity will increase the scientific quality of the data and the overall consumer’s awareness of the FB injury issue;
3. identify higher risk population groups, to be targeted with specific educational and prevention programs;

4. contributing to the process of lowering disparities in access to the EU market by people with inadequate self-protection with respect to potential injuries.

Project description

Duration of the project is two years.

The project is organized in 6 Work packages:

1. Establishing a discussion floor among participating countries in order to create a protocol to make use of evidence and to produce indications on the product safety. In practice, the definition of the risk communication mechanism has to be part of the protocol, as it emerges from the Susy Safe risk evaluation system, among the different official bodies of the participating countries and the participating countries themselves, in order to promote a knowledge-based action.
2. Establishing a self-reporting system of injuries for consumers. The “Susy Safe Injury Reporting System” will be tuned and tested. The system will be translated in the languages of all participating countries.
3. Survey system setup. The statistical engine and the web interface will be implemented, for the purposes of providing an estimate of the unknown number of injuries in EU.
4. Susy Safe portal. The information for the Susy Safe Portal will be collected and included in the web system. Clinical data management and risk information will be included in the portal.
5. Susy Safe project dissemination among consumer. Ties with EU-level and country-level consumer associations will be established, to disseminate the project and to promote the contribution of consumers to the injury reporting system.
6. Enlarging the Susy Safe registry. Active spreading of the project among potential hospital or clinics in each country to push the data collection of cases who reached the hospital.

Work Packages Details

WP1 – Development of a protocol for using Susy Safe evidence for market regulatory purposes

The Susy Safe Registry is a valuable source of information for assessing the risk of products already in the market which are thus expected to complain with the EU regulatory requirements. Nevertheless, the need of understanding additional risks, as emerging from the actual use of these products is still a priority. Information like those coming out from the Susy Safe Registry must be analyzed and interpreted to shift the information from a pure scientific setting to a regulatory perspective. To meet this goal, the following steps will be adopted:

1. establishing a technical consensus among participating countries. This consensus should elaborate on the guidelines regarding the aspects to be considered for regulatory purposes and alerting

2. publishing a yearly technical report on the evidences coming out from the Susy Safe Risk engine and following the consensus guidelines, to be made available to the DGSANCO for discussion

WP2 – Self Reporting System of injuries at consumers’ level

A WEB-based system will be implemented to allow the collection on data as spontaneously reported from the consumers. The consumer will be asked to report on an injury regarding his/her child, actually happened under his/her control. Details will be collected on (i) characteristics of the child, (ii) characteristics of the FB, (iii) details on adult supervision and on the general knowledge about FB injury safety measures and (iv) finally on the circumstances of the accident and its consequences. Additional details, like pictures of the FB, details on the Medical Doctor in charge of the case (if any), and availability for being recalled will be asked. Some questions will be also dedicated, for statistical purposes, at collecting data on general characteristics of the respondent (not necessarily related with the injury), to allow the estimation of the propensity score function, useful for making inference on the data collected. Following the procedures successfully adopted in the Susy Safe Phase I, the data collection report form will be decided after having established a consensus among participating members. The survey will be translated and validated in all languages of the participating countries.

WP3 – Survey System

As pointed out in recent scientific work, there are several difficulties in providing a reasonable (from a statistical point of view) estimation of the overall figures related to FB injuries, when both the hospitalized and not hospitalized injuries are considered. Indeed, the number of the so-called self-resolved injuries, i.e. those injuries that, for the immediate reaction of the adult supervisor, the spontaneous action of the child or any other possible mechanism, are not referred to the Health Care System, is still unknown. To open this black box, several approaches have been proposed, all based on various formats of WEB surveys. In this WP a specific survey will be implemented, aimed exactly at the estimation of the “hidden” part of the phenomenon. Clearly, all survey results in such difficult setting, are conditioned from the accuracy of the questions posed to the consumer. In this sense a deep involvement of all project partners is foreseen at the stage of survey design, to assure that the survey will be homogeneous among countries and to foster the comparability of results.

WP4 – Susy Safe Portal

As emerged from the Susy Safe Phase I, in spite of the great activity promoted both at EU level and by member states in advising the consumers about the risk of choking due to non food objects, an impressive portion of the injuries is actually happening under the supervision of adults. This is a clear indication that additional, further activities should be implemented to foster consumers’ knowledge about this issue.

This work package is addressing this issue in two directions:

1. creating a unified web portal, available in all languages of the participating bodies, where detailed information can be found on: *(i)* which objects should receive particular attention when given in hand of a child, *(ii)* which is the best intervention strategy to intervene if an accident occur, *(iii)* a list of reference centers in each country for treating FBs, *(iv)* additional material and information useful for increasing awareness of consumers. This information will use all kind of information sources, with a strict preference with those coming from the Susy Safe Registry.
2. creating an information package, containing material aimed for implementing school or pre-school educational campaigns, made available to the public in the web portal.

WP5 – Project dissemination

The link with the consumers associations is a crucial step in increasing awareness of the issue and in stimulation proper behaviors among consumers. In this sense, a series of links with the consumers associations, both at EU level and at national level will be promoted in view of a proper usage, for safety improvement, of the information coming out from the Susy Safe Registry. In particular, this will end-up in two main activities:

1. a joint workshop with consumers associations and public bodies to activate a common path and an active cooperation on the issue of safe product usage and design with respect to FB injuries risks
2. a newsletter, aimed at being circulated among the consumers' associations' members

WP 6 – Enlarging the Susy Safe Registry

The data already collected in the Susy Safe Registry a representing a valuable and perhaps unique source of information, both from the qualitative and at the quantitative point of view. Nevertheless, the Registry must continue its activity of cases registration, to ensure timely information as soon as new treats are appearing to emerge. This activity will consist in two main steps:

1. improve the data collection form including a set of fields on the FB treatment and more details on the FB location, as suggested by some of the participating centers
2. enlarge the data collection involving new centers in as many countries as possible, through the dissemination of information about the project at specialized scientific meetings and through scientific publications

Participants

The project will involve the participation of the countries actually being partners of the Susy Safe Registry, which is now collecting data in 16 countries, out of which 4 were also formal participating partners to the project. Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, Poland, Romania, Slovak Republic, Slovenia, Spain, Sweden, the Netherlands, UK. We thus shall expect an active involvement in the project of some of these countries.

Expected results and benefits

The creation of fixed informative paths that connect the evidence production phase (data collection and quantitative risk analysis) to the indication and action production in order to promote safety is of paramount importance. The use of evidence in the safety promotion field is an essential way to define the intervention priorities as well as to identify the unexpected risk areas, to be provided with indications both in terms of products and, above all, of targeted educational tools. From this perspective, the involvement of consumers in the market surveillance activities has both the advantage of allowing a data collection on aspects usually not available to the policy maker and to promote the participation and the attention of the citizens to the aspects related to injuries and product safety. Taking into account, as resulting clearly from the data of the Susy Safe registry, that most injuries occur under the supervision of adults, the involvement of consumers is also a big educational step toward a safer fruition of the products.