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The TESS Database

Use in Product Safety Assessment

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Summary

The Toxic Exposure Surveillance System or TESS is a comprehensive poisoning surveillance database maintained by the American Association of Poison Control Centers. It now includes data on more than 20.3 million human poison exposures reported to US poison centres. TESS data are submitted by 67 of the 75 US poison control centres, covering 87% of the US population. Reports to US poison centres included in TESS originate both from the general public and from health professionals (12.9%) and include both patients managed at home or at the site of the exposure (73.6%) and those managed in hospitals, emergency departments, or other healthcare facilities (22.8%).

TESS data are used by the pharmaceutical industry to monitor or defend product safety, by regulatory agencies proposing new regulations or considering new approvals or over-the-counter switches, and by clinical researchers attempting to characterise toxicity profiles or determine treatment protocols. TESS is a key component of an effective post-marketing surveillance programme, allowing early identification of previously unsuspected hazards, and early changes in formulations, labelling, or packaging when needed, thereby minimising injuries, deaths and product liability. Deaths, severe outcomes and comparisons of poisoning outcomes and hospitalisation rates between products or product categories are used to identify safety outliers.

TESS data for each case of poisoning include identification of the substances implicated (including brand and formulation where known), patient age, outcome, specific clinical effects, exposure route, reason for the exposure (unintentional, suicidal, therapeutic error, etc.), antidotes used and the level of healthcare intervention utilised. Pharmaceuticals are implicated in 42% of TESS poisoning cases. About 53% of all cases of poisoning occur in children under 6 years of age. Of the more than 2.1 million cases reported to TESS in 1996, 123 095 (5.7%) were therapeutic errors and 32 866 (1.5%) were adverse reactions to pharmaceuticals.

TESS is an essential but under-utilised resource for product-specific toxicity and safety data. Use of TESS data to identify hazards, followed by remedial action to reformulate, repackage, re-label, or recall, will protect patients and consumers from needless hazards, and prevent unnecessary product-related morbidity and mortality.

1. What is TESS?

TESS is the American Association of Poison Control Centers (AAPCC) Toxic Exposure Surveillance System. It is the only comprehensive poisoning surveillance database in the US, containing reports of both hospitalised poisonings and cases not requiring treatment in a healthcare facility, and both fatal and nonfatal poison exposures. Developed in 1983, TESS contains detailed clinical information on more than 20.3 million poison exposures reported to US poison centres. That includes more than 2.1 million reports to poison centres for 1996 alone, an estimated 87% of all poison exposures reported to poison centres in the US in that year.[1]

2. The Top 5 Uses of TESS

TESS data are regularly used by the pharmaceutical industry, regulatory agencies, clinical researchers, attorneys and the media.

2.1 Post Marketing Surveillance

TESS data can be used to identify problems with newly-approved or newly-marketed products. Early detection of problems can lead to changes in formulations, warnings, or packaging to limit product-related injuries. In addition, careful scrutiny of the toxicity profile of the first few hundred significant poisonings provides highly useful data for clinicians managing patients poisoned with a new drug or product, suggesting clinical effects which should be anticipated, treatments which are effective and treatment protocols based on exposure dose. Post marketing surveillance may be either voluntary, initiated by the pharmaceutical industry or may be mandated by regulatory agencies.

2.2 Routine Review to Prevent Poisonings and Limit Morbidity and Mortality

Routine analysis of safety data before deaths and serious injuries are identified allows the pharmaceutical industry to minimise the risk of product liability suits and regulatory action and maximise consumer safety. Detailed analysis may demonstrate, for example, a high rate of therapeutic errors or product misuse. Further investigation may reveal a misleading label, dispensing cup/spoon/dropper confusion, or misguided consumer assumptions. Similarly, excessive paediatric poisonings may be caused by a package which mimics a food container, by a package design which is unusually attractive to children, or by the use of a scent or flavouring agent in the product. Furthermore, TESS data can point to the exposure route which is implicated in cases with more severe outcomes, showing, for example, a problem with ocular exposures which may exceed the ingestion hazard.

2.3 Comparison of Brands with Product Categories

Individual brands can be compared with product categories or groups of products with similar formulations, concentrations, or packaging. These comparisons facilitate detection of safety outliers. Hazards are suspected when products with similar uses have significantly different clinical outcome distributions or extent of utilisation of healthcare facility-based intervention. Mere exposure counts cannot be used to assess toxicity as they often serve only as a reflection of market share and accessibility rather than inherent product toxicity.

2.4 Demonstrating Product Safety to Regulatory Agencies or Consumer Groups, or Fulfilling Regulatory Requirements

Pharmaceutical manufacturers routinely provide TESS data to the US Food and Drug Administration (FDA) when seeking a switch from prescription to over-the-counter status, to support a new drug application using data from products with similar structure or delivery vehicles, or to satisfy post marketing surveillance requirements implemented with new drug approvals. Similarly, pesticide manufacturers provide TESS data to the US Environmental Protection Agency (EPA) when seeking to re-register pesticides or in response to agency data call-ins. TESS data have been used to refute or support public allegations of safety haz-

ards posed by unusual packaging and to challenge or defend claims that product warning labels are inadequate in product liability lawsuits.

2.5 Limiting Animal Testing

Human poisoning data can occasionally provide a useful alternative to animal testing. TESS data for ocular, dermal, or ingestion exposures to products containing the questioned ingredient may confirm safety or provide evidence of harmful effects, obviating the need for animal studies.

3. History of TESS

TESS emerged from the deficiencies of the former US National Clearinghouse for Poison Control Centers (NCPCC). The NCPCC, created in 1957, just 4 years after the first US poison centre was established in 1953, was the coordinating agency for the flow of information to and from poison centres. But the NCPCC had neither regulatory authority over, or funding for, poison centres, thus participation in its data collection programme was voluntary and erratic and data compilations experienced lengthy delays. With the proliferation of US poison centres from 17 in 1957 to 661 by 1978, the limitations of the existing poison control system became apparent. Fuelled by the Emergency Medical Services Systems Act of 1973, efforts intensified in the late 1970s to develop consolidated, larger, high-quality regional centres with greater specialised expertise, commitment and focus.[2]

The newly-formed large regional poison centres immediately recognised the inadequacies of data collection on the NCPCC's small reporting cards. A comprehensive medical record was required along with more timely information and the ability to analyse local data. The regional centres began to develop autonomous data collection systems, with no uniformity of format or field definitions. While each of these regional centres collected data on 20 000 to 70 000 poison exposures per year, the data reported to the NCPCC contained only 150 000 cases reported nationally, predominantly from smaller, nonregional centres.

Design of a new AAPCC National Data Collection System (later renamed TESS) began with the development of a uniform data set and standard definitions in the early 1980s. In 1982 the US FDA offered a one year fellowship to the chair of AAPCC's Data Collection Committee to organise, pilot and implement a functional system, developing the necessary software, instructions, generic classification scheme and uniform reporting forms. A 2-month pilot test was conducted in January and February of 1983 in 9 regional centres, leading to system refinements and national implementation in 1984. The new AAPCC system was widely embraced by poison centres and the NCPCC closed in 1985.

TESS participation continued to expand over the next decade (table I), and by 1996, 67 of 75 US poison centres were reporting poison exposure data to TESS. Nonparticipation by poison centres covering 13% of the US population is a reflection of inadequate local funding for poison control services.

4. How are TESS Data Collected?

The vast majority of TESS reports are generated by specialists in poison information at the time

Table I. Growth of the Toxic Exposure Surveillance System (TESS)[1]

Year	No of participating centres	Population served (millions)	Human exposures reported
1983	16	43.1	251 012
1984	47	99.8	730 224
1985	56	113.6	900 513
1986	57	132.1	1 098 894
1987	63	137.5	1 166 940
1988	64	155.7	1 368 748
1989	70	182.4	1 581 540
1990	72	191.7	1 713 462
1991	73	200.7	1 837 939
1992	68	196.7	1 864 188
1993	64	181.3	1 751 476
1994	65	215.9	1 926 438
1995	67	218.5	2,023,089
1996	67	232.3	2 155 952
Total			**20 370 415**

they provide telephone consultations for poisoning emergencies. Poison exposures are reported both by the general public and health professionals. Telephone follow-up is conducted whenever possible on exposures that have the potential for producing significant toxicity. In addition, about 52% of nontoxic and minimally toxic exposures are followed until a final definitive outcome can be ascertained (resolution of any clinical effects and/or progression beyond the time point at which clinical effects could develop).

About half of poison centres participating in TESS enter data on a standardised AAPCC report form containing detachable (perforated) medical and data records. The data portion of the record is completed with a high-carbon marker, separated from the medical record, then scanned through an optical scanner which is programmed to edit for information consistency and data completeness. Scanned data are submitted to TESS 2 to 4 times each year. Error checking occurs again when data are uploaded to TESS, and cases are rejected for later re-submission if they fail to pass logic, accuracy and completeness checks. Medical records are retained by each participating poison centre.

The other half of poison centres participating in TESS enter data using one of several computerised data collection programmes that produce standardised, TESS-compatible outputs. Most of these centres enter data as cases are handled, although a few enter data hours to weeks later. Data from these systems are submitted to TESS and must pass a second set of error checks when uploaded to TESS. An increasing number of centres are switching from reporting on AAPCC forms to computerised data entry.

5. What Information is Available?

Table II lists the extensive data captured for each TESS poison exposure report. TESS users generally focus on patient age, substance, route of exposure, reason for the exposure, outcome, patient disposition and clinical effects. In the majority of cases, the substance implicated is coded to brand and formulation. Where this detail is unavailable, a generic category classification scheme is used instead. Additional information is published annually for fatalities, including the highest recorded blood concentration of the implicated toxic substance, the time post exposure the specimen was drawn (where known), and abstracts of about 8 to 10% of fatalities that are selected based on anticipated interest to clinical toxicologists are also provided.

The following information cannot be obtained from the TESS database:

(1) Narrative descriptions of cases or case abstracts. Instead a case log provides case details including report date, patient age, gender, exposure reason, route, substances implicated, outcome and a list of clinical effects with an indication of whether these effects were related. Additional data beyond the standard TESS data set can only be obtained at additional expense by retrieving the original poison centre medical record for selected, unusual cases, such as those with severe outcomes.

(2) Patient identifiers (name, birth date, address).

(3) Socioeconomic data (patient race, religion, income level).

(4) Amount/dose data for substances implicated in each exposure.

6. Examples of TESS Data Uses by the Pharmaceutical Industry, Regulatory Agencies and Researchers

Many pharmaceutical companies routinely assess the relative safety of their products by reviewing the distribution of TESS outcomes. For example, table III shows the outcomes for poisonings from various antidepressants and demonstrates the relatively higher case fatality rate for desipramine. This same type of comparison can be made using TESS data for individual products. Table IV shows the distribution of outcomes for 'pure' calcium antagonists ingestions (i.e. exposures where no other substances were ingested). Calcium antagonists, ingested alone, have a 10-fold greater fatality rate compared to the database overall (0.327% compared to 0.034%). Furthermore, Table V shows an

Table II. Data captured for each Toxic Exposure Surveillance System (TESS) exposure case

Fields	Coding options	Observations from 1996 TESS data
Site of caller	Own residence, other residence, workplace, healthcare facility, school, restaurant, public area, other, unknown	12.9% of calls originated in healthcare facilities; additional patients were referred in by the poison centres
Site of exposure	See 'Site of Caller'	87.6% of exposures occurred in the patient's own residence
Age of patient	*Actual age* coded in days, months or years, or *age ranges* (≤5 yrs, 6-12 yrs, 13-19 yrs, 20s, 30s, etc.), or *unknown child* (≤19 yrs), or *unknown adult* (>19 yrs), or *unknown age*	Children under 6 years comprised 52.8 of cases, but just 4.0% of fatalities; 60.6% of deaths occurred in 20- to 49-year-old patients
Gender	Male, female, pregnant female, unknown	More males were implicated in cases occurring in children under 13 years of age; a female predominance was noted in older patients
Pregnancy duration	Reported in weeks	7103 pregnant women with poison exposures were reported
Exposure duration	Acute, acute-on-chronic, chronic (repeated or continuing exposure over more than 8 hours), unknown	93.7% of poison exposures were acute
Reason	*Unintentional:* general, environmental, occupational, therapeutic error, misuse, bite/sting, food poisoning, unknown *Intentional:* suspected suicide, misuse, abuse, unknown *Other*: contaminant/tampering, malicious *Adverse reaction*: drug, food, other *Unknown reason*	Most cases were unintentional (85.7%); 123 095 therapeutic errors and 32 866 adverse reactions to pharmaceuticals were reported
Route(s) of exposure	Ingestion, inhalation/nasal, aspiration, ocular, dermal, bite/sting, parenteral, other, unknown	Multiple routes may be applicable for an individual case; 74.0% of exposure routes were ingestions
Substance(s)	Coded to brand and formulation if known; coded by generic or category if brand unknown; up to 2 substances coded per case	42% of substances were pharmaceuticals
Number of substances involved	Only 2 substances are actually coded for each case; exposure to additional substances is indicated through a count of the total number of substances (1 to 8, or ≥9)	7.2% of cases had exposures to >1 substance
Management site	*Managed on site (non-healthcare facility)* *Patient already in (enroute to) healthcare facility when poison centre called* Treated/evaluated and released Admitted to critical care unit Admitted to noncritical care unit Admitted to psychiatric facility Patient lost to follow-up/left against medical advice *Patient referred by poison centre to a healthcare facility* Treated/evaluated and released Admitted to critical care unit Admitted to noncritical care unit Admitted to psychiatric facility Patient refused referral Patient lost to follow-up/left against medical advice *Other* *Unknown*[a]	73.6% of cases reported to a poison centre were managed without treatment in, or referral to, a healthcare facility.
No therapy	No therapy provided Observation only Patient refused any help Unknown if therapy provided	If none of these options are selected, then specific interventions are coded (see 'Decontamination' and 'Other therapies')

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Table II. continued

Fields	Coding options	Observations from 1996 TESSdData
Decontamination	Ipecac; charcoal, single dose; charcoal, multiple doses; lavage; cathartic; whole bowel irrigation; other emetic; dilute/irrigate/wash; fresh air; food/snack	Multiple decontamination options may be coded for an individual case
Other therapies	Alkalinisation; amyl nitrite; antiarrhythmic; anticonvulsants; antihistamines; antihypertensives; antivenin/antitoxin; atropine; BAL; bronchodilators; calcium; cardioversion; CPR; deferoxamine; ECMO; EDTA; ethanol; extracorporeal procedure (other); Fab fragments; IV fluids; flumazenil; folic acid; glucagon; glucose, >5%; hemodialysis; haemoperfusion; hydroxocobalamin; hyperbaric oxygen; intubation; methylene blue (methylthioninium chloride); IV *N*-acetylcysteine; oral *N*-acetylcysteine; naloxone; neuromuscular blocker; oxygen; 2-PAM; penicillamine; physostigmine; phytomenadione (vitamin K_1); pyridoxine; sodium nitrite; sodium thiosulfate; succimer; transplantation; vasopressors; ventilator; other	Multiple specific therapies may be coded for an individual case
Medical outcome	No effect Minor effect Moderate effect Major effect Death Not followed, judged as nontoxic exposure (clinical effects not expected) Not followed, minimal clinical effects possible Unable to follow, potentially toxic exposure Unrelated effect Confirmed non exposure (these cases are excluded from TESS)	726 deaths verified as related to the poison exposure were reported in 1996
Duration of clinical effect(s)	For minor, moderate, or major outcomes, one of the following is selected to indicate the duration of the clinical effect(s): ≤2 hours; >2 hours and ≤8 hours; >8 hours and ≤24 hours; >24 hours and ≤3 days; >3 days and ≤1 week; >1 week and ≤1 month; >1 month; anticipated permanent; or unknown	
Clinical effects	**Cardiovascular** (bradycardia; cardiac arrest; chest pain; conduction disturbance; dysrhythmia, other; dysrhythmia – ventricular tachycardia, ventricular fibrillation; hypotension; hypertension; tachycardia)	Each clinical effect which is observed is also coded as related to the exposure, unrelated to the exposure, or unknown if related to the exposure
	Dermal (bullae, burns, superficial; burns 2° or 3°; cellulitis; ecchymosis; oedema; erythema/flushed; hives/welts; irritation/pain; necrosis; pallor; pruritus; puncture wound/sting; rash)	
	Gastrointestinal (abdominal pain; anorexia; constipation; dehydration; diarrhoea; dysphagia; oesophageal injury; oesophageal stricture; faecal incontinence; haematemesis; melena; nausea; oral burns; oral irritation; throat irritation; vomiting)	
	Haematological/hepatic (AST and/or ALT>100 and ≤1000; AST and/or ALT >1000; increased bilirubin; cytopenia; disseminated intravascular coagulation; haemolysis; prothrombin time prolonged; other coagulopathy; other liver function test abnormality)	

Table II. contd

Fields	Coding options	Observations from 1996 TESS Data
	Neurological (agitation/irritable; ataxia; coma; confusion; CVA; dizziness/vertigo; drowsiness/lethargy; dystonia; fasciculations; hallucinations/delusions; headache; intracranial bleed; muscle rigidity; muscle weakness; paralysis; peripheral neuropathy; seizure, single; seizures, multiple/discrete; seizures, status; slurred speech; syncope; tinnitus; tremor)	
	Ocular (blurred vision; burns; corneal abrasion; irritation/pain; lacrimation; miosis; mydriasis; nystagmus; pupil(s) nonreactive; papilledema; visual defect)	
	Renal/genitourinary (increased creatinine levels; haematuria; haemo/myoglobinuria; oliguria/anuria; polyuria; renal failure; urinary incontinence; urinary retention)	
	Respiratory (bronchospasm; cough/choke; cyanosis; dyspnoea; hyperventilation/tachypoena; pneumonitis; pulmonary oedema; respiratory arrest; respiratory depression; x-ray findings)	
	Miscellaneous (acidosis; adverse reaction to treatment; alkalosis; anion gap increase; bleeding, other; deafness; diaphoresis; electrolyte abnormality; excess secretions; fever/hyperthermia; hyperglycaemia; hypothermia; multiple chemical sensitivities; osmolal gap increased; pain; rhabdomyolysis)	
Date and time case reported	Date and time of report, not of exposure	

a Only the highest level of intervention is coded, for example a patient admitted to an intensive care unit who recovers and is transferred to a psychiatric service is coded as admitted to critical care unit.

Abbreviations: 2-PAM = pralidoxime; BAL = bronchoalveolar lavage; CPR = cardiopulmonary resuscitation; CVA = cerebral vascular accidents; ECMO = extra-corporeal membrane oxygenation; EDTA = ethylene diamine tetra-acetic acid.

unusually high rate of therapeutic errors (40% of cases), with calcium antagonists although the outcome for these was somewhat less severe than for suicidal cases.

TESS data have provided the sentinel case or first stimulus for a number of regulatory actions. For example, TESS paediatric fatality data for 1983 through 1990 showed that 10% of paediatric unintentional ingestion fatalities were attributed to iron, increasing to 11 of 44 paediatric poisoning deaths reported to TESS in 1991. Based on these and other substantiating data, the US FDA issued regulations in January 1997, requiring a labelled warning and individual dose packaging for products containing 30mg iron or more per dosage unit. In the process of considering and developing these regulations, FDA reviewed TESS data comparing the relative safety of various iron formulations and, based on TESS data and animal studies, provided a temporary exemption for products containing carbonyl iron, pending review of additional safety data.[3]

TESS data are often used by the pharmaceutical industry and regulators to support regulatory actions to protect the public health. The US Consumer Product Safety Commission used TESS data to support requirements for child-resistant closures on ethanol mouthwashes and topical preparations of dibucaine and lidocaine (lignocaine).

TESS data have also been used to support prescription to over-the-counter switches, as has occurred with various NSAIDs, H_2-blockers and nicotine transdermal patches. For each of these medications, TESS data were helpful in demonstrating a

Table III. Outcome distribution for selected antidepressants (from Toxic Exposure Surveillance System data received in 1996)[a]

Antidepressant	Number of exposures	Moderate effect (%)	Major effect (%)	Death (%)
Amitriptyline	8255	23.99	10.59	0.65
Desipramine	822	17.88	5.84	1.58
Doxepin	2544	22.48	10.38	0.28
Imipramine	3115	15.06	5.01	0.48
Lithium	5102	18.33	2.76	0.20
MAO inhibitors	451	23.28	6.43	0.67
Nortriptyline	2004	17.96	6.24	0.55
Trazodone	8520	11.43	1.57	0.12
Newer antidepressants (mostly SSRIs)	28 156	9.00	1.33	0.05

a The data above include cases with co-ingestants. Data limited to cases without co-ingestants would provide a more accurate assessment of inherent product toxicity, but less of an appreciation for the total number of cases implicated.

Abbreviations: MAO = monoamine oxidase; SSRIs = selective serotonin reuptake inhibitors.

reasonable safety profile following paediatric unintentional overdose.

Regulators may require, or manufacturers may voluntarily use, TESS data for post marketing surveillance. By monitoring newly introduced pharmaceuticals, new formulations, or new packaging, TESS serves as an early warning system for product problems. In addition, as new pharmaceuticals are introduced, emergency physicians and intensive care specialists manage overdoses with these products with very limited information. TESS offers a mechanism for rapidly amassing clinical overdose data, facilitating characterisation of the clinical manifestations, appropriate diagnostic options, and effective therapeutic interventions. Gathering this information quickly may be lifesaving to future patients.

7. TESS Quality Control

Quality control and improvement of TESS occurs at many levels. Initial training of specialists in poison information includes review of the AAPCC coding manual and coding workbook. Internal centre audits and chart reviews are used to maintain coding quality but are dependent on the individual centre's commitment to submitting quality data. Both the optical scanner and online computer data entry systems have computerised data checks and edits, rejecting cases with errors from the scanner, or forcing correction before closing or submitting

Table IV. Outcome for 5500 'pure' calcium anatgonist ingestions, from Toxic Exposure Surveillance System (TESS) data received in1996 (cases with concomitant exposure to another drug/substance are excluded)

	Calcium antagonists		All TESS cases
Outcome	Number	%	%
No effect	2409	43.80	24.0
Minor effect	484	8.80	18.8
Moderate effect	359	6.53	4.0
Major effect	72	1.31	0.4
Death	18	0.33	0.0[a]
No follow-up, nontoxic exposure	416	7.56	18.3
No follow-up, minimal toxicity anticipated	1259	22.89	26.8
No follow-up, potentially toxic exposure	369	6.71	4.2
Unrelated effect	114	2.07	3.3

a The actual overall fatality rate is 0.034%.

Table V. Reason by outcome for calcium antagonist exposures using data collected from the Toxic Exposure Surveillance System (TESS) (selected reasons listed to conserve space)

	Unintentional general	Therapeutic error	Suspected suicidal	Adverse drug reaction
No effect	1385	807	150	2
Minor effect	129	212	76	27
Moderate effect	67	94	154	19
Major effect	4	10	55	2
Death	1	2	15	0
No follow-up, nontoxic exposure	160	222	8	4
No follow-up, minimal toxicity anticipated	315	726	30	58
No follow-up, potentially toxic exposure	118	92	108	14
Unrelated effect	21	41	20	18
Total	**2200**	**2206**	**616**	**144**

a case in an on-line system. Furthermore, data uploaded to the national TESS database must meet error checks, and cases with errors are returned to the centres for correction and re-submission.

Data quality factors are calculated for each participating centre annually based on submission of data which are invalid, missing or have excessive use of 'unknown' coding options. Centres naturally strive to achieve high quality factors and some competitiveness between centres has developed for the recognition of high data quality. Minimal quality factor levels are required both for poison centre certification and for participation in TESS.

AAPCC conducts quality audits, approximately every 2 years, comparing poison centre medical records with computerised data to identify systematic errors, areas where definitions are unclear or misinterpreted and areas where individual centres need additional staff training or monitoring.

Special efforts are focused on the verification of fatalities. Each fatality is abstracted by the participating poison centre, reviewed by that poison centre's medical director and submitted to AAPCC with an assessment of whether the poison exposure was responsible for the fatality along with the appropriate coding for the case. At AAPCC, 2 additional medical toxicologists review each fatality report and query the centre about apparent clinical or data inconsistencies. Each fatality in the TESS database is then re-coded, if necessary, to reflect the final assessment of the case.

8. Caveats: What Not to Determine from TESS

TESS reports are labelled 'poison exposures' rather than 'poisonings' as many cases logged in this database never develop clinical effects as a result of the exposure. The absence of clinical effects may result from:

- prompt treatment intervention or decontamination, as guided by the poison centre,
- limited toxicity of the substance involved in the exposure,
- limited amounts/concentrations of substances implicated in the exposure, or
- the exposure was suspected but may not have actually occurred.

It should be noted that cases originally reported as an exposure, but later confirmed not to have occurred (for example, pills were later found), are *not* included in compiled TESS data.

TESS data also suffer the limitations of telephone reporting. Often final case coding occurs without access to comprehensive hospital or medical records or complete laboratory results. Furthermore, many cases in the TESS database never have laboratory confirmation of the exposure.

TESS is a passive reporting system. Cases are reported by concerned parents and patients or by health professionals seeking advice in the management of a poisoning emergency. Healthcare providers would be expected to seek assistance more frequently for cases which are complex, unusual,

Table VI. Standard data tables in each Toxic Exposure Surveillance System (TESS) report: frequency distributions or cross-tabulations

Exposure duration (acute, acute-on-chronic, chronic)
Reason
Exposure site
Exposure to multiple substances
Route of exposure
Distribution of clinical effects
Management site
Use of decontamination and therapeutic intervention
Decontamination
Other therapies
Medical outcome
Duration of clinical effects by medical outcome
Age by gender
Reason by age categories (adults lumped)
Reason by age categories (adults in decades)
Reason by gender
Clinical effects by age
Clinical effects by reason
Medical outcome by intentional versus unintentional
Medical outcome by specific reasons
Medical outcome by management site
Reason by exposure chronicity
Management site by age
Treatment by management site
Decontamination by management site
Outcome by age categories (adults lumped)
Outcome by age categories (adults in decades)
Generic codes by category by age
Generic codes by category by reason
Generic codes by category by medical outcome
Generic codes by category by management site
Log of individual cases by medical outcome
Medical outcome by route of exposure

difficult to manage, serious, protracted or require ingredient or toxicity information. As a result, poison centre data would be expected to under-represent cases with pre-hospital cardiac or respiratory arrests, deaths occurring at home, deaths not suspected as related to a poisoning until the autopsy is performed, and cases which emergency physicians manage frequently [alcohol (ethanol) intoxication, carbon monoxide toxicity, drug abuse cases, etc]. The under-reporting of adult suicides and adult poisoning fatalities in TESS has been previously documented.[4,5] In contrast, TESS captures paediatric poisoning deaths with much greater reliability.[6]

A simple count of TESS exposures to a given product does not suggest the presence of a poisoning hazard unless exposure counts are out of proportion to market share. Exposure frequency often indicates only ready accessibility, which, if related only to a high market share and not to inadequate packaging, is unlikely to be controlled. More appropriately, the disproportionate occurrence of severe outcomes (moderate effects, major effects and/or deaths) or excessive hospitalisations should prompt further investigation into the safety of a product. To identify a disproportionate occurrence of severe outcomes, TESS data generally must be used with comparison categories or comparison products.

9. How Can TESS Data be Obtained?

TESS data can be obtained from AAPCC at 3201 New Mexico Ave, Suite 310, Washington, DC 20016. Phone: 202-362-7217; Fax: 202-362-8377.

TESS Annual Reports are published annually in the September issue of the American Journal of Emergency Medicine. Reprints can be ordered from AAPCC directly.

More detailed TESS data analyses, such as analyses of data on an individual product, group of products, or category, can be ordered from AAPCC as a standard set of printed reports. The set includes about 30 cross-tabulations and frequency distributions (see Table VI), run twice, once for all applicable exposures and a second time limited only to those cases where no concomitant exposure (additional substance) is implicated. Data provided in the first set (all exposures) allow an assessment of the frequency with which a product or group of products is implicated. Data in the second set (without concomitant exposure) allow a more accurate assessment of toxicity directly attributable to the product or category in question. Brand specific product data are generally provided only to the manufacturer of the product, unless these data are needed for compelling scientific, safety or public health purposes.

TESS data are currently available for 1985 through 1996. Because of the fatality verification process, final verified data for a given calendar year do not become available until 10 weeks after the year has closed, however partial year data are available at any time. Data on specific clinical effects are only captured after 1992. Charges for reports, currently about $US1000 to 1400 per report (for each year and product or product grouping), are used to defray the cost of analysing, maintaining and collecting the data.

10. Conclusions

Ensuring product safety and preventing unintentional poisonings is a team effort. Poison centres manage poisonings, collect data on these cases, make the data available for product surveillance and analysis and educate the public about hazards. Regulatory agencies use the data as a sentinel warning system, identifying extreme hazards and prompting recall, reformulation, repackaging or re-labelling. To further limit poisoning morbidity and mortality, each manufacturer needs to pursue a proactive product safety surveillance program, analysing available data on each marketed product and aggressively seeking ameliorable hazards. TESS offers an under-utilised but valuable resource and allows industry to conduct inexpensive safety assessments on a regular basis. Furthermore, TESS data frequently support industry safety claims and can be used to defend products or support regulatory applications and registrations.

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