FRAMEWORK FOR OTIS MotherToBaby
AFFILIATED TERATOLOGY INFORMATION SERVICES

Teratology Information Services (TIS) are comprehensive and multidisciplinary resources for medical consultation on prenatal exposures and maternal exposures during breastfeeding. Teratology Information Services bridge the gap between an often conflicting, inadequate, ever-changing body of literature and the primary health care provider who must respond to an individual's concerns regarding exposures and potential reproductive risks.

Within this document, individuals utilizing TIS will be referred to as *callers.*

The Teratology Information Specialist interprets the available scientific data regarding known and potential reproductive risks into risk assessments that are communicated to individuals of reproductive age and to health care providers. Inquiries to the TIS may be answered via telephone, fax, electronic communication or in-person. A comprehensive data set is used to gather information from the caller regarding the exposure(s) and other important health information.

TIS in the United States and Canada have formed an organization to facilitate communication among programs, provide access to common database information, increase visibility, and provide a forum for utilizing prospective pregnancy outcome data in a scientific manner. OTIS, the Organization of Teratology Information Specialists, functions to strengthen existing programs in their abilities to provide accurate and timely information regarding reproductive risks without interfering with the individual program philosophy or the character of individual services. The purpose of this framework is to describe ideal staffing arrangements, training, resource utilization, operational guidelines and approaches to the adherence of the OTIS MotherToBaby Affiliate program model.

I. ORGANIZATION

A. STAFFING

Medical Director:

The Medical Director is an individual with a doctoral degree who has expertise in genetics, toxicology, pharmacology, obstetrics/gynecology, perinatology or dysmorphology and who has received additional training in teratology. The Medical Director must be able to clearly demonstrate ongoing interest and expertise in teratology as evidenced by publications, research, and attendance at national meetings.

Role of Medical Director: To provide supervision and training of program personnel. The Medical Director also directs program design, research projects, data collection,

and internal quality assurance. Other responsibilities may include public and professional education, supervision of students in relevant training programs, and other related activities.

Program Coordinator:
The Program Coordinator is an individual with a background in genetics, health education, nursing, toxicology, pharmacology, public health or other related fields. Program coordinators must be qualified to understand and interpret standard teratology information resources, and to communicate that information in a logical, concise and understandable way to both health professionals and/or the public.

Role of Program Coordinator: To supervise program personnel and training of personnel, program design and administration, data collection, research projects and internal quality assurance (QA). Other responsibilities may include public and professional education, supervision of students in relevant training programs, and other related activities.

Teratology Information Specialist:
The Teratology Information Specialist should have a background in genetics, health education, nursing, toxicology, pharmacology, public health or other related fields and have received training in a program designed to provide teratology education or through the TIS program to provide teratology education or through the TIS in a program supervised by the Medical Director/ Program Director. This individual must be qualified to understand and interpret standard teratology information resources, and to communicate that information in a logical, concise and understandable way to both health professionals and/or the public.

Role of Teratology Information Specialist: To provide teratology information to the general public and health professionals utilizing standard teratology information resources, communicating this information in a logical, concise and understandable way. Other responsibilities may include participation in public and professional education efforts, research projects, and other related activities.

One person may function in more than one role.

Other: Any person who is not one of the designated staff (e.g. student or trainee) must be under the supervision of the Medical Director/Program Coordinator.

B. TRAINING AND EDUCATION:

The background of the staff of each Teratology Information Service should include formal or "on the job" training in, as a minimum, the following:

Principles of Teratology
Interpreting Scientific Literature
Known and Suspected Teratogenic Exposures
Exposures Known Not to Pose a Significant Teratogenic Risk
Teratogen Counseling
Epidemiology
Risk Assessment
Basic Principles of Genetics
Prenatal Diagnosis
Embryology

A Teratology Information Specialist is considered a trainee until he/she has been evaluated by the Program Coordinator as demonstrating competence in responding to inquiries on varied kinds of exposures.

C. CONTINUING EDUCATION

The field of Teratology is an ever changing one. Therefore, continuing education is essential. Ways to remain up-to-date include staff conferences where new literature, research projects and problem cases are discussed, as well as attendance at relevant national and/or international meetings and relevant educational courses.

D. PUBLIC ACCESS TO TERATOLOGY INFORMATION SERVICES

Teratology Information Services are used by both patients and their health care providers. Access is via telephone, fax, electronic communication, mail, or clinical visits. Access must be available to all individuals within the targeted service population and a TIS should strive to provide service to as many as possible within that targeted service population. Public and professional education related to the dissemination of teratology information may aid in increasing awareness of available TIS resources.

E. NETWORKING

Teratology Information Services should network with medical professionals and community service providers in their catchment area and must be accessible to traditionally underserved populations. Networking should include the ability to make appropriate referrals to genetics providers or other medical specialists, provide

educational information regarding human teratogens and have a working knowledge of community services for the population which the TIS serves.

This model consolidates resources, avoids duplication of services, enables close proximity of medical providers to the public, increases awareness and increases usage by underserved populations.

F. SOURCES OF INFORMATION

A TIS must have in place adequate resources to maintain an updated teratology information base in order to provide accurate and timely information to users of the service. Examples of these resources include:

1. The scientific literature and reference books
2. An online teratology-related database
3. Consultants in teratology related fields such as: toxicology/pharmacology, occupational health, genetics, radiation biology, infectious disease, perinatology and epidemiology

G. RISK ASSESSMENT

A TIS should develop a minimum data set in order to provide risk assessment regarding the exposure in question. An example of a comprehensive data set follows:

1. Intake Date
2. Agent(s) of primary concern
3. Dose of agent
4. Route of exposure
5. Timing of exposure
6. Reason for exposure
7. Maternal symptoms from exposure
8. Pregnancy Dating (LMP, EDC, or other)
9. Maternal illness or fever during pregnancy
10. Exposure to other drugs, chemicals and/or environmental agents
11. Use of tobacco and alcohol
12. Complications with pregnancy
13. Maternal age
14. Family history of pregnancy loss, birth defects, mental retardation
15. Identity of caller – Is caller a health care provider, adopting parent, etc.)
16. Caller's name
17. Caller's address
18. Caller's phone, email

19. Maternal race or ethnicity
20. Maternal educational level
21. Maternal occupation

BREASTFEEDING

1. Infant age
2. Gestational age at delivery
3. Health of infant
4. Prenatal exposure to the agent

A TIS may individualize data sets as they see fit for their own service and/or research purposes. Data collection allows the following capabilities: to adequately assess exposure, to send a follow-up letter to the caller, to triage for genetic counseling or other subspecialties as indicated, to access caller data for research purposes, to collect statistical information on the caller population.

In addition, a service may gather pregnancy outcome data from callers.

Responses provided by TIS staff to public and professional inquiries should integrate current medical literature and other relevant information in order to provide a concise, understandable, timely, customized reproductive risk assessment.

A TIS should be able to provide appropriate referral to medical and other services as indicated (e.g. genetic counseling, subspecialty consultation and community resources).

II. RESEARCH

Teratology Information Services play a unique role in the public health sector by providing information directly to pregnant women and their health care providers about potential reproductive risks from environmental agents. TIS have ability to make contributions to both scientific and public health research.

Because of the direct service model of operation, TIS can prospectively ascertain pregnancies that have been exposed to specific environmental agents in an efficient and cost-effective manner. TIS, especially with collaboration among services, have the ability to collect significant prospective case series of unusual or new exposures that have been questioned as possible teratogens either in animal models or case reports.

TIS may, and are encouraged to, participate in OTIS Research Studies providing the identified research protocol has been met. OTIS Research Criteria are available through the OTIS Research Committee.

III. QUALITY ASSURANCE FOR OTIS PROGRAM AFFILIATION

A. QUALITY ASSURANCE

Quality of the individual TIS must be assured through internal mechanisms. The Program Coordinator/Medical Director is responsible for developing and maintaining an internal quality assurance program in order to assure that the guidelines delineated in Part I Organization are met. An internal QA program should include regular staff supervision, review of: program operations, record keeping practices and research related activity if applicable. QA programs may also include case reviews and in-services.

OTIS affiliated TIS staff members are encouraged to publish articles relevant to teratology or teratology services, contribute expertise in OTIS MotherToBaby fact sheet creation or review, or have an active role in one or more OTIS committees.

OTIS quality assurance and program affiliation guidelines may undergo periodic review or evaluation and are the responsibility of OTIS.

IV. FUNDING

Funding sources for operation of TIS are varied and include private, state or provincial government, federal government (NIH, MCH), hospital, university, fee for service, and research grants. Program funding may be from more than one source. TIS operations are funded as entities of academic institutions, hospitals and/or not-for profit organizations.

V. LEGAL CONSIDERATIONS

Minimizing the risk of liability for TIS can best be achieved by maintaining a quality assurance program, by accurate record keeping and by ensuring information provided to callers is offered in a non-directive fashion, and in addition to medical advice of a health care provider.

Each program is responsible for complying with state laws regarding liability, confidentiality and statute of limitations for record keeping.