ALASKA LEGISLATURE COMMITTEE FILES 1995-1996 8672
8867 SENATE HEALTH EDUCATION & SOCIAL SERVICES

SENATE BILL NO. 159

IN THE LEGISLATURE OF THE STATE OF ALASKA

NINETEENTH LEGISLATURE - FIRST SESSION

BY SENATOR RIEGER

Introduced: 4/13/95
Referred: HES, JUD

A BILL

FOR AN ACT ENTITLED

"An Act relating to advance directives for mental health treatment."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

* **Section 1.** AS 47.30 is amended by adding new sections to read:

ARTICLE 11. PERSONAL DECLARATION OF PREFERENCES FOR MENTAL HEALTH TREATMENT.

Sec. 47.30.950. DECLARATION. (a) An adult of sound mind may make a declaration of preferences or instructions regarding mental health treatment. The preferences or instructions may include consent to or refusal of mental health treatment.

(b) A declaration for mental health treatment continues in effect for three years or until revoked, whichever is sooner. The authority of a named attorney-in-fact and an alternative attorney-in-fact named in the declaration continues in effect as long as the declaration appointing the attorney-in-fact is in effect or until the attorney-in-fact has withdrawn. If a declaration for mental health treatment has been invoked and is in effect at the expiration of three years after its execution, the declaration remains

effective until the principal is no longer incapable.

Sec. 47.30.952. DESIGNATION OF ATTORNEY-IN-FACT. (a) A declaration may designate a competent adult to act as attorney-in-fact to make decisions about mental health treatment. An alternative attorney-in-fact may also be designated to act as attorney-in-fact if the original designee is unable or unwilling to act at any time. An attorney-in-fact who has accepted the appointment in writing may make decisions about mental health treatment on behalf of the principal only when the principal is incapable. The decisions must be consistent with desires the principal has expressed in the declaration.

(b) The following may not serve as attorney-in-fact:

(1) the attending physician or mental health service provider, or an employee of the physician or provider, if the physician, provider, or employee is unrelated to the principal by blood, marriage, or adoption;

(2) an owner, operator, or employee of a health care facility in which the principal is a patient or resident if the owner, operator, or employee is unrelated to the principal by blood, marriage, or adoption.

(c) An attorney-in-fact may withdraw by giving notice to the principal. If a principal is incapable, the attorney-in-fact may withdraw by giving notice to the attending physician or provider. The attending physician or provider shall note the withdrawal as part of the principal's medical record. A person who has withdrawn under the provisions of this subsection may rescind the withdrawal by executing an acceptance after the date of the withdrawal. The acceptance must be in the same form as provided by AS 47.30.970 for accepting an appointment. A person who rescinds a withdrawal shall give notice to the principal if the principal is capable or to the principal's health care provider if the principal is incapable.

(d) The designation of an attorney-in-fact under this section supersedes a previous or subsequent designation of an attorney-in-fact regarding mental health treatment unless otherwise specifically provided in the declaration executed under AS 47.30.950 - 47.30.980 or in the document that designates the other attorney-in-fact.

Sec. 47.30.954. SIGNATURE, WITNESSES. (a) A declaration is effective only if it is signed by the principal and two competent adult witnesses. The witnesses

must attest that the principal is known to them, signed the declaration in their presence, appears to be of sound mind, and is not under duress, fraud, or undue influence.

(b) The following may not serve as a witness to the signing of a declaration:

(1) the attending physician or mental health service provider or a relative of the physician or provider;

(2) an owner, operator, or relative of an owner or operator of a health care facility in which the principal is a patient or resident; or

(3) a person related to the principal by blood, marriage, or adoption.

Sec. 47.30.956. OPERATION OF DECLARATION. (a) A declaration becomes operative when it is delivered to the principal's physician or other mental health treatment provider and remains valid until revoked or expired. The physician or provider shall act in accordance with an operative declaration when the principal has been found to be incapable. The physician or provider shall continue to obtain the principal's informed consent to all mental health treatment decisions if the principal is capable of providing informed consent or refusal.

(b) Upon being presented with a declaration, a physician or other provider shall make the declaration a part of the principal's medical record. When acting under authority of a declaration, a physician or provider shall comply with it to the fullest extent possible, consistent with reasonable medical practice, the availability of treatments requested, and applicable law. If the physician or other provider is unwilling at any time to comply with the declaration, the physician or provider may withdraw from providing treatment consistent with the exercise of independent medical judgment and shall promptly notify the principal and the attorney-in-fact and document the notification in the principal's medical record.

Sec. 47.30.958. POWERS OF ATTORNEY-IN-FACT. (a) The attorney-in-fact does not have authority to make mental health treatment decisions unless the principal is incapable.

(b) The attorney-in-fact is not, as a result of acting in that capacity, personally liable for the cost of treatment provided to the principal.

(c) Except to the extent the right is limited by the declaration or any federal law, an attorney-in-fact has the same right as the principal to receive information

regarding the proposed mental health treatment and to receive, review, and consent to disclosure of medical records relating to that treatment. This right of access does not waive any evidentiary privilege.

(d) In exercising authority under the declaration, the attorney-in-fact has a duty to act consistently with the desires of the principal as expressed in the declaration. If the principal's desires are not expressed in the declaration and not otherwise known by the attorney-in-fact, the attorney-in-fact has a duty to act in what the attorney-in-fact in good faith believes to be the best interests of the principal.

(e) An attorney-in-fact is not subject to criminal prosecution, civil liability, or professional disciplinary action for an action taken in good faith under a declaration for mental health treatment.

Sec. 47.30.960. LIMITATIONS. A person may not be required to execute or to refrain from executing a declaration as a criterion for insurance, as a condition for receiving mental or physical health services, or as a condition of discharge from a health care facility.

Sec. 47.30.962. ACTIONS CONTRARY TO DECLARATION. The physician or provider may subject the principal to mental health treatment in a manner contrary to the principal's wishes as expressed in a declaration for mental health treatment only

(1) if the principal is committed to a treatment facility under this chapter and treatment is authorized in compliance with AS 47.30.825; or

(2) in cases of emergency endangering life or health.

Sec. 47.30.964. RELATION TO OTHER STATUTES. A declaration does not limit any authority provided in this chapter either to take a person into custody or to admit, retain, or treat a person in a health care facility.

Sec. 47.30.966. REVOCATION. A declaration may be revoked in whole or in part at any time by the principal if the principal is not incapable. A revocation is effective when a capable principal communicates the revocation to the attending physician or other provider. The attending physician or other provider shall note the revocation as part of the principal's medical record.

Sec. 47.30.968. LIMITED IMMUNITY. A physician or provider who administers or does not administer mental health treatment according to and in good

faith reliance upon the validity of a declaration is not subject to criminal prosecution, civil liability, or professional disciplinary action resulting from a subsequent finding of a declaration's invalidity.

Sec. 47.30.970. FORM OF DECLARATION. A declaration for mental health treatment shall be in substantially the following form:

DECLARATION FOR MENTAL HEALTH TREATMENT

I,_____

_____, being an adult of sound mind, wilfully and voluntarily make this declaration for mental health treatment to be followed if it is determined by a court or by two physicians that my ability to receive and evaluate information effectively or communicate decisions is impaired to such an extent that I lack the capacity to refuse or consent to mental health treatment. "Mental health treatment" means electroconvulsive treatment, treatment of mental illness with psychotropic medication, and admission to and retention in a health care facility for a period up to 17 days.

I understand that I may become incapable of giving or withholding informed consent for mental health treatment due to the symptom: of a diagnosed mental disorder. These symptoms may include:

_____

_____.

PSYCHOTROPIC MEDICATIONS

If I become incapable of giving or withholding informed consent for mental health treatment, my wishes regarding psychotropic medications are as follows:

_____ I consent to the administration of the following medications: _____

_____

_____ I do not consent to the administration of the following medications: ___

_____

Conditions or limitations: _____

_____.

ELECTROCONVULSIVE TREATMENT

If I become incapable of giving or withholding informed consent for mental health treatment, my wishes regarding electroconvulsive treatment are as follows:

_____ I consent to the administration of electroconvulsive treatment.

_____ I do not consent to the administration of electroconvulsive treatment.

Conditions or limitations:_____

_____.

ADMISSION TO AND RETENTION IN FACILITY

If I become incapable of giving or withholding informed consent for mental health treatment, my wishes regarding admission to and retention in a health care facility for mental health treatment are as follows:

_____ I consent to being admitted to a health care facility for mental health treatment for up to ____ days.

_____ I do not consent to being admitted to a health care facility for mental health treatment.

This directive cannot, by law, provide consent to retain me in a facility for more than 17 days. maximum # of days

Conditions or limitations:_____

_____.

ADDITIONAL PREFERENCES OR INSTRUCTIONS

_____

_____

_____

Conditions or limitations: _____

_____.

ATTORNEY-IN-FACT

I appoint:

NAME _____

ADDRESS _____

TELEPHONE NO _____

to act as my attorney-in-fact to make decisions regarding my mental health

treatment if I become incapable of giving or withholding informed consent for that treatment.

If the person named above refuses or is unable to act on my behalf, or if I revoke that person's authority to act as my attorney-in-fact, I authorize the following person to act as my attorney-in-fact:

NAME _____

ADDRESS _____

TELEPHONE NO. _____

My attorney-in-fact is authorized to make decisions that are consistent with the wishes I have expressed in this declaration or, if not expressed, as are otherwise known to my attorney-in-fact. If my wishes are not expressed and are not otherwise known by my attorney-in-fact, my attorney-in-fact is to act in what my attorney-in-fact believes to be my best interests.

OTHER DOCUMENTS

_____ I have executed a general power-of-attorney or a power-of-attorney under AS 13.26 that includes the power to make decisions regarding health care services for myself. I authorize the attorney-in-fact appointed under this declaration and the attorney-in-fact appointed under a general power-of-attorney under AS 13.26 to serve

_____ jointly with consent of each other as to my mental health treatment;

_____ separately without each other's consent as to my mental health treatment.

_____ I have not executed a general power-of-attorney or a power-of-attorney under AS 13.26 that includes the power to make decisions regarding health care services for myself.

_____

(Signature of Declarant/Date)

AFFIRMATION OF WITNESSES

We affirm that the principal is personally known to us, that the principal signed or acknowledged the principal's signature on this declaration for mental

health treatment in our presence, that the principal appears to be of sound mind and not under duress, fraud, or undue influence, and that neither of us is a person appointed as an attorney-in-fact by this document; the principal's attending physician or mental health service provider or a relative of the physician or provider; the owner, operator, or relative of an owner or operator of a facility in which the principal is a patient or resident; or a person related to the principal by blood, marriage, or adoption.

Witnessed By:

_____ _____

(Signature of Witness/Date) (Printed Name of Witness)

_____

(Address)

_____

(Telephone Number)

_____ _____

(Signature of Witness/Date) (Printed Name of Witness)

_____

(Address)

_____

(Telephone Number)

ACCEPTANCE OF APPOINTMENT AS ATTORNEY-IN-FACT

I accept this appointment and agree to serve as attorney-in-fact to make decisions about mental health treatment for the principal. I understand that I have a duty to act in a manner consistent with the desires of the principal as expressed in this appointment. I understand that this document gives me authority to make decisions about mental health treatment only while the principal is incapable as determined by a court or two physicians. I understand that the principal may revoke this declaration in whole or in part at any time and in any manner when the principal is not incapable.

_____ _____

(Signature of Attorney-in-fact/Date) (Printed name)

_____

(Address)

_____

(Telephone Number)

_____ _____

(Signature of Alternate Attorney-in-fact/Date) (Printed name)

_____

(Address)

_____

(Telephone Number)

NOTICE TO PERSON MAKING A DECLARATION
FOR MENTAL HEALTH TREATMENT

This is an important legal document. It creates a declaration for mental health treatment. Before signing this document, you should know these important facts:

(1) This document allows you to make decisions in advance about three types of mental health treatment: psychotropic medication, electroconvulsive therapy, and short-term (up to 17 days) admission to a treatment facility. The instructions that you include in this declaration will be followed only if a court, two physicians that include a psychiatrist, or a physician and a professional mental health clinician believe that you are incapable of making treatment decisions. Otherwise, you will be considered capable to give or withhold consent for the treatments.

(2) You may also appoint a person as your attorney-in-fact to make these treatment decisions for you if you become incapable. The person you appoint has a duty to act consistent with your desires as stated in this document or, if your desires are not stated or otherwise made known to the attorney-in-fact, to act in a manner consistent with what the person in good faith believes to be in your best interest. For the appointment to be effective, the person you appoint must accept the appointment in writing. The person also has the right to withdraw from acting as your attorney-in-fact at any time.

(3) This document will continue in effect for a period of three years

unless you become incapable of participating in mental health treatment decisions. If this occurs, the directive will continue in effect until you are no longer incapable.

(4) You have the right to revoke this document in whole or in part at any time you have not been determined to be incapable. YOU MAY NOT REVOKE THIS DECLARATION WHEN YOU ARE CONSIDERED INCAPABLE BY A COURT, TWO PHYSICIANS THAT INCLUDE A PSYCHIATRIST, OR A PHYSICIAN AND A PROFESSIONAL MENTAL HEALTH CLINICIAN. A revocation is effective when it is communicated to your attending physician or other provider.

(5) If there is anything in this document that you do not understand, you should ask a lawyer to explain it to you. This declaration will not be valid unless it is signed by two qualified witnesses who are personally known to you and who are present when you sign or acknowledge your signature.

Sec. 47.30.972. PENALTY. It is a class A misdemeanor for a person without authorization of the principal to knowingly alter, forge, conceal, or destroy a declaration executed under AS 47.30.950 - 47.30.980, the reinstatement or revocation of a declaration executed under AS 47.30.950 - 47.30.980, or any other evidence or document reflecting the principal's desires and interests with the intent or effect of affecting a mental health care decision. In this section, "knowingly" has the meaning given in AS 11.81.900(a).

Sec. 47.30.980. DEFINITIONS. In AS 47.30.950 - 47.30.980,

(1) "attending physician" means the licensed physician who has primary responsibility for the care and treatment of the declarant;

(2) "attorney-in-fact" means an adult properly appointed under AS 47.30.950 - 47.30.980 to make mental health treatment decisions for a principal under a declaration for mental health treatment and also means an alternative attorney-in-fact;

(3) "facility" means a

(A) designated treatment facility, as defined in AS 47.30.915;

(B) nursing home; or

(C) assisted living home licensed under AS 47.33;

(4) "incapable" means that, in the opinion of the court in a guardianship proceeding under AS 13.26, in the opinion of two physicians that include a psychiatrist, or in the opinion of a physician and a professional mental health clinician, a person's ability to receive and evaluate information effectively or communicate decisions is impaired to such an extent that the person currently lacks the capacity to make mental health treatment decisions;

(5) "mental health treatment" means electroconvulsive treatment, treatment with psychotropic medication, and admission to and retention in a facility for a period not to exceed 17 days.

* Sec. 2. AS 13.26.335 is amended to read:

Sec. 13.26.335. ADDITIONAL OPTIONAL PROVISIONS TO STATUTORY FORM POWER OF ATTORNEY. Each of the following provisions may be included in a statutory form power of attorney:

(1) IF YOU HAVE GIVEN THE AGENT AUTHORITY REGARDING HEALTH CARE SERVICES UNDER SUBDIVISION (L), COMPLETE THE FOLLOWING:

( ) I have executed a separate declaration under AS 18.12, known as a "Living Will."

( ) I have not executed a "Living Will."

( ) I have executed a separate declaration under AS 47.30.950 - 47.30.980 regarding mental health treatment. If I have appointed an attorney-in-fact under AS 47.30.950 - 47.30.980, I authorize that attorney-in-fact and the attorney-in-fact whom I have appointed in this document to serve

( ) jointly with consent of each other as to my mental health treatment

( ) separately without each other's consent as to my mental health treatment.

( ) I have not executed a separate declaration under AS 47.30.950 - 47.30.980.

(2) YOU MAY DESIGNATE AN ALTERNATE ATTORNEY-IN-

FACT. AN'' ALTERNATE YOU DESIGNATE WILL BE ABLE TO EXERCISE THE SAME POWERS AS THE AGENT(S) YOU NAMED AT THE BEGINNING OF THIS DOCUMENT. IF YOU WISH TO DESIGNATE AN ALTERNATE OR ALTERNATES, COMPLETE THE FOLLOWING:

If the agent(s) named at the beginning of this document is unable or unwilling to serve or continue to serve, then I appoint the following agent to serve with the same powers:

First alternate or successor attorney-in-fact

_____

(Name and address of alternate)

_____

Second alternate or successor attorney-in-fact

_____

(Name and address of alternate)

(3) YOU MAY NOMINATE A GUARDIAN OR CONSERVATOR. IF YOU WISH TO NOMINATE A GUARDIAN OR CONSERVATOR, COMPLETE THE FOLLOWING:

In the event that a court decides that it is necessary to appoint a guardian or conservator for me, I hereby nominate <u>(Name and address of person nominated)</u> to be considered by the court for appointment to serve as my guardian or conservator, or in any similar representative capacity.

* Sec. 3. AS 13.26.344(l) is amended to read:

(l) In the statutory form power of attorney, the language conferring general authority with respect to health care services, shall be construed to mean that, as to the health care of the principal, whether to be provided in the state or elsewhere, the principal authorizes the agent to

(1) have access to and disclose to others medical and related information and records;

(2) consent or refuse to consent to medical care or relief for the principal from pain, but the agent may not authorize the termination of life-sustaining

procedures;

(3) take all steps necessary to enforce a properly executed declaration under AS 18.12;

(4) **take all steps necessary to enforce a properly executed declaration under AS 47.30.950 - 47.30.980 unless the principal has provided that an attorney-in-fact appointed under AS 47.30.950 - 47.30.980 shall have exclusive authority with regard to mental health treatment and the attorney-in-fact appointed under AS 47.30.950 - 47.30.980 has not withdrawn;**

(5) consent or refuse to consent to the principal's psychiatric care, but the consent does not authorize a voluntary commitment or placement in a mental health treatment facility, **electroconvulsive** [CONCLUSIVE] or electric-shock therapy, psychosurgery, sterilization, or an abortion **except that, if the principal has properly executed a declaration under AS 47.30.950 - 47.30.980, the agent may consent to voluntary commitment or placement in a mental health treatment facility and electroconvulsive or electric-shock therapy if that consent is consistent with the wishes expressed in the declaration under AS 47.30.950 - 47.30.980 and if the principal has not designated another attorney-in-fact to have exclusive authority to make decisions regarding mental health treatment;**

(6) [(5)] arrange for care or lodging of the principal in a hospital, nursing home, or hospice;

(7) [(6)] grant releases to health care professionals or health care institutions;

(8) [(7)] hire, discharge, or compensate an attorney, accountant, expert witness, or assistant when the agent considers the action to be desirable for the proper execution of the powers described in this subsection; and

(9) [(8)] do any other act or acts, that the principal can do through an agent, and that the agent considers desirable or necessary to provide for the principal's physical or mental well being.

* **Sec. 4.** AS 47.30.825(b) is amended to read:

(b) The patient and the following persons, at the request of the patient, are entitled to participate in formulating the patient's individualized treatment plan and to

participate in the evaluation process as much as possible, at minimum to the extent of requesting specific forms of therapy, inquiring why specific therapies are or are not included in the treatment program, and being informed as to the patient's present medical and psychological condition and prognosis: (1) the patient's counsel, (2) the patient's guardian, (3) a mental health professional previously engaged in the patient's care outside of the evaluation facility or designated treatment facility, (4) a representative of the patient's choice, **(5) a person designated as the patient's attorney-in-fact with regard to mental health treatment decisions under AS 13.26.332 - 13.26.358, AS 47.30.950 - 47.30.980, or other power-of-attorney,** and **(6)** [(5)] the adult designated under AS 47.30.725. The mental health care professionals may not withhold any of the information described in this subsection from the patient or from others if the patient has signed a waiver of confidentiality **or has designated the person who would receive the information as an attorney-in-fact with regard to mental health treatment**.

* **Sec. 5.** AS 47.30.825(f) is amended to read:

(f) A patient capable of giving informed consent has the absolute right to accept or refuse **electroconvulsive** [ELECTRO-CONVULSIVE] therapy or aversive conditioning. A patient who lacks substantial capacity to make this decision may not be given this therapy or conditioning without a court order **unless the patient expressly authorized that particular form of treatment in a declaration properly executed under AS 47.30.950 - 47.30.980 or has authorized an attorney-in-fact to make this decision and the attorney-in-fact consents to the treatment on behalf of the patient**.

* **Sec. 6.** AS 47.30.836 is amended to read:

Sec. 47.30.836. PSYCHOTROPIC MEDICATION IN NONEMERGENCIES. An evaluation facility or designated treatment facility may not administer psychotropic medication to a patient in a situation that does not involve a crisis under AS 47.30.838(a)(1) unless **the patient**

(1) [THE PATIENT] has the capacity to give informed consent to the medication, as described in AS 47.30.837, and gives that consent; the facility shall document the consent in the patient's medical chart; [OR]

(2) **authorized the use of psychotropic medication in a declaration properly executed under AS 47.30.950 - 47.30.980 or authorized an attorney-in-fact to consent to the use of psychotropic medication for the patient and the attorney-in-fact does consent; or**

(3) [THE PATIENT] is determined by a court to lack the capacity to give informed consent to the medication and the court approves use of the medication under AS 47.30.839.

* **Sec. 7.** AS 47.30.838(a) is amended to read:

(a) Except as provided in (c) **and (d)** of this section, an evaluation facility or designated treatment facility may administer psychotropic medication to a patient without the patient's informed consent, regardless of whether the patient is capable of giving informed consent, only if

(1) there is a crisis situation, or an impending crisis situation, that requires immediate use of the medication to preserve the life of, or prevent significant physical harm to, the patient or another person, as determined by a licensed physician or a registered nurse; the behavior or condition of the patient giving rise to a crisis under this paragraph and the staff's response to the behavior or condition must be documented in the patient's medical record; the documentation must include an explanation of alternative responses to the crisis that were considered or attempted by the staff and why those responses were not sufficient; and

(2) the medication is ordered by a licensed physician; the order

(A) may be written or oral and may be received by telephone, facsimile machine, or in person;

(B) may include an initial dosage and may authorize additional, as needed, doses; if additional, as needed, doses are authorized, the order must specify the medication, the quantity of each authorized dose, the method of administering the medication, the maximum frequency of administration, the specific conditions under which the medication may be given, and the maximum amount of medication that may be administered to the patient in a 24-hour period;

(C) is valid for only 24 hours and may be renewed by a

physician for a total of 72 hours, including the initial 24 hours, only after a personal assessment of the patient's status and a determination that there is still a crisis situation as described in (1) of this subsection; upon renewal of an order under this subparagraph, the facts supporting the renewal shall be written into the patient's medical record.

* Sec. 8. AS 47.30.838 is amended by adding a new subsection to read:

(d) An evaluation facility or designated treatment facility may administer psychotropic medication to a patient without the patient's informed consent if the patient is unable to give informed consent but has authorized the use of psychotropic medication in a declaration properly executed under AS 47.30.950 - 47.30.980 or has authorized an attorney-in-fact to consent to this form of treatment for the patient and the attorney-in-fact does consent.

SB 159

Advance directives for Mental Health Treatment

Overview

Section 1. Authorizes an individual of sound mind to make a declaration of preferences or instructions regarding mental health treatment. The preferences or instructions may include consent to or refusal of mental health treatment.

Authorizes an individual to designate an attorney-in-fact to make mental health decisions based upon preferred treatment under the declaration. Section also specifies who may no. serve as an attorney-in-fact.

Requires signatures from the principal and two competent adult witnesses before a declaration is effective. Section also specifies who may not serve as a witness.

Requires a declaration to be delivered to the principal's physician or other mental health treatment provider before it becomes operative. The declaration must become part of the principal's medical record.

Authorizes an attorney-in-fact the following powers:

(a) to make mental health decision only if the principal is incapable.

(b) the attorney-in-fact in not liable for the costs of the treatment.

(c) grants the attorney-in-fact the same right as the principal to receive information and to review and consent to disclosure of medical records relating to that treatment.

(d) act within the scope of the declaration and if the principal's desires are not expressed in the declaration, the attorney-in-fact has a duty to act in the best interest of the principal.

(e) grants attorney-in-fact immunity from criminal prosecution, civil liability, or professional disciplinary action for an action taken in good faith under a declaration for mental health treatment.

Permits a declaration to be revoked at any time by the principal if the principal is not incapable.

Authorizes an individual who has granted a power of attorney or an attorney-in-fact under Title 13 to specify whether they would like the power of attorney or the attorney-in-fact to work jointly or separately with the attorney-in-fact authorized under this legislation.

Alaska State Senate

SENATOR STEVE RIEGER
District I

Senate Finance Committee
Chair, Senate Transportation Committee

Legislative Budget and Audit Committee
Administrative Regulation Review Committee
Legislative Council

During Session:
State Capitol, Room 516
Juneau, Alaska 99801
(907) 465-3879

716 West 4th Avenue, Suite 530
Anchorage, Alaska 99501
(907) 258-8188

SPONSOR STATEMENT

SB 159 "An Act relating to advance directives for mental health treatment."

Senate Bill 159 allows individuals to make decisions in advance about three types of mental health treatment: psychotropic medication, electroconvulsive therapy, and a short-term admission of up to 17 days into a treatment facility. These decisions are documented in a declaration for mental health treatment and will be used only during any period in which a patient is incapable of consenting to or refusing treatment.

The declaration is set up so that an individual may also appoint a person as an attorney-in-fact to make those treatment decisions for them if they become incapable. The attorney-in-fact would make sure those written instructions are followed or make treatment decisions for the individual if the instructions have not been written down. The attorney-in-fact must accept the appointment in writing and may withdraw from this duty at any time.

The declaration will remain in effect for three years unless the individual becomes incapable of making mental health treatment decisions. If this occurs, the directive continues in effect until the individual is no longer incapable. The individual has the right to revoke all or part of the declaration at any time as long as they have not been determined to be incapable.

This legislation would enable persons to make their own mental health decisions prior to any future mental health crisis they might encounter. The legislation was requested by the Mental Health Consumers of Alaska.

Declaration for Mental Health Treatment

By Dorothy Peavey, Executive Director of Mental Health Consumers of Alaska

An advanced directive is a written instruction, such as a living will or durable power of attorney for heath care, relating to the provision of health care when an individual's condition makes him or her unable to make treatment decisions.

The Declaration for Mental Health Treatment is an attempt to bring the advanced directive philosophy to the provision of mental health care – psychotropic medications, electroconvulsive therapy, or short-term (up to 17 days) admission to a treatment facility.

Based on a similar law in Oregon, the Declaration provides an individual the opportunity to spell out his or her preferences in the event of his or her incapacitation. It provides the individual the opportunity to make his or her wishes known on the treatments that have worked in the past and that he or she desires in the future, treatments that have not worked in the past or that he or she does not desire in the future, which physician cares for him or her, in which hospital he or she is treated. Most importantly, it provides for a substitute decisionmaker with whom the doctors would consult should the Declaration not be specific enough or the doctors are recommending a treatment not specified.

The Declaration is initiated when an individual is "of sound mind." Declarations may not name attending physicians or mental health providers as the "attorney-in-fact" (substitute decisionmaker). The attorney-in-fact does not have authority to make mental health treatment decisions unless the principal is "incapable." The instructions that are included in a Declaration will be followed only if a court, two physicians that include a psychiatrist, or a physician and professional mental health clinician believe that the person is incapable of making treatment decisions. Otherwise, an individual is considered capable to give or withhold consent for treatment.

A Declaration may be revoked in whole or in part at any time an individual has not been determined to be incapable. An individual is "incapable," when it is the opinion of a court, two physicians that include a psychiatrist, or a physician and a professional mental health clinician, an individual's ability to receive and evaluate information effectively or communicate decisions is impaired to such an extent that the person currently lacks the capacity to make mental health treatment decisions.

In the past two years in Oregon, where they have Declarations, they have found that individuals who had fought hospitalization and medication in the past, now were more willing to go to the hospital because they felt their decisions would be heeded.

Initially introduced into the Alaska Legislature as House Bill 318 by Representative Cynthia Toohey and as Senate Bill 159 by Senator Steve Rieger, the Declaration should be scheduled for hearings early in the next Legislative Session.

Endorsements of the Declaration may be mailed to either Mental Health Consumers of Alaska, Representative Toohey, or Senator Rieger at "Alaska State Legislature, State Capitol, Juneau, AK 99801-1182."

Dorothy Peavey, Executive Director of Mental Health Consumers of Alaska, would welcome comments and questions at 907-277-3817 or 800-478-3817. Ψ

Nineteenth Alaska State Legislature

All mail should be sent to: State Capitol
Juneau, AK 99801-1182

Representatives:

Alan Austerman
Ramona Barnes
Tom Brice
Kay Brown
Con Bunde
John Davies
Bettye Davis
Gary Lee Davis
Kim Elton
David Finkelstein
Richard Foster
Joseph Green
Ben Grussendorf
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Pete Kelly
Vic Kohring
Pete Kott
Gene Kubina
Don Long
Jerry Mackie
Terry Martin
Beverly Masek
Carl Moses
Eldon Mulder
Mike Navarre
Irene Nicholia
Scott Ogan
Sean Parnell
Gail Phillips
Brian Porter
Caren Robinson
Norman Rokeberg
Jerry Sanders
Gene Therriault
Cynthia Toohey
Al Vezey
Bill Williams
Ed Willis

Senators:

Al Adams
Dave Donley
Jim Duncan
Johnny Ellis
Steve Frank
Lyda Green
Rick Halford
Lyman Hoffman
Tim Kelly
Loren Leman
Georgianna Lincoln
Mike Miller
Drue Pearce
Randy Phillips
Steve Rieger
Judith Salo
Bert Sharp
Robin Taylor
John Torgerson
Fred Zharoff

— ADDITIONAL MATERIAL —

Post-it™ Fax Note 7671	Date 1/31/96	# of pages ▶ 1
To Betty	From Dorothy Peavey	
Co./Dept. Sen. Rieger	Co. MHCA	
Phone #	Phone # 277 3817	
Fax # 465-2069	Fax # 277 2193	

Working for Alaska's Mental Health

Mental Health Association in Alaska
4050 Lake Otis Parkway, Suite 202 • Anchorage, Alaska 99508-5221 • (907) 563-0880 • Fax (907) 563-0881

October 24, 1995

Dorothy Peavey, M.S.W.
Executive Director
Mental Health Consumers of Alaska
101 East 9th Avenue, Suite 3-A
Anchorage, Alaska 99501

Re: **Senate Bill No. 159**
"An Act relating to advance directives for mental health treatment."

Dear Dorothy:

The Board of Directors would like to support the legislation the Mental Health Consumers of Alaska has brought to the attention of Alaskan lawmakers, i.e. Senate Bill No. 159. It is our belief that this kind of self-advocacy and self-empowerment process in allowing consumers of mental health treatment services the ability to pre-plan and direct caregivers in treatment issues is simply a matter of basic human rights.

We compliment you personally on the hard work you have completed on this issue. We will stand by you and the Mental Health Consumers of Alaska in assuring this legislation is brought to the attention of the public and those for whom we advocate. Please do not hesitate in listing the Mental Health Association in Alaska as a strong supporter of the advance directives for mental health treatment.

Sincerely;

Jan McGillivary, M.Ed.
CEO/President

Sharon Lundy, M.S.
Chair of the Board

Southcentral
COUNSELING CENTER

4020 Folker Street · Anchorage, Alaska 99508

(907) 563-1000
FAX 563-2045

November 29, 1995

Senator Steve Rieger
Room 516
State Capitol
Juneau, Ak 99801-1182

Dear Senator Rieger:

This letter is in support of Senate Bill 159, Declaration for Mental Health Treatment. Mental Health Consumers of Alaska used declaration models from other states to work towards developing legislation that would allow Alaskans to establish a document stipulating the consumer's mental health treatment preferences, much like a living will. The consumer would have this document prepared in the event they are declared mentally incompetent.

The management and staff at Anchorage Community Mental Health Services, Inc., support Senate Bill 159, and feel that the declaration process would help to empower the consumer. The ACMHS Board of Directors adopted a recommendation in support of the Declaration for Mental Health Treatment at their October 20, 1994, Board meeting.

The Board, management, and staff of Anchorage Community Mental Health Services appreciated your introduction of Senate Bill 159, and the mental health community applauds your continued support of this bill.

Sincerely,

Ken Taylor
Executive Director

cc: Dorothy Peavey
Mental Health Consumers of Alaska

Charter North
Behavioral Health System

2930 DeBarr Road
Anchorage, Alaska 99508
(907) 258-7575 • Fax (907) 277-7844

April 16, 1995

Marveen Coggins
Legislative Aid
Representative Cynthia Toohey
Room 104
State Capital
Juneau, Alaska 99801-1182

Dear Marveen:

Please accept my apology for being so late in responding to your request to review the mental health treatment bill Representative Toohey is considering. I have reviewed the bill and found no problems with it from a facility perspective.

Please feel free to contact me with any further questions or if I can be of further assistance.

Sincerely,

Kathleen M. Cronen
Chief Executive Officer

RECEIVED FEB 05 1996

SUBJECT

DATE 01-25-96

Dear Senator Rieger:

I would appreciate you passing SB 159. If I am ever in a hospital for treatment I would like to have a part in the decision making.

My ex husband was hospitalized and forced to be strapped into bed. This wasn't fair and he should be able to make decisions with the assistance of an advocate.

Thank you for your support and taking time to listen

Sincerely,

Donna Hart
100 Heritage Drive
Wasilla, AK 99654
373-7404

29 January 96

Dear Senator Rieger:

I support House Bill 318 and Want to see passed Senate Bill 159.

Sincerely,

Janett Grady
P.O. Box 1853
Palmer, AK 99645

RECEIVED FEB 0 5 1996

Dear Senator Reigu

HB-318 would help Mental Illness with (milestones) Having Bio-polar, and a single parent, with numerous hospitalizations I know now what works well that is why I haven't been in for 2 years. Please work with us. These programs + Bills. Really work, when used right

Thank You

Jaymie

Jaymie Murphy
2107 Chickaloon
Wasilla AK 99654

RECEIVED FEB 0 5 1996

Box 1107
Palmer, Ak. 99645
24 Jan 96

Dear Senator Reiger

I am writing to you in regard to SB 159. I would like to see SB159 passed. This bill would allow me choices of care that I can make before I am in an incapable position. This is an important step in helping our mentally ill.

Sincerely,

Jay Fields

SB

165

Alaska State Legislature

Sen. Lyda Green, Chairman
Sen. Loren Leman, Vice-Chairman
Sen. Mike Miller
Sen. Johnny Ellis
Sen. Judith Salo

State Capitol
Room 123
Juneau, Alaska 99801-1182
907-465-3762

Senate Committee on
Health, Education and Social Services

SB 165
Psychologists and Psychological Associates

Sponsor Statement

Currently under Alaska law, psychological associates are held to a more stringent standard in the licensure process than other masters-level mental health practitioners. For example, psychological associates are now the only mental health practitioners required to have three years of supervision by a Ph.D. psychologist prior to examination, followed by five years of supervision before they are eligible for independent practice. These provisions are too restrictive and often dissuade or prohibit individuals from entering into this particular profession.

The goal of this legislation is to bring the psychological associates into conformity with other masters-level programs (i.e. social workers, marriage and family therapists). It also insures the quality of these professionals by maintaining the examination, education, and ethical standards prior to licensure.

This bill has a zero fiscal note from the Department of Commerce and Economic Development.

Alaska State Legislature

Sen. Lyda Green, Chairman
Sen. Loren Leman, Vice-Chairman
Sen. Mike Miller
Sen. Johnny Ellis
Sen. Judith Salo

State Capitol
Room 423
Juneau, Alaska 99801-1182
907-465-3762

Senate Committee on
Health, Education and Social Services

SB 165
Psychologists and Psychological Associates

SECTIONAL SUMMARY

Section 1: Allows the board to order a licensed psychologist or licensed psychological associate to submit to a reasonable physical or mental examination if the board finds credible evidence that the individual's physical or mental capacity to practice safely is at issue.

Section 2: Prohibits the board from issuing a license to an applicant who has conducted her or himself dishonorably in providing mental health services.

Section 3: Provides for psychologists (Ph.D.-level) to work under supervision and with the board's oversight for a limited time period to meet the experience requirements for licensing.

Section 4: Consolidates licensing requirements located under this chapter. Also this section clarifies and simplifies the licensing requirements for a masters-level psychological associate and makes them consistent with masters-level social workers and marital and family therapists.

Section 5: Removes redundant section of statute.

Section 6: Provides for psychological associates (masters-level) to work under supervision and with the board's oversight for a limited time period to meet the experience requirements for licensing. This provision also conforms to requirements already in place for social workers and marital and family therapists.

Section 7: Provides for psychological associates and psychologists to hold case conference with other mental health professionals outside the psychology and medical fields, e.g. psychiatrists, social workers, and marital and family therapists.

Section 8: Replaces the current reference to lewd or immoral conduct as a basis for the board taking disciplinary action with specific language prohibiting sexual

contact between a mental health provider and a client during the course of therapy and within two years after therapy.

Section 9: Authorized the board to suspend the license of a licensee who refuses to submit to a physical or mental examination under AS 08.86.075.

Section 10: Defines psychological associate

9-LS1106\F
Lauterbach
1/16/96

CS FOR SENATE BILL NO. 165(HES)

IN THE LEGISLATURE OF THE STATE OF ALASKA

NINETEENTH LEGISLATURE - SECOND SESSION

BY THE SENATE HEALTH, EDUCATION AND SOCIAL SERVICES COMMITTEE

Offered:
Referred:

Sponsor(s): SENATE HEALTH, EDUCATION AND SOCIAL SERVICES COMMITTEE BY REQUEST

A BILL

FOR AN ACT ENTITLED

"An Act relating to psychologists and psychological associates."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

* Section 1. AS 08.86 is amended by adding a new section to read:

Sec. 08.86.075. POWER TO ORDER EXAMINATIONS. The board may order a licensed psychologist or licensed psychological associate to submit to a reasonable physical or mental examination if the board has credible evidence sufficient to conclude that the psychologist's or psychological associate's physical or mental capacity to practice safely is at issue.

* Sec. 2. AS 08.86.130(a) is amended to read:

(a) The board shall issue a license to a person who

(1) holds an earned doctorate degree, from an academic institution whose program of graduate study for a doctorate degree in psychology meets the criteria established by the board by regulation, in

(A) <u>clinical</u> psychology;

(B) <u>counseling</u> [EDUCATIONAL] psychology; <u>or</u>

(C) education in a [WITH THE] field of specialization [IN COUNSELING PSYCHOLOGY OR EDUCATIONAL PSYCHOLOGY; OR (D) A SUBJECT] considered equivalent by the board;

(2) has not engaged in dishonorable conduct related to the practice of counseling or psychometry;

(3) has one year of post doctoral supervised experience approved by the board; and

(4) [(3)] takes and passes the objective examination developed or approved by the board.

* Sec. 3. AS 08.86.135 is amended to read:

Sec. 08.86.135. TEMPORARY LICENSE. The board may issue a temporary license to a person who meets the requirements of AS 08.86.130(a)(1) and (2). A temporary license issued under this section is valid only for the time period identified in the person's plan for the purpose of obtaining supervised experience to meet the requirements of AS 08.86.130(a)(3) [UNTIL THE RESULTS OF THE EXAMINATION FOLLOWING THE ISSUANCE OF THE TEMPORARY LICENSE ARE PUBLISHED].

* Sec. 4. AS 08.86.160 is repealed and reenacted to read:

Sec. 08.86.160. LICENSING REQUIREMENTS. (a) The board shall issue a license to a person who

(1) holds an earned master's degree from an academic institution whose program of graduate study for a master's degree in psychology meets the criteria established by the board by regulation in

(A) clinical psychology;

(B) counseling psychology; or

(C) education in a field of specialization considered equivalent by the board;

(2) has not engaged in dishonorable conduct related to the practice of counseling or psychometry;

(3) has two years of post master's supervised experience approved by the board; and

(4) takes and passes the objective examination developed or approved by the board for psychological associates.

(b) The board may not deny recognition as an accredited or approved academic institution to an educational institution solely because its program has not been accredited by a professional organization of psychologists.

* Sec. 5. AS 08.86.164(a) is amended to read:

(a) A psychological associate shall be licensed for specific activities or areas of competence as determined by the nature and extent of the psychological associate's train , and experience [, AND THOSE AREAS SHALL BE SPECIFIED ON THE LICENSE].

* Sec. 6. AS 08.86 is amended by adding a new section to article 4 to read:

Sec. 08.86.166. TEMPORARY LICENSE. The board may issue a temporary license to a person who meets the requirements of AS 08.86.160(a)(1) and (2). A temporary license issued under this section is valid only for the time period identified in the person's plan for the purpose of obtaining supervised experience to meet the requirement of AS 08.86.160(a)(3).

* Sec. 7. AS 08.86.200(a) is amended to read:

(a) A psychologist or psychological associate may not reveal to another person a communication made to the psychologist or psychological associate by a client about a matter concerning which the client has employed the psychologist or psychological associate in a professional capacity. This section does not apply to

(1) a case conference with other **mental health professionals** [PSYCHOLOGISTS, PSYCHOLOGICAL ASSOCIATES,] or with physicians and surgeons;

(2) a case in which the client in writing authorized the psychologist or psychological associate to reveal a communication;

(3) a case where an immediate threat of serious physical harm to an identifiable victim is communicated to a psychologist or psychological associate by a client;

(4) disclosures of confidential communications required under Rule 504, Alaska Rules of Evidence; or

(5) proceedings conducted by the board or the department where the disclosure of confidential communications is necessary to defend against charges that the psychologist or psychological associate has violated provisions of this chapter; **information obtained by the board or department under this paragraph is confidential and is not a public record for purposes of AS 09.25.110 - 09.25.140.**

* **Sec. 8.** AS 08.86.204 is amended to read:

Sec. 08.86.204. GROUNDS FOR IMPOSITION OF DISCIPLINARY SANCTIONS. After a hearing, the board may impose a disciplinary sanction on a person licensed under this chapter when the board finds that the licensee

(1) secured a license through deceit, fraud, or intentional misrepresentation;

(2) engaged in deceit, fraud, or intentional misrepresentation in the course of providing professional services or engaging in professional activities;

(3) advertised professional services in a false or misleading manner;

(4) has been convicted of a felony or other crime **that** [WHICH] affects the licensee's ability to continue to practice competently and safely;

(5) intentionally or negligently engaged in or permitted the performance of patient care by persons under the licensee's supervision **that** [WHICH] does not conform to minimum professional standards regardless of whether actual injury to the patient occurred;

(6) failed to comply with this chapter, with a regulation adopted under this chapter, or with an order of the board;

(7) continued to practice after becoming unfit due to

(A) professional incompetence;

(B) failure to keep informed of current professional practices;

(C) addiction or severe dependency on alcohol or other drugs which impairs the ability to practice safely;

(D) physical or mental disability **or a combination of physical and mental disabilities**;

(8) engaged in **sexual misconduct with a patient during the course of therapy, either within or outside the treatment setting, or within two years**

redefined

after therapy or counseling with the patient has terminated; in this paragraph, "sexual misconduct" includes sexual contact, as defined in regulations adopted under this chapter, or attempted sexual contact, regardless of the patient's or former patient's consent or lack of consent [LEWD OR IMMORAL CONDUCT IN CONNECTION WITH THE DELIVERY OF PROFESSIONAL SERVICE TO PATIENTS].

* **Sec. 9.** AS 08.86.204 is amended by adding a new subsection to read:

(b) The board may summarily suspend the license of a licensee who refuses to submit to a physical or mental examination under AS 08.86.075. A person whose license is suspended under this subsection is entitled to a hearing by the board within seven days after the effective date of the order. If, after a hearing, the board upholds the suspension, the licensee may appeal the suspension to a court of competent jurisdiction.

* **Sec. 10.** AS 08.86.230(4) is amended to read:

(4) 'psychological associate" means a person licensed under this chapter who renders specific psychological services [IN ASSOCIATION WITH A LICENSED PSYCHOLOGIST] and complies with AS 08.86.164;

* **Sec. 11.** AS 08.86.162(3), 08.86.164(b), 08.86.164(c), 08.86.164(d), and 08.86.164(e) are repealed.

LIFE QUEST

COMPREHENSIVE MENTAL HEALTH SERVICES

230 E. Paulson Ave., Suite 68, Wasilla, Alaska 99654-7001
(907) 376-2411 • 800-478-2410 • FAX (907) 376-1626 • TDD (907) 373-3197

December 12, 1995

Senator Lyda Green
4000 Palmdale Drive
Wasilla AK 99654

Dear Senator Green:

We, the undersigned, are Master's level clinicians employed with Life Quest, a nonprofit community mental health facility in Wasilla. It has been our continuing concern that access to Alaska's licensing has been too restrictive, especially when compared to other states. For many of us, the requirements to become a licensed Psychological Associate have been too cost prohibitive and unreasonable. Specifically, the duration and number of supervision hours are a major roadblock.

Please consider Senate Bill #165 as a positive change to make the licensure process more reasonable and user-friendly.

Sincerely,

LIFE QUEST'S MASTER'S LEVEL CLINICIANS

Member Agency United Way

Life Quest
Comprehensive Mental Health Services

230 E. Paulson Ave., Suite 68, Wasilla, Alaska 99654-7001
(907) 376-2411 • 800-478-2410 • FAX (907) 376-1626 • TDD (907) 373-5197

December 12, 1995

Senator Lyda Green
4000 Palmdale Drive
Wasilla AK 99654

Dear Senator Green:

As Life Quest's Chief Executive Officer, I am writing you to encourage your support of Senate Bill #165. It is in the best interest of both our consumers and our employees to have licensure statutes which are reasonable and which encourage participation. We have clinicians who are actively pursuing Psychological Associate licensure, and further refinement of this statute will be greatly appreciated.

Sincerely,

Robert S. Irvine, Ed.D.

Robert S. Irvine, Ed.D., L.C.S.W., M.B.A.
Chief Executive Officer

/sd

UNIVERSITY OF ALASKA ANCHORAGE

3211 Providence Drive
Anchorage, Alaska 99508-8224

COLLEGE OF ARTS AND SCIENCES
Department of Psychology
(907) 786-1711
FAX (907) 786-4898

December 19, 1995

To: Allen Moma

From: Mark E. Johnson, Associate Professor MEJ
Department of Psychology

Re: SB 165: Changes to Psychologist and Psychological Associate Regulations

On behalf of our graduate students, I would like to thank you for your efforts in proposing the changes to the regulations governing psychologists and psychological association as included in Senate Bill 165. I unequivocally support these changes and believe they are crucial to the ongoing success of graduates from our M.S. in Clinical Psychology program. Given the changes in the health care arena, it is critical that our students become licensed. The changes that are included in SB 165 will improve and streamline the licensing process to such a degree that more of our graduates will be license eligible. This will not only improve the marketability and employability of our students, but it will serve to protect better the consumers of mental health consumers. Further, I have heard from several agencies, including rural ones, that they would like to hire more of our graduates but are unable to do so because of the licensure issue. Thus, I believe that the changes encompassed in SB 165 will benefit not only our students, but mental health consumers throughout the State.

Thank you again for your efforts. I will express my strong support for this bill in any setting or arena; please let me know if this is needed.

UNIVERSITY OF ALASKA ANCHORAGE

3211 Providence Drive
Anchorage, Alaska 99508-8224

COLLEGE OF ARTS AND SCIENCES
Department of Psychology
(907) 786-1711
FAX (907) 786-4898

December 19, 1995

Re: SB 165

Dear Legislators of the State of Alaska,

With this memo I would like to express my strong support for SB 165 and the changes it makes in the regulations governing psychologists and psychological associates. It is critical that graduates from master's level programs in psychology become licensed to participate fully in meeting the mental health needs of Alaska. The proposed changes encourages the pursuit of licensure among these professionals by 1 making the licensing process more comparable to other masters level licenses, i.e., Marriage and Family Therapist and Social Worker, and 2 by establishing the opportunity to define an agreement between the applicant and the licensing board that will identify what a specific applicant needs to complete to be license eligible.

Because this bill encourages more master's level practitioners to seek licensure, it will ultimately benefit the consumers of mental health services in Alaska. Most importantly, it will serve to improve service delivery in the bush, where licensed psychological associates are the exception not the rule. Overall, it will improve the quality of mental health care delivery by ensuring the quality control that licensure provides.

Thus, I believe that SB 165 represents a very proactive and positive move in meeting the mental health needs of Alaskans and I strongly supports its passage.

Sincerely,

Christiane Brems, Ph.D.
Associate Professor

ALASKA PACIFIC UNIVERSITY

February 6, 1996

Re: SB 165 and HB 420

Dear Legislators of the State of Alaska:

On behalf of the graduate students and the faculty of the Master of Science in Counseling Psychology program at Alaska Pacific University I wish to express my support for **SB 165 and HB 420**. It is critical that graduates from master's level programs at both the University of Alaska and Alaska Pacific University be eligible for licensure to be able to fully participate in meeting the mental health needs of Alaska's residents.

Given recent trends and changes in mental health, such as the advent of managed care and the consequent need for clinicians who are trained to provide short-term treatment, it is urgent that master's level practitioners are license eligible, and that there is a sensible process for such licensure. The proposed changes in the law will enable more of our graduates to become licensed, and therefore they will be better able to serve the needs of Alaskans, particularly in rural villages. Further, the proposed changes make the licensing process for master's level psychologists more comparable to the procedures that currently exist for Marriage and Family Therapists and Social Workers, as it ought to be. And finally, the proposed changes will make master's level psychologists more directly accountable to the licensing board which will ensure greater quality control and consumer protection.

Sincerely,

Ellen Cole

Ellen Cole, Ph.D.
Professor
Acting Director,
Master of Science in Counseling Psychology Program

4101 University Drive • Anchorage • Alaska 99508
Phone 907-561-1266 • Fax 907-562-4276

Anchorage
Center for Families

3745 Community Park Loop, Suite 102 • Anchorage, Alaska 99508 • (907) 276-4994 • FAX (907) 276-6930
INTERMISSION Crisis Nursery • 24 Hours • (907) 276-8511

Re: HB420

Dear Legislators of the State of Alaska,

As a licensed psychological associate and clinical director of a private, non-profit family service agency, I write you to express my wholehearted support for the changes proposed in HB420.

In my agency, I have supervised licensed clinical social workers, licensed marriage family therapists, masters level student interns and an unlicensed Psy.D. The proposed changes in HB420 would make the licensing process for psychological associates much more comparable to other masters level licenses. I know first hand from supervising masters level students from the University of Alaska - Anchorage, and Alaska Pacific University as interns at my agency the fine job our State's Universities do in preparing these masters level practitioners to provide quality mental health services. I have listened to the discouragement of these students when faced with state licensing requirements that are much more stringent than social workers and marriage and family therapists.

I believe HB420 can only benefit mental health consumer services in Alaska while continuing to uphold the integrity of licensing requirements in their intent to ensure quality professional care to our Alaskan communities.

Sincerely,

Dee Foster

Dee Foster, M.S.
Clinical Director

SB

185

MEMBER

TENTH ALASKA LEGISLATURE
ELEVENTH ALASKA LEGISLATURE
TWELFTH ALASKA LEGISLATURE
THIRTEENTH ALASKA LEGISLATURE
FOURTEENTH ALASKA LEGISLATURE
FIFTEENTH ALASKA LEGISLATURE
SIXTEENTH ALASKA LEGISLATURE
EIGHTEENTH ALASKA LEGISLATURE
NINETEENTH ALASKA LEGISLATURE

ALASKA STATE SENATE

SENATOR TIM KELLY

STATE CAPITOL
JUNEAU, ALASKA 99801-1182
(907) 465-3822
FAX (907) 465-3756

716 WEST 4TH, SUITE 400
ANCHORAGE, ALASKA 99501
(907) 258-8180
FAX (907) 258-4524

1-800-770-3822
(JANUARY 1998 - MAY 1998)
INTERNET: //http://www.state.ak.us/

Sponsor Statement

SB 185
"An Act relating to immunization records for children under the age of seven"

SB 185 was introduced in response to a growing concern over the safety of childhood immunizations. For more than a century, childhood immunizations have been one of the foremost public health concerns. Immunization of our children has lead to the near elimination of diseases which were once devastatingly fatal. However, some vaccines including the whooping cough vaccine and the German measles vaccine typically contain small quantities of material derived from disease-causing organisms which could possibly be linked to childhood death or injury.

SB 185 requires the funeral director or the person acting as the funeral director to include a record of the dates of any immunizations a deceased child under the age of seven has received when filing the death certificate. Further, the death certificate must include the name and type of each vaccine administered, as well as the name of the vaccine's manufacturer and the lot and batch number.

If the immunization record cannot be obtained within three days of death the funeral director shall file the death certificate in compliance with existing state law and shall continue to make efforts to obtain the records from the next of kin or other source.

If the records are unavailable from these sources, the funeral director is required to request the immunization record from the Immortality Review Committee established by the commissioner of the Department of Health and Social Services. The committee must provide this information within 90 days.

There are approximately 125 deaths every year of children under the age of seven. SB 185 might help to establish a link between immunizations and childhood death.

STATE OF ALASKA
1996 LEGISLATIVE SESSION

BILL NO. SB 185.

Revision Date:
Dept. Affected: Health and Social Services
Title: An act relating to immunization records for children under the age of seven
BRU: State Health Services
Component: Bureau of Vital Statistics
Sponsor: Kelly
COMPONENT SERIAL NO. 961
Requestor: Senate HES
See also (SN#):

Expenditures/Revenues: (Thousands of Dollars)

OPERATING EXPENDITURES	FY97	FY98	FY99	FY00	FY01	FY02
PERSONAL SERVICES	8.2	8.4	8.6	8.8	9.1	9.3
TRAVEL						
CONTRACTUAL	30.0					
SUPPLIES	1.0	0.5	0.5	0.5	0.5	0.5
EQUIPMENT	1.6	0.1	0.1	0.1	0.1	0.1
LAND & STRUCTURES						
GRANTS, CLAIMS						
MISCELLANEOUS						
TOTAL OPERATING	40.8	9.0	9.2	9.4	9.7	9.9
CAPITAL EXPENDITURES						
CHANGES IN REVENUES ( )						

FUND SOURCE (Thousands of Dollars)						
1002 Federal Receipts						
1003 GF Match						
1004 GF	40.8	9.0	9.2	9.4	9.7	9.9
1005 GF/Program Receipts						
1037 GF/Mental Health						
Other (please specify)						
TOTAL	40.8	9.0	9.2	9.4	9.7	9.9

Estimate of any current year (FY96) cost: $0.0

POSITIONS:

FULL-TIME						
PART-TIME	0.25	0.25	0.25	0.25	0.25	0.25
TEMPORARY						

ANALYSIS: (Attach a separate page if necessary)

Of the approximately 2,500 deaths per year in Alaska, 125 deaths are of children who are under the age of 7 years. During the lifetime of a 7 year-old, s/he will receive 16 immunizations, most of these occurring before the age of two. Using an average of 9 immunizations per child, the cost associated with this legislation would:

Personal Services - $8.2

A quarter time administrative clerk II would be needed to key, verify, query and correct the increased workload mandated by this legislation to include the immunization record of children under the age of seven years. The assumption would be that the cost for the position would increase by 2.5% for inflation.

Contractual - $30.0

The bill requires that there be six data fields for each immunization. This will mean a maximum increase of 96 fields to the

Prepared by: Peter M. Nakamura, MD, MPH
Division: Public Health
Phone: (907) 465-3090
Date: 01/09/96

Approved by Com: Karen Perdue, Commissioner
Agency: Department of Health & Social Services
Date: 1-9-96

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ANALYSIS (cont.):

existing 58 fields that are now required for each death certificate. Modification would be required to all the programs that constitute the death record file.

Supplies - $1.0

The current forms would have to be redesigned and reprinted. This will cost $1.0 for the first year and $0.5 for each year thereafter.

Equipment - $1.6

Data storage requirements will double for the entire death file requiring a purchase of 16 megabytes of storage for the WANG minicomputer the first year at $100/megabyte and 1 megabyte for each following year.

Position Title	No. of Positions	Range/Step	Bargaining Unit
Administrative Clerk II	1	8A	GGU

Time Status	Staff Months	Location	Election District
PPT	3	Juneau	

TYPE of EXPENDITURE		AMOUNT
Salary		5.5
Benefits		2.7
Premium Pay		
Other		
Total Personal Services		8.2
Travel		
Contractual		
Commodities		
Equipment		
Other		
Total Cost		8.2
FUNDING SOURCE for TOTAL COST		
1002 Federal Receipts		
1003 GF Match		
1004 General Fund		8.2
1005 GF/Program Receipts		
1007 I/A Receipts		
1037 GF/MH		
1061 CIP Receipts		
Other ( )		

Justification

A quarter time administrative clerk II would be needed to assume the extra workload created by the additional fields which would need to be keyed, verified and corrected on the 125 death certificates for children under seven years of age.

REQUEST for NEW POSITION

AGENCY: Health and Social Services

BRU: State Health Services

COMPONENT: Bureau of Vital Statistics

Revised Date:

FY97

Institute of Medicine Testimony, January 16, 1993

Thank you for allowing me to speak.

My name is Sandy Mintz and I live in Alaska. I am a full-time, parent volunteer for the National Vaccine Information Center/Dissatisfied Parents Together, as well as founder of a local group called "Parents Concerned About the Safety of Vaccines".

The points I would like to raise in my testimony today revolve around 3 main areas of concern: 1) problems with the 1991 report I hope the current committee can avoid, 2) specific concerns about vaccines, using measles as a model, and 3) suggestions for the direction and design of future vaccine safety and efficacy research.

In the 1991 IOM review, the Committee quite fairly pointed out that it had been handicapped by the lack of adequate studies, including the poor design of many. The Committee also properly concluded that the absence of appropriate studies meant that there was insufficient evidence to indicate whether or not there was a causal relationship between many of the adverse reactions being studied and vaccination. Imponderably, however, similarly flawed information was cited as evidence AGAINST causality in their report in a number of instances.

The Committee's conclusions concerning SIDS and DPT vaccine are a case in point. Although they admitted in their review, and I quote, "Prior to the 1960's, little was known about the epidemiology of sudden infant death syndrome (SIDS)", they concluded, and again I quote, "Studies showing a temporal relation between these events are consistent with the expected occurence of SIDS over the age range in which DPT immunization typically occurs". Without information on the background rate of SIDS in historically, socioeconomically, and otherwise comparable never vaccinated groups, data on the expected frequency of SIDS merely reflects its incidence among vaccinated populations, rather than absent vaccination and cannot be considered accurate or meaningful. Given that such background information was not presented by the Committee, conclusions about the absence of a relationship between SIDS and vaccination were not justified.

Nor were any studies cited - in fact, to my knowledge none exist - in which the only proper control group, never vaccinated children, was used. If, as is the case in most studies, "less recently", but nonetheless vaccinated, children were used as controls, and an adverse vaccine event can be either a delayed or long-term consequence of vaccination, one would EXPECT to find no differences between the study groups, even if vaccination HAD caused an adverse event. Conclusions about causality drawn from any study with such serious limitations are not justified.

The fact is, all controls are not equal. More importantly, many groups are improperly designated as controls. The 1991 IOM statement that a nontreatment group, i.e., control, might be one using an established alternate vaccine, is an example of an improper definition of a control. In no way can any form of vaccination, whether "established" or less recently administered, be considered lack of intervention. The

extent to which various established vaccines and times since administration of vaccine are similar to non-vaccination should be studied, not assumed. Only a placebo, which in the case of vaccination studies equals the absence of vaccination, is appropriate.

As to the notion that it is unethical to withhold vaccination due to "widespread acceptance" of vaccination, I would submit that to the contrary, if anything, it is unethical to administer vaccinations of unknown safety and efficacy. It is unsound to argue we can't withhold vaccines beause of "widespread acceptance", as the 1991 IOM Committee did, when the reason there is such widespread acceptance of vaccinations is that we have been told the vaccines are safe and effective. Their argument is particularly ironic given their finding that serious consequences can result from the two vaccines, and lament about the absence of adequate information. To the contrary, the conclusion that must be drawn from their review is that randomized, long-term, placebo-controlled, prospective clinical trials are urgently needed, in spite of ethical concerns about ADMINISTERING vaccines of unknown safety. Indeed, no reassuring claims about the infrequency of any linked adverse event should be made until and unless the false premises underlying study designs and the many study design flaws, including the lack of reasonable and time appropriate controls, and reporting system inadequacies, are corrected.

Please note that in any study of long-term vaccine consequences, in which proper experimental and control groups are used, a comprehensive and longitudinal medical assessment is necessary in order to discern all observable and measurable effects of vaccination, both good and bad, known and unknown.

An insidious way in which the risks of vaccination can be incorrectly estimated is by using the number of doses of vaccine which appear to result in injury, rather than the number of children that are administered how ever many doses it takes to injure them. Since nearly all vaccines are currently being recommended to be administered in multiple doses, using doses rather than children can result in gross underestimation of actual risk. We also cannot ignore confounding which occurs when high-risk children are eliminated, either by not receiving the vaccine in question at all, or by receiving only one dose.

Take as an example convulsions resulting from either whooping cough vaccine or whooping cough. The CDC says that 1/1750 vaccinations result in convulsions but that 2/100 children who get whooping cough have convulsions. If we divide the 1750 vaccinations by the between 4 and 5 doses children are required to get, the result is 1/350 to 1/438 children getting convulsions after whooping cough vaccine, not nearly as dramatic a difference.

If we further try to factor in the impact of underreporting of adverse reactions, the actual incidence of which is unknown but presumed to be significant, it becomes clear that there may be no difference, and in fact, that it is possible convulsions are more likely to result after vaccination than after disease.

The fact is, however, that we do not know the true incidence of vaccine adverse reactions, of whooping cough itself, of convulsions after whooping cough or many other relevant and critical factors, including

the actual number of children receiving a vaccine once high-risk children have been removed. We should simply admit it and set about trying to learn what we can. We should not, however, be issuing reassuring assessments of vaccine risk.

When evaluating the risks of vaccines, it is imperative that we look at the big picture. We simply cannot accurately evaluate vaccine benefits or risks in a vacuum, nor consider the evaluation static. Among the many things which need to be considered are the following:

1) The true risk of contracting a disease, in comprable, never vaccinated populations, as well as the true risk of suffering serious consequences from a disease, must be determined. Included in any such analysis should be historical morbidity and mortality data from years prior to the introduction of vaccines, preferably smallpox vaccine. When considering the true risk of long-term serious consequences of disease, new treatment strategies, like erythromycin for whooping cough, and vitamin A for rubeola, should be factored in. The role breastfeeding plays in preventing and/or mitigating the effects of diseases needs to be better understood and factored in as well.

2) The background rate of an event occurring in comparable never vaccinated populations, should be compared to recently and not so recently vaccinated ones. However, as useful and important as background rates are, when making comparisons between groups, such rates should never be used to substantiate claims about whether or not a particular child suffered "residual effects" from some untoward event following vaccination, since a particular child's potential can never be predicted. This holds especially true when estimating an infant's potential.

3) Graphs should be presented fairly, and if they have not been, primary data, rather than graphs, should be used. Included in my submissions is a graph found in the MMWR which provides an excellent example of the dangers of their unquestioned use and "how to lie with statistics". The Y axis uses an inappropriately applied logarithmic scale, the result being that drops in both morbidity and mortality prior to vaccination are made to appear insignificant, while drops occurring post-vaccination are made to appear dramatic. In fact, the opposite is true.

We also cannot ignore the impact of vaccines on changing epidemiology when considering their risks and benefits. For instance, measles may have been made a more serious disease because of measles vaccination. Prior to widespread vaccination, once a population had been exposed to measles, few adults or infants contracted it, adults due to lifelong immunity and infants due to maternal antibodies. Now, adults AND infants are getting the measles, with serious consequences. I would like to include reference to a recent Washington Post article entitled:

"Measles Still Menace to Infants: Vaccinated Moms Pass Less Immunity to Babies". In this article it was noted that although in 1976 3% of measles cases occurred in children less than one, today, more than 25% do. The author also indicated that prior to vaccination, 3 to 4 million measles cases occurred with around 500 deaths. This would make the case-fatality ratio for that period between 1 to 2 per 10,000. In the years 1989, 1990 and 1991 combined, however, it was reported that

around 55,000 people got the measles and 165 died, making the case-fatality ratio dramatically higher at 3 out of 1,000. At this rate, fewer than 175,000 cases per year would be necessary to result in the same number of deaths which used to occur when there were millions of cases.

The CDC says that, although worrisome, the problem would be solved were all preschoolers vaccinated and measles virus eliminated from circulation. Yet I would submit that with waning measles vaccine immunity a fact of life, and subclinical cases of the measles occurring routinely among the vaccinated and considered to boost vaccine-induced immunity, vaccinating preschoolers will not prevent measles from circulating. Indeed, an obvious major source of infection for infants and unimmunized toddlers has been properly vaccinated school-age children who developed most of the clinical measles cases, as well as many subclinical ones. It is, in fact, puzzling that the CDC would offer such reassurances given that they have admitted even 100% vaccinated populations can have outbreaks.

The CDC also says that about 40% of mothers currently do not have protective antibodies and that at the end of the decade that figure will be 100%. This, of course, means that as the percentage of mothers without antibodies rises, the death rate should rise as well, since an even higher percentage of cases will be infants.

Morbidity and mortality statistics for measles should also rise as fewer and fewer adults have natural immunity and more and more adults have waning vaccine immunity. The scenario is quite believeable in which mothers would get measles and pass them on to their infants, whereas before they would never have gotten the measles, and would instead of passing the measles on to their infants, have passed on protective measles antibodies to them.

In other words, measles may not be controllable, and may have been made vastly more serious, by the use of measles vaccination. Adults, in fact, may now be faced with the unsavory prospect of getting measles or receiving a vaccine, neither of which has been proven to be safe for them. Any risk/benefit analysis should take into consideration the impact of vaccine-program induced changing epidemiology on the seriousness of any diseases vaccines are designed to prevent, as well as the consequences, including efficacy, of vaccinating adults against what were once childhood diseases.

The problems which can be overlooked if vaccine analysis is taken out of context are well exemplified in the case of rubella vaccine. A normally benign disease in childhood, usually affording lifelong immunity, it can result in devastating effects if a non-immune pregnant woman is exposed during the critical time period. As devastating as the consequences can be for an infant, it is important to not only determine the actual incidence in epidemic years of congenital rubella syndrome, but whether or not an unvaccinated child allowed exposure to rubella is more or less likely to be immune in adulthood than a previously vaccinated child, given that vaccine immunity is now generally thought to be short-lived. Indeed, it is entirely possible that the risk to the fetus is greater from once-vaccinated mothers, given waning vaccine immunity, and the overall risk to the population greater, once the risks of adult rubella vaccination have been factored

in.

Aside from my earlier recommendations concerning properly designed studies (and by long-term, I mean 20-30 years at least), I would also urge that you recommend some enforcement mechanism vis a vis doctors reporting adverse reactions. Although I realize that adverse reaction reporting is an extremely flawed method, as we all know, in theory as well as in fact, and can neither be viewed as proof of causation or as exhaustive, still we need to get some idea of the range of possible vaccine consequences, as well as to follow up on those we do know about.

Among the many other questions which need to be asked and answered, I would recommend the following:

1. Is cancer more or less likely to occur among the vaccinated? Included in any studies should be reference to SV40, other vaccine contaminants, the role of chromosomal damage as a result of vaccination, and immune system suppression. The notion that a subclinical case of a disease is preferable to a full-blown case should be studied, not assumed. Submitted is a tantalizing study by Ronne in The Lancet in which he found that subclinical cases of the measles resulted in significantly increased rates of serious disease among adults.

2. What, if anything, is the role of vaccine contaminants in causing adverse reactions and new diseases? Included in any such studies would be the role played by such contaminants in the outbreak of AIDS and other recent immune system disorders like chronic fatigue syndrome, Kawasaki's disease and others.

3. Why, during polio epidemics, do most people get polio, gaining lifelong immunity while apparently suffering no ill effects, while a small percentage of the population gains that lifelong immunity at a great price? Included in any examination of this issue should be the role provocation polio and tonsillectomy play in predisposing a person to paralytic or bulbar polio, and the extent to which they each effect the incidence of serious polio.

4. Can vaccination result in post-polio syndrome? If it can, then we need to find out if instead of the small percentage of the population who got polio being susceptible to post-polio syndrome, whether now the entire vaccinated population is at risk.

5. What is the effect of combining vaccines in vivo and in vitro? Studies of this should include clinical trials of all vaccines individually, as well as the effects of their simultaneous administration. The practice of administering vaccinations in combination without data to support their safety and effectiveness should stop until the safety and effectiveness of the practice can be firmly established. Relevant to this discussion, and included among my submissions is a paper by Javier et al in Science magazine in which it was found that two harmless herpes viruses recombined in vivo and became extremely lethal as a result.

6. Has a relatively small risk of long-term consequences from childhood diseases been traded for a vaccine-induced, larger risk of chronic childhood disease? I refer you to a New York Times article I have

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Honorable Lyda Green
Alaska State Senate
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February 20, 1996

Dear Senator Green:

I would like to respond to as many of the points made by the Department of Health and Social Services as I can on such short notice.

1. VAERS (The Vaccine Adverse Events Reporting System) is a passive reporting system. It requires that someone make a connection between a vaccination and a possible adverse event, and that someone report it. Compared to an active surveillance system, which post-marketing surveillance is, considerable under-reporting can be expected. As Dr. James Froeschle of Connaught Laboratories (a vaccine maker) testified to the Institute of Medicine (IOM), and as reported on page 328 of "Adverse Events Associated with Childhood Vaccines - Evidence Bearing on Causality", "From a comparison of spontaneous reports with postmarketing surveillance data, the company estimates about a 50-fold underreporting of adverse events in the passive reporting system." BECAUSE OF THIS AND OTHER LIMITATIONS OF VAERS, ADDITIONAL METHODS OF DATA COLLECTION NEED TO BE DEVISED.
2. Given that neither VAERS nor post-marketing surveillance is proof of causality, ultimately it would be hoped that evidence of temporal association would be followed up by well-designed, controlled studies.
3. Data on the incidence of SIDS goes back only about 25 years. Vaccinations have been around for a lot longer than that (for instance, the first pertussis vaccination was, according to "Vaccines" by Plotkin and Mortimer, developed in 1926). NO ONE HAS ANY IDEA WHAT THE INCIDENCE OF SIDS WOULD BE IF CHILDREN WERE NOT BEING VACCINATED. IT IS ENTIRELY POSSIBLE THAT THERE WAS VERY LITTLE SIDS PRIOR TO VACCINATION. GLIB REJECTION OF THE POSSIBILITY OF A RELATIONSHIP IS BASED ON OPINION, NOT FACT.
4. Please request from the Department copies of all studies which show that "children who had recently gotten a DTP shot were less likely to get SIDS". In the only one which I am aware of, "Diphtheria-tetanus-pertussis immunization and sudden infant death: results of the National Institute of Child Health Development Cooperative Epidmiological Study of Sudden Infant Death Syndrome risk factors", by Hoffman et al in Pediatrics, April of 1987, the authors make it clear that the lesser rate among DPT vaccinated children had nothing to do with protective effects from the vaccine, contrary to what was implied by the Department.
5. The fact that "No deaths caused by anaphylaxis following DTP vaccination have been reported to the CDC since the inception of vaccine-adverse-events reporting began in 1978" merely proves that the CDC is uninformed and that SB185 is sorely needed. Why are they unaware that the IOM found a causal link between the whole cell pertussis vaccine and anaphylaxis, and the drug companies themselves report that such deaths occur (one can consult the PDR for drug company warnings), and THAT SUCH DEATHS HAVE BEEN REPORTED TO VAERS AND COMPENSATED BY THE GOVERNMENT?
6. It is not clear that the risks from the diseases are greater than the risks from the vaccines when it becomes clear that little is known about the magnitude of vaccination risks. Take the CDC's own figures regarding convulsions and DPT vaccine vs. whooping cough the disease. According to the CDC, 1/1750 vaccinations result in convulsion, whereas 2/100 children with whooping cough will have a convulsion. But children get between 4 and 5 doses of vaccine. If we divide 1750 by the

between 4 and 5 doses most children get, the result is 1/350 ro 1/438 children getting convulsions after vaccination. Furthermore if we multipy by 50 the number of incidences one might expect in a post-marketing survey, we arrive at 1/7 to 1/9 temporally associated convulsions. If only 10% of these were deemed caused by the vaccine, 1/70 to 1/90 children could be having convulsions as a result of DPT vaccine.

THE FACT IS, WE DO NOT KNOW HOW MANY TEMPORALLY ASSOCIATED EVENTS ARE ACTUALLY OCCURRING, NOR DO WE KNOW HOW MANY OF THEM ARE ACTUALLY CAUSED BY VACCINATION. SB185 WOULD BEGIN TO RECTIFY THIS SITUATION BY COLLECTING DATA ON ONLY ONE EVENT - TEMPORALLY ASSOCIATED VACCINE DEATHS.

7. It is interesting that the Department failed to note that the death rate in England in 1978 was considerably below prior whooping cough death rates. According to figures I received from the CDC, in 1920 there were 5,122 deaths and 107,473 cases in the U.S. In 1978 in England, there were only 36 deaths for 100,000 cases. It is also interesting to note that no mention was made of possible deaths due to the vaccine which might have been compared to the number of deaths from whooping cough.

Thank you for your fair-minded consideration of the points made here.

Sincerely,

Sandy Mintz

To Senator Kelly
Reference HES, STA
12th Feb. 1996

From Archivides Kalokerinos
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Australia
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Born 28th Sept. 1927. Glen Innes, Australia
Graduated M.b ,B.S. Jan. 1951, University Sydney
Fellow Royal Society of Tropical Medicine, London

Retired from full-time practice.
Consultant to various organisations in Australia and overseas and Australian Aboriginal communities.
Special interests - Aboriginal infant and adult health, Vitamin and mineral supplements, nutrition, and problems associated with routine vaccine administrations.

In 1957 I commenced work as the sole medical practitioner in the remote township of Collarenebri, 500 miles north-west of Sydney. There were about 500 Caucasians in the town, 200 Aborigines on the nearby reserve and about 500 Caucasians in the surrounding district.

Before my time in Collarenebri and for the first ten years of my period there an extraordinarily high infant mortality rate, amongst Caucasians and Aborigines, was apparent. During one 24 hour period three Caucasian babies died.

The infant deaths were strange. Some infants who were apparently well or suffering from a trivial illness, were found dead in their cots - typical sudden, unexpected, infant deaths. Other infants who were apparently well, or suffering from trivial complaints, went into unexplained shock from which they could not be resuscitated. Others became excessively irritable, then unconscious and died. In all cases autopsies failed to offer satisfactory explanations for death. In some cases autopsies revealed yellow patches in the liver and it was observed, before death, that these cases displayed varying degrees of liver pain and tenderness.

All other doctors in Australia, including academic staff and State and Commonwealth Departments of Health, denied that infant death rates were high in other areas and denied the existence of the clinical patterns observed by myself. Years later I learned that the problems were widespread across Australia and, indeed, worse in many areas.

In other words, I was deliberately misinformed by some and others appeared incapable of recognising what was going on before their eyes. Sometimes, for reasons not fully understood, epidemics of one of the disease patterns occurs - for example, *The Dark Disease Of Naples,* (Italy) during the late 1970's where infants and children became suddenly unconscious, for no known reason, and died. Two thirds of these cases had upper respiratory infections, the other third had recently received routine vaccinations.

Eventually I found that intramuscular or intravenous Vitamin C, if administered early, reversed the shock state and the unconscious state. I was fortunate because I was always able to commence treatment early.

The first injection of Vitamin C was given in December 1967. From that time on, until I left the area in November 1975, there were no more infant deaths under my care. I was also able to drop the infant mortality rates in neighbouring districts. Other doctors who followed my methods achieved similar results.

However, I did observe that routine immunisations had a dreadful effect on some infants for a period of some weeks following the administration. A few suffered from an apparent immune paralysis and contracted serious bacterial infections. Others went into the strange state of shock or became excessively irritable , then unconscious. Both states could be reversed by intravenous Vitamin C. Bacterial infections were difficult to control.

Because of this routine immunisations were sometimes delayed. The percusses component was sometimes omitted and sick infants received injections of vitamin C.

It is important to note that most standard methods of medical treatment were always employed, before and after the realisation of the importance of Vitamin C and the harm sometimes done by routine vaccinations. What made the difference to mortality rates (and the figures could hardly be more dramatic) was the uses of Vitamin C and care with routine vaccinations.

I should also inform you that in the state of NSW records of vaccinations, including batch numbers, are kept and copies given to all parents.

Family Health Pataline

IN THIS ISSUE:

- Women who gave birth to an infant who died during 1992-94 had less prenatal care than the overall population of women giving birth in Alaska during 1992.
- Among women who gave birth to an infant who died, the highest rates of inadequate prenatal care were identified in young mothers and those with chart documentation of prepregnancy alcohol drinking.
- The infant mortality rate due to extreme prematurity or low birthweight declined 52% from 1979-80 to 1991-92.
- All of the decrease in mortality due to extreme prematurity or low birthweight occurred because of increased survival of premature or low birthweight infants rather than a decrease in the premature or low birthweight birth rate.
- Alaska Natives, blacks, and teenage mothers have significantly higher mortality rates due to extreme prematurity or low birthweight because of higher premature or low birthweight birth rates.

In this issue we present a description of the Alaska Maternal-Infant Mortality Review (MIMR) Process and an evaluation of data from this project regarding pregnancy related risk factors and prematurity.

The MIMR Process

The MIMR review team

The MIMR review team consists of representatives from the Section of Maternal, Child, and Family Health (MCFH), the Bureau of Vital Statistics, and the Division of Family and Youth Services; private physicians, nurses, and other medical providers; and medical and programmatic staff from the Alaska Area Native Health Service (Indian Health Service) and the Regional Native Health Corporations.

Identification of an infant death

The MIMR review team attempts to identify infant deaths through several sources.

- Deaths occurring outside the hospital and of questionable etiology are referred to one of the state coroners. The state coroners in turn call an Infant Death Hotline located at MCFH.
- The Bureau of Vital Statistics matches the death and birth certificates for any infant under one year of age and sends this information to the MIMR program.
- MIMR staff read the newspaper obituaries section to identify infant deaths.

Collecting data for each infant death

Multiple data sources are used to create a complete picture of the circumstances leading to an infant's death.

- Birth and death certificates. We collect information from matched birth and death certificates including date and time of death, number of prenatal visits, trimester prenatal care began, birthweight, and APGAR scores.
- Infant medical records. A standard abstraction tool is used to collect information from hospital and clinic records on the immediate neonatal circumstances as well as subsequent illnesses, clinic or emergency room visits, hospitalizations, treatments and immunizations, and a clinical summary of events immediately preceding death.
- Maternal medical records. A standard abstraction tool is used to collect information on the mother's medical history, previous pregnancy history, and prenatal course. If the number of prenatal care visits or the trimester prenatal care visits were initiated is not available from the birth certificate, this information is collected from the maternal medical record.
- Autopsies. Infants who die outside of the hospital usually have an autopsy. Autopsies are performed on infants who die in the hospital less frequently. A standard abstraction tool is used to collect information on the gross anatomic, organ specific, and microscopic findings.

- **Family interviews.** MIMR staff offer a home interview, administered by a public health nurse, to the familes of infants who died outside of the hospital. Information collected through the home interview includes family demographic data, maternal reproductive history and pregnancy planning, prenatal care and delivery history (including payment methods for these services), family life circumstances, infant health care, and the immediate circumstances of the infant's death.

The review process

Three steps constitute the review process.

- **Monthly mortality reviews.** Each month, a representative sample of committee members from various disciplines, including physicians, nurses, administrative staff, and public health program managers meet to review the information collected for each infant. The committee determines a consensus cause of death and identifies potentially modifiable contributing factors to the infant's death.

- **Data entry and analysis.** Information from the various sources, including the monthly mortality reviews, is entered into a computerized database and analyzed by the MIMR chairman and a pediatric epidemiologist.

- **Yearly MIMR committee meetings.** Once each year, committee members meet to discuss findings, identify problems with the review process and develop consensus recommendations.

Findings and Recommendations

General

The MIMR committee has reviewed 121 deaths: we reviewed 43 of 92 deaths which occurred during 1992, 45 of 90 deaths which occurred during 1993, and 33 of an unknown number of deaths which occurred during 1994. During 1992, we included only deaths which occurred from June forward. Failure to review a death was most commonly due to lacking complete records for a particular infant. This in turn usually resulted from a failure to obtain maternal prenatal records from the Alaska Native Health Service: 96%, 97%, and 66% of incomplete charts during 1992, 1993, and 1994, respectively, were for Alaska Native children. Home interviews were offered only for children who died outside of the hospital setting. To date, 24 interviews have been completed, 8 women declined an interview, 8 women have moved and could not be located, and 44 interviews are pending.

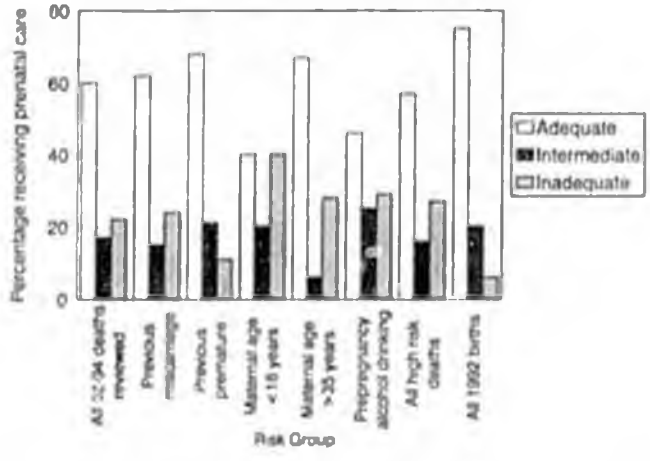
Pregnancy related risk factors

Findings

Among the cohort of mothers who gave birth to the 121 infants who died, 20% had chart documented evidence of alcohol consumption during the three months before pregnancy, 4% were younger than 18 years and 9% were older than 35 years, 16% had at least one previous preterm birth, 28% had at least one previous miscarriage, and 55% had at least one of these risk factors.

We used the Kessner Index to define adequacy of prenatal care. Women who gave birth to an infant who died during 1992-94 had less prenatal care than the overall population of women giving birth in Alaska during 1992 (Figure 1), particularly in the inadequate prenatal care category. Women in our study with risk factors identifiable before pregnancy - such as maternal age, substance use history, and previous adverse pregnancy outcomes - received no greater prenatal care than the general cohort of women. The highest rates of inadequate prenatal care were identified among young mothers and those with chart documentation of prepregnancy alcohol drinking.

Figure 1. Adequacy of prenatal care for 121 infants who died during 1992-94 by various risk groups; for comparison adequacy of prenatal care for all 1992 births is also included.



Recommendations

Identification of women with a high risk of adverse pregnancy outcomes and enrollment of these women into prenatal care programs theoretically contributes to lower rates of premature delivery and hence lower infant mortality rates[1]. Unfortunately, research has failed to document the effectiveness of this approach[2,3]. Researchers may have failed to document the efficacy of prenatal care because they measured the quantity rather than the quality of prenatal services. For example, prenatal care programs connected with substance use, nutrition, domestic violence, and financial assistance services may more effectively decrease adverse pregnancy outcomes than prenatal care programs which focus only on the physical aspect of pregnancy. Additionally, recent research indicates that identification and treatment of bacterial vaginosis during pregnancy may reduce the incidence of preterm delivery[4]. Finally, recent

research suggests that premature birth clusters in families[5], a finding supported by our data. This emphasizes the importance of early identification and monitoring of women who have had previous preterm births or who were born preterm themselves.

Based on our findings, the MIMR committee recommends:

- **Encouraging innovative approaches designed to increase prenatal care and to link prenatal care with other services. Health care providers should identify pregnant women at high risk for domestic violence, substance abuse, poverty, and pregnancy related infections AND refer them for appropriate services.**
- **Identifying and closely monitoring women who have had a previous preterm birth or who were born prematurely themselves.**
- **Using the Pregnancy Risk Assessment Monitoring System (PRAMS)[6] to determine barriers to prenatal care.**

Prematurity and Low Birthweight

Findings

From 1979-80 to 1991-92, the infant mortality rate due to extreme prematurity or low birthweight (defined as an infant born at less than 1000 g or less than 28 weeks gestation, who dies before 28 days of life, and who did not die of SIDS, trauma, congenital anomalies [except pulmonary hypoplasia], or cancer) declined from 2.9 to 1.7 per 1000 live births per year (chi-square for trend = 9.6, p=0.002) a decline of 52% (Figure 2).

A decline in mortality rate due to low birthweight or prematurity can occur for two reasons: a decline in the proportion of infants born with extreme prematurity/low birthweight or a decrease in the proportion of infants born with extreme prematurity/low birthweight who die. The proportion of infants born with extreme prematurity/low birthweight who died decreased from 44% during 1979-80 to 26% during 1991-92 (chi-square for trend, 9.1; p=0.003) (Figure 3). During the same time period, the rate of extremely premature/low birthweight births did not change.

Compared to whites, the risk ratio for mortality due to extreme prematurity/low birthweight among Alaska Natives was 1.23 (95% confidence interval [CI], 0.95 to 1.58) and among blacks was 2.96 (95% CI, 2.09 to 4.21). All of the increase in mortality for Alaska Natives and blacks resulted from higher extreme prematurity/low birthweight birth rates. Compared to whites, Alaska Natives had a risk ratio of 1.62 (95% CI, 1.42, 1.86) and blacks had a risk ratio of 3.31 (95% CI, 2.72 to 4.04) for delivering an extremely premature or low birthweight infant.

Compared to mothers 20-29 years of age, the risk ratio for mortality due to extreme prematurity/low birthweight among mothers less than 20 years of age was 1.84 (95% CI, 1.37 to 2.47) and among mothers 30 years or older was 1.09 (95% CI, 0.86 to 1.39). All of the increased risk for younger mothers occurred because of an increase in the extreme prematurity/low birthweight birth rate: compared to mothers 20-29 years of age, mothers less than 20 years had a risk ratio of 1.84 (95% CI, 1.37 to 2.47).

Figure 2. Mortality rate due to extreme prematurity or low birthweight: Alaska, 1979-92

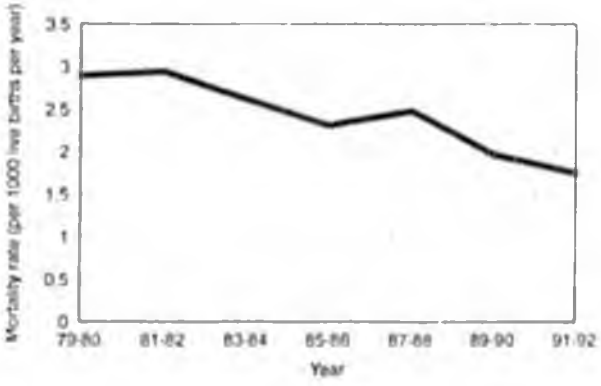
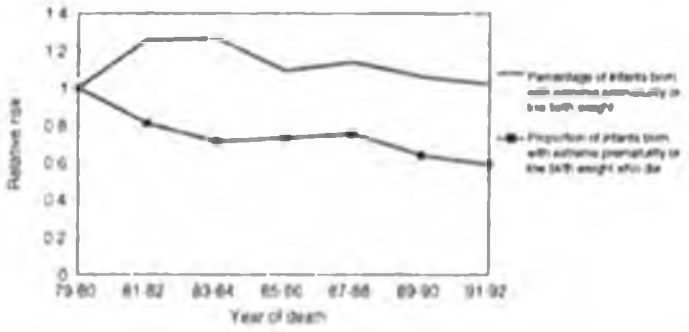


Figure 3. Using 1979-80 data as baseline, the relative risk by year for the percentage of infants born with extreme prematurity or low birth weight, and the proportion of infants born with extreme prematurity or low birthweight who die; Alaska, 1979-92



Recommendations

The cause of prematurity and low birthweight remains one of the most perplexing problems of medical research. As indicated by our data, advances have occurred in the survival of babies born with extreme prematurity or low birthweight, primarily through technology advances such as mechanical ventilation, surfactant therapy, nutritional and fluid support, and infection control. Unfortunately, no improvement has occurred in decreasing the number of children born with

prematurity or low birthweight, a trend found throughout the country[7]. Thus prematurity and low birthweight continue to cause a disproportionate amount of neonatal mortality in the U.S.[8].

In Alaska distinct racial differences exist among mortality rates due to extreme prematurity/low birthweight. These differences reflect differences in the rate of premature delivery rather than differences in survival. Similar to findings in the rest of the United States, blacks had increased rates of extreme premature/low birthweight delivery. Additionally, younger mothers had increased rates of extreme premature/low birthweight births, a result recently documented in Utah[9].

Based on our findings, the MIMR Committee recommends:

- **Directing efforts primarily toward decreasing the rate of preterm/low birthweight birth, rather than emphasizing postnatal care.**
- **Focusing efforts to decrease the rate of preterm/low birthweight birth on specific high risk groups such as blacks, Alaska Natives, and teenage mothers.**

Submitted by:
Bradford D. Gessner, M.D.

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Adverse Events Associated with CHILDHOOD VACCINES

Evidence Bearing on Causality

Kathleen R. Stratton, Cynthia J. Howe, and
Richard B. Johnston, Jr., *Editors*

Vaccine Safety Committee

Division of Health Promotion and Disease Prevention

INSTITUTE OF MEDICINE

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1

Executive Summary

"Our aim, therefore, must be to study these [complications] as fully as possible in the confident expectation that, as in other branches of science, knowledge will bring enlightenment" (Wilson, 1967).

Childhood immunization has been one of the foremost public health measures of the twentieth century. It has allowed control and prevention of many diseases from which morbidity and mortality can be staggering. Medical personnel in the United States currently rarely see a case of the infectious diseases against which the vaccines are directed. Yet, recent measles epidemics on college campuses and in inner cities suggest that vaccine-preventable disease is not to be ignored. The first health initiative of the new presidential administration was to increase funding for childhood immunization programs to boost vaccination rates in the United States, particularly for children under age 2 years.

BACKGROUND AND HISTORY

The public policy debate regarding immunization stretches beyond the question of how to meet the goals of universal immunization. Concern over the safety of pertussis vaccine was long-standing in Great Britain by the time of the 1982 airing in the United States of a documentary entitled "DPT: Vaccine Roulette" (WRC-TV, 1982) and the 1985 publication of *DPT: A Shot in the Dark* (Coulter and Fisher, 1985). Concern has stretched to other vaccines and has spawned the formation of groups of interested citizens throughout the United States, for example, National Vaccine Information Center/Dissatisfied Parents Together, Determined Parents to Stop Hurting Our Tots, Concerned Health Professionals and Others, and Parents

Concerned About the Safety of Vaccines. More articles and books have been published (e.g., Coulter, 1990; Miller, 1992) to alert the public to the potential risks of vaccination.

In 1986, the U.S. Congress passed the National Childhood Vaccine Injury Act (NCVIA; P.L. 99-660) in response to worries about the safety of currently licensed childhood vaccines and in response to the economic pressures that were threatening the integrity of childhood immunization programs. The litigation costs associated with claims of damage from vaccines had forced several companies to end their vaccine research and development programs as well as to stop producing already licensed vaccines. The NCVIA was an attempt to encourage and ensure vaccine production by creating a no-fault compensation program (the National Vaccine Injury Compensation Program) as a required first resort for those who believed that they or their children had been injured by certain vaccines. The need for a compensation program had long been recognized, and several groups had proposed possible mechanisms for compensating people believed to be injured by vaccination (Institute of Medicine, 1985; Office of Technology Assessment, 1980). This program was envisioned to alleviate, but not completely eliminate, manufacturer liability and encourage research and development of more and safer vaccines. The compensation program is administered by the federal government and is financed by an excise tax on the sale of vaccines covered by the program (Iglehart, 1987; Mariner, 1992).

In addition to establishing the compensation program, the NCVIA set forth other vaccine-related efforts to be carried out by the U.S. Department of Health and Human Services, including mandatory reporting of specific adverse events following childhood immunizations against diphtheria, tetanus, pertussis, measles, mumps, rubella, and polio (see box entitled The Vaccine Injury Table in Chapter 10); voluntary reporting of any reaction to any immunization to the Vaccine Adverse Event Reporting System (see Chapter 10 for a discussion of this passive surveillance system and Figure 1-1 for a copy of the reporting form); the creation of a National Vaccine Program Office to coordinate federal vaccine initiatives and to help meet immunization coverage goals; the establishment of advisory groups to the National Vaccine Program and the National Vaccine Injury Compensation Program; and better communication of the potential risks of vaccines through public information pamphlets that are distributed at the time of vaccination (under the direction of the Centers for Disease Control and Prevention) and changes in vaccine package inserts (under the direction of the U.S. Food and Drug Administration).

The NCVIA also mandated that the Secretary of the U.S. Department of Health and Human Services enlist the help of the Institute of Medicine (IOM) of the National Academy of Sciences to study the adverse effects of childhood vaccines. The NCVIA called for two specific studies. The first, mandated under Section 312 of P.L. 99-660, was to address the serious adverse effects of pertussis and rubella vaccines. The Committee to Review the Adverse Consequences of Pertussis and Rubella Vaccines published its findings in 1991 (Institute of Medicine, 1991). Appendix A contains the Executive Summary of that report.

The second study, mandated under Section 313 of P.L. 99-660, was to review adverse events associated with other vaccines commonly administered during childhood. The Vaccine Safety Committee, which was charged with performing the second study, was convened early in 1992. The results of that inquiry are provided in this report.

THE CHARGE TO THE COMMITTEE

The members of the interdisciplinary, 14-member Vaccine Safety Committee have expertise in such areas as immunology, pediatrics, internal medicine, infectious diseases, neurology, virology, microbiology, epidemiology, and public health. The committee was charged with (1) reviewing the relevant scientific and medical literature on specific risks to children associated with the vaccines or vaccine components directed against tetanus, diphtheria, measles, mumps, polio, *Haemophilus influenzae* type b, and hepatitis B currently licensed for use in the United States and (2) reviewing the available data on specific risk-modifying factors, that is, circumstances under which administration of these vaccines increases the risk of an adverse event, characteristics of groups known to be at increased risk of an adverse event, and timing of vaccination that increases the risk of an adverse event.

Risk-benefit comparisons or recommendations about immunization schedules were not within the charge to the Vaccine Safety Committee. Despite the name of the committee, many aspects of vaccine safety, such as purity standards or production techniques, also were beyond the committee's charge.

Both IOM studies mandated in P.L. 99-660 entailed the evaluation of the weight of scientific and medical evidence bearing on the question of whether a causal relation exists between certain vaccines and specific serious adverse events. Like the Committee to Review the Adverse Consequences of Pertussis and Rubella Vaccines, the Vaccine Safety Committee approached its task from a position of neutrality, presuming neither the presence nor the absence of a causal relation between the vaccines and the adverse events under consideration.

THE STUDY PROCESS

Over the course of 18 months, the committee met six times, reviewed more than 7,000 abstracts of scientific and medical studies, read more than 2,000 published books and articles (including many sources in the non-

English literature), analyzed information from U.S. Public Health Service-administered reporting systems for adverse reactions to vaccines, and considered material submitted by interested parties. The committee solicited input from scientists who were invited to participate in two open scientific meetings and from other interested parties at two open public meetings. Details regarding how the committee gathered information are given in Appendix B. All salient information from those reviews is contained in this report.

P.L. 99-660 stated that the review was to include those vaccines covered by the National Vaccine Injury Compensation Program. *Haemophilus influenzae* type b (Hib) and hepatitis B vaccines were added for consideration because of the increasing use of these vaccines and the supposition that in the near future they could be mandatory vaccines covered by the National Vaccine Injury Compensation Program. The list of adverse events investigated for this report derived primarily from negotiations with representatives of the U.S. Public Health Service. However, preliminary investigations into additional adverse events were prompted by queries from interested parties or committee members. After considering the information from these preliminary investigations, the committee added several vaccine-adverse event relations to the original list. Table B-1 in Appendix B contains a complete listing of the specific vaccine-adverse event relations under study.

The report begins with background information. Chapter 2 contains an in-depth discussion of the approach used by the committee to weigh the evidence and assess causality. Information on the neurologic disorders and immunologic reactions discussed in much of the report is contained in Chapters 3 and 4. Chapters 5 through 9 include the vaccine-specific evidence and conclusions. All information (evidence, causality argument, and conclusions) regarding death as an adverse event associated with vaccination is contained in Chapter 10.

Adverse Effects of Pertussis and Rubella Vaccines (Institute of Medicine, 1991), the report of the predecessor IOM committee, provides an in-depth review of the literature concerning the adverse events associated with diphtheria and tetanus toxoids and pertussis vaccine (DPT), as well as pertussis vaccine, and should be referred to for conclusions regarding DPT. Appendix A contains the Executive Summary of that report. The charge to the Vaccine Safety Committee was to examine adverse events associated with tetanus toxoid as well as tetanus and diphtheria toxoid combination preparations. The committee reviewed data concerning DPT if the data also concerned diphtheria and tetanus toxoids for pediatric use (DT); however, it was beyond the committee's scope to make conclusions about pertussis vaccine or DPT.

The IOM Committee to Review the Adverse Consequences of Pertussis

and Rubella Vaccines made determinations of causality only for rubella vaccine and the rubella vaccine component of multivalent vaccines, but not for measles-mumps-rubella vaccine (MMR). Thus, the Vaccine Safety Committee reviewed data regarding immunization with MMR as well as data on monovalent measles and mumps preparations. The committee has made separate determinations of causality for the measles and mumps vaccine components for the adverse events for which data were available, particularly if measles or mumps vaccine-strain virus was isolated from the patient. In circumstances in which a causality assessment specific to monovalent measles or mumps vaccine was not possible, this is stated in the conclusion regarding that specific adverse event.

In circumstances in which the committee determined that a component of a multivalent preparation was causally related to a specific adverse event, but there is no direct experience of such an adverse event being caused by the multivalent preparation, the committee states this, but judges that the combined preparation also is causally related to that adverse event.

Many case reports described an adverse event(s) in a patient who received more than one vaccine. A common combination, as a result of the immunization schedules recommended in the United States, is DPT, oral polio vaccine, and Hib vaccine. Assessment of causality in those reports was more difficult than if the patient had received only one vaccine or vaccine component, but the committee considered that the reports could be theoretically supportive of causality for the combination but not in themselves sufficient to allow a firm judgment regarding causality.

CAUSALITY AND WEIGHT OF EVIDENCE

As discussed in detail in Chapter 2, the committee considered four types of evidence: biologic plausibility; case reports, case series, and uncontrolled observational studies; controlled observational studies; and controlled clinical trials. The committee used qualitative and quantitative approaches to weigh each type of evidence. Table 1-1 contains a summary of the different types of evidence for every vaccine-adverse event relation studied. The committee believes that although it is plausible that there is a causal relation between any of the vaccine-adverse event associations under review, plausibility has been demonstrated only for certain ones of these. Therefore, information on the plausibility of a causal relation was classified in Table 1-1 as either theoretical only or as demonstrated. The other types of evidence were classified in Table 1-1 as nonexistent, indeterminate, or as weighing, on the whole, for or against a determination of a causal relation. The consideration of all four types of evidence as a whole led to a conclusion of the final weight of evidence regarding causality. Table 1-2 contains these conclusions.

Vaccine and Adverse Event	Biologic Plausibility[a]	Case Reports, Case Series, and Uncontrolled Observational Studies	Controlled Observational Studies and Controlled Clinical Trials
Diphtheria and Tetanus Toxoids[c]			
Encephalopathy	Demonstrated	Indeterminate	Against (DT) No data (Td, T)
Infantile spasms[d] (DT only)	Theoretical only	No data	Against
Residual seizure disorders other than infantile spasms	Theoretical only	Indeterminate (DT, T) No data (Td)	No data
Demyelinating diseases of the central nervous system	Demonstrated	For	No data
Guillain-Barre syndrome	Demonstrated	For (T) Indeterminate (DT, Td)	No data
Mononeuropathy	Theoretical only	Indeterminate (T, Td) No data (DT)	No data
Brachial neuritis	Theoretical only	For (T) Indeterminate (Td) No data (DT)	No data
Arthritis	Theoretical only	Indeterminate	No data
Erythema multiforme	Theoretical only	Indeterminate (DT, Td) No data (T)	No data
Anaphylaxis	Demonstrated	For (T) Indeterminate (DT, Td)	No data
Death from SIDS (DT only)[e]	Theoretical only	Indeterminate	Against
Measles Vaccine[f]			
Encephalopathy	Demonstrated	Indeterminate	Indeterminate
Subacute sclerosing panencephalitis	Demonstrated	Indeterminate	Indeterminate
Residual seizure disorder	Demonstrated	Indeterminate	No data
Sensorineural deafness	Theoretical only	Indeterminate (MMR)	No data
Optic neuritis	Demonstrated	Indeterminate	No data
Transverse myelitis	Demonstrated	Indeterminate	No data
Guillain-Barre syndrome	Demonstrated	Indeterminate	No data
Thrombocytopenia	Demonstrated	Indeterminate (measles) For (MMR)	Indeterminate (measles) No data (MMR)
Insulin-dependent diabetes mellitus	Theoretical only	Indeterminate	Indeterminate

continued

TABLE 1-1 *(continued)*

Vaccine and Adverse Event	Biologic Plausibility[b]	Case Reports, Case Series, and Uncontrolled Observational Studies	Controlled Observational Studies and Controlled Clinical Trials
Anaphylaxis	Theoretical only	For	No data
Death from vaccine-strain viral infection[c]	Demonstrated	For	No data
Mumps Vaccine[d]			
Encephalopathy	Demonstrated	Indeterminate	No data
Aseptic meningitis	Demonstrated	Indeterminate	No data
Residual seizure disorder	Theoretical only	No data	No data
Neuropathy	Theoretical only	No data	No data
Sensorineural deafness	Demonstrated	Indeterminate (MMR)	No data
Insulin-dependent diabetes mellitus	Demonstrated	Indeterminate	Indeterminate
Sterility	Demonstrated	No data	No data
Thrombocytopenia	Demonstrated	Indeterminate	No data
Anaphylaxis	Theoretical only	Indeterminate (MMR)	No data
Polio Vaccine (OPV and IPV)[e]			
Guillain-Barre syndrome	Demonstrated (OPV) Theoretical only (IPV)	For (OPV) Indeterminate (IPV)	For (OPV) No data (IPV)
Transverse myelitis	Demonstrated (OPV) Theoretical only (IPV)	Indeterminate (OPV) No data (IPV)	No data
Poliomyelitis (OPV only)	Demonstrated	For	No data
Thrombocytopenia (IPV)	Theoretical only	No data	No data
Anaphylaxis (IPV)	Theoretical only	No data	No data
Death from SIDS[c]	Theoretical only	Indeterminate	Indeterminate
Death from vaccine-strain viral infection, including from paralytic poliomyelitis (OPV only)[c]	Demonstrated	For	No data
Hepatitis B Vaccine			
Guillain-Barre syndrome	Demonstrated	Indeterminate	No data
Demyelinating diseases of the central nervous system	Demonstrated	Indeterminate	No data
Arthritis	Demonstrated	Indeterminate	No data
Anaphylaxis	Theoretical only	For	No data
Death from SIDS[c]	Theoretical only	Indeterminate	No data

(continued)

TABLE 1-1 *(continued)*

Vaccine and Adverse Event	Biologic Plausibility[2]	Case Reports, Case Series, and Uncontrolled Observational Studies	Controlled Observational Studies and Controlled Clinical Trials
Haemophilus influenzae type b Vaccine			
Guillain-Barre syndrome	Theoretical only	Indeterminate	No data
Transverse myelitis	Theoretical only	Indeterminate	No data
Thrombocytopenia	Theoretical only	Indeterminate	Indeterminate
Susceptibility to early Hib disease[n]	Demonstrated	Indeterminate	For (PRP) Against (conjugated)
Anaphylaxis	Theoretical only	Indeterminate	No data
Death from SIDS[r]	Theoretical only	Indeterminate	No data

[q]*Indeterminate* indicates that there is evidence in this category, but the committee did not consider that, on the whole, it weighed either for or against a causal relation. *No data* indicates that the committee did not find data of this type directly bearing on a causal relation between the vaccine and the adverse event.

[p]The committee considered all adverse events to be theoretically plausible and, therefore, classified plausibility in support of causality as either theoretical only or demonstrated. Demonstrated biologic plausibility refers to information on the known effects of the natural disease against which the vaccine is given and the results of animal experiments and in vitro studies.

[o]Unless noted otherwise, the classification for tetanus toxoid (T), diphtheria-tetanus toxoid for pediatric use (DT), and tetanus-diphtheria toxoid for adult use (Td) is the same. The committee was not charged with assessing monovalent diphtheria toxoid or the combined diphtheria and tetanus toxoids and pertussis vaccine (DPT). In Appendix A, see the Executive Summary of *Adverse Effects of Pertussis and Rubella Vaccines* for conclusions about DPT.

[n]Infantile spasms occur only in the age group that receives DT but not Td or T. A possible causal relation between infantile spasms and Td and T was not examined.

[r]In this table, the committee summarizes the data regarding the causal relation between the vaccine and only those deaths that are classified as sudden infant death syndrome (SIDS) or that are a consequence of vaccine-strain viral infection. SIDS occurs primarily in infants too young to receive tetanus and diphtheria toxoids for adult use, measles vaccine, mumps vaccine, or usually, tetanus toxoid. Therefore, a relation between these vaccines and SIDS was not assessed. If the evidence favors the acceptance of (or establishes) a causal relation between a vaccine and an adverse event, and if that adverse event can be fatal, then in the committee's judgment the evidence favors the acceptance of (or establishes) a causal relation between the vaccine and death from the adverse event. Direct evidence regarding death in association with a potentially fatal adverse event that itself is causally related to the vaccine is limited to tetanus-diphtheria toxoid for adult use and Guillain-Barre syndrome, tetanus toxoid and anaphylaxis, and oral polio vaccine (OPV) and poliomyelitis. Direct evidence regarding death in association with a potentially fatal adverse event that itself is causally related to the vaccine is lacking for measles vaccine and anaphylaxis, MMR and anaphylaxis, OPV and Guillain-Barre syndrome, hepatitis B vaccine and anaphylaxis, and *Haemophilus influenzae* type b unconjugated PRP vaccine and early-onset *Haemophilus influenzae* type b disease in children age 18 months or older who receive their first Hib immunization with unconjugated PRP vaccine. See Chapter 10 for details. The data are indeterminate regarding the causal relation between the vaccine and causes of death other than those discussed above. Data regarding death as an adverse consequence of the vaccines under review are discussed in Chapter 10 rather than in the vaccine-specific chapters.

[s]The committee was charged with assessing the causal relation between several adverse events and measles vaccine or mumps vaccine. The committee was not charged with assessing monovalent rubella vaccine. In Appendix A, see the Executive Summary of *Adverse Effects of Pertussis and Rubella Vaccines* for conclusions regarding rubella vaccine. [t]MMR1 indicates that the data derive exclusively from the multivalent preparation.

[u]OPV is oral polio vaccine; IPV is inactivated polio vaccine.

[v]The committee assessed data regarding the increased susceptibility to *Haemophilus influenzae* type b disease within 7 days of immunization with *Haemophilus influenzae* type b vaccine. For this adverse event only, the committee was able to separate the data regarding the unconjugated (PRP) vaccine from the data regarding the conjugated vaccines.

TABLE 1-2 Conclusions Based on the Evidence Bearing on Causality

DT/Td/T	Measles[a]	Mumps[a]	OPV/IPV[a]	Hepatitis B	*H. influenzae* type b
Category 1: No Evidence Bearing on a Causal Relation					
		Neuropathy	Transverse myelitis (IPV)		
		Residual seizure disorder	Thrombocytopenia (IPV)		
			Anaphylaxis (IPV)		
Category 2: The Evidence Is Inadequate to Accept or Reject a Causal Relation					
Residual seizure disorder other than infantile spasms	Encephalopathy	Encephalopathy	Transverse myelitis (OPV)	Guillain-Barre syndrome	Guillain-Barre syndrome
Demyelinating diseases of the central nervous system	Subacute sclerosing panencephalitis	Aseptic meningitis	Guillain-Barre syndrome (IPV)	Demyelinating diseases of the central nervous system	Transverse myelitis
Mononeuropathy	Residual seizure disorder	Sensorineural deafness (MMR)	Death from SIDS[c]	Arthritis	Thrombocytopenia
Arthritis	Sensorineural deafness (MMR)	Insulin-dependent diabetes mellitus		Death from SIDS[c]	Anaphylaxis
	Optic neuritis	Sterility			Death from SIDS[c]
Erythema multiforme	Transverse myelitis	Thrombocytopenia			
	Guillain-Barre syndrome	Anaphylaxis[d]			
	Thrombocytopenia				
	Insulin-dependent diabetes mellitus				
Category 3: The Evidence Favors Rejection of a Causal Relation					
Encephalopathy[e]					Early onset *H. influenzae* b disease (conjugate vaccines)
Infantile spasms (DT only)[f]					
Death from SIDS (DT only)[f,g]					
Category 4: The Evidence Favors Acceptance of a Causal Relation					
Guillain-Barre syndrome[h]	Anaphylaxis[d]		Guillain-Barre syndrome (OPV)		Early-onset *H. influenzae* b disease in children age 15 months or older who receive their first Hib immunization with unconjugated PRP vaccine
Brachial neuritis[h]					

(continued)

TABLE 1-2 *(continued)*

DT,Td/T	Measles[a]	Mumps[a]	OPV/IPV[b]	Hepatitis B	*H. influenzae* type b
Category 3: The Evidence Establishes a Causal Relation					
Anaphylaxis[a]	Thrombocytopenia (MMR)		Poliomyelitis in recipient or contact (OPV)	Anaphylaxis	
	Anaphylaxis (MMR)[d]				
	Death from measles vaccine-strain viral infection[c,d]		Death from polio vaccine-strain viral infection[c,d]		

[a]If the data derive from a monovalent preparation, then in the committee's judgment the causal relation extends to multivalent preparations. If the data derive exclusively from MMR, that is so indicated by (MMR). In the absence of any data on the monovalent preparation, in the committee's judgment the causal relation determined for the multivalent preparations does not extend to the monovalent components.

[b]For some adverse events, the committee was charged with assessing the causal relation between the adverse event and only oral polio vaccine (OPV) (paralytic and nonparalytic poliomyelitis) or only inactivated polio vaccine (IPV) (anaphylaxis and thrombocytopenia). If the conclusions are different for OPV than for IPV for the other adverse events, that is so noted.

[c]This table lists weight-of-evidence determinations only for deaths that are classified as SIDS and deaths that are a consequence of vaccine-strain viral infection. However, if the evidence favors the acceptance of (or establishes) a causal relation between a vaccine and an adverse event, and that adverse event can be fatal, then in the committee's judgment the evidence favors the acceptance of (or establishes) a causal relation between the vaccine and death from the adverse event. Direct evidence regarding death in association with a vaccine-associated adverse event is limited to tetanus-diphtheria toxoid for adult use (Td) and Guillain-Barré syndrome, tetanus toxoid and anaphylaxis, and OPV and poliomyelitis. Direct evidence regarding death in association with a potentially fatal adverse event that itself is causally related to the vaccine is lacking for measles vaccine and anaphylaxis, MMR and anaphylaxis, OPV and Guillain-Barré syndrome, hepatitis B vaccine and anaphylaxis, and *H. influenzae* type b unconjugated PRP vaccine and early-onset *H. influenzae* type b disease in children age 18 months or older who receive their first Hib immunization with unconjugated PRP vaccine. See Chapter 10 for details.

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[d]The evidence that establishes a causal relation for anaphylaxis derives from MMR. The evidence regarding monovalent measles vaccine favors acceptance of a causal relation, but are less convincing, mostly because of incomplete documentation of symptoms or the possible attenuation of symptoms by medical intervention.

[e]The evidence derives from studies of diphtheria-tetanus toxoid for pediatric use (DT). If the evidence favors rejection of a causal relation between DT and encephalopathy, then in the committee's judgment the evidence favors rejection of a causal relation between Td and tetanus toxoid and encephalopathy.

[f]Infantile spasms and SIDS occur only in an age group that receives DT but not Td or tetanus toxoid.

[g]The evidence derives mostly from DPT. Because there are supportive data favoring rejection of a causal relation between DT and SIDS as well, if the evidence favors rejection of a causal relation between DPT and SIDS, then in the committee's judgment the evidence favors rejection of a causal relation between DT and SIDS.

[h]The evidence derives from tetanus toxoid. If the evidence favors acceptance of (or establishes) a causal relation between tetanus toxoid and an adverse event, then in the committee's judgment the evidence favors acceptance of (or establishes) a causal relation between DT and Td and the adverse event as well.

[i]The data come primarily from individuals proven to be immunocompromised.

The committee organized these conclusions into five categories. Because some confusion has arisen over the meaning of the category descriptions used by the Committee to Review the Adverse Consequences of Pertussis and Rubella Vaccines, despite extensive explanations in both the footnotes and the text, the Vaccine Safety Committee adopted some minor modifications in wording intended to help in the interpretation of the present report. To facilitate reading by those familiar with the report of the previous committee, the present committee maintained both the number of categories (five) and the order of those categories but modified the wording in an attempt to clarify its meaning. However, the Vaccine Safety Committee (which has some overlap in committee membership and staff with the earlier committee) believes that the categories represent the same concepts intended by the predecessor committee. The categories are:

1. No evidence bearing on a causal relation
2. The evidence is inadequate to accept or reject a causal relation
3. The evidence favors rejection of a causal relation
4. The evidence favors acceptance of a causal relation
5. The evidence establishes a causal relation

Chapter 2 contains a discussion of the criteria used by the committee for each determination of the final weight of evidence.

The evidence favors rejection of, favors acceptance of, or establishes a causal relation between a vaccine and an adverse event in approximately one third of the relations studied. For the other relations the evidence was inadequate to accept or reject a causal relation or there was no evidence bearing on the relation. It is important to note that the use of the term *inadequate* does not necessarily imply that the data were scarce. In some cases the committee identified an abundance of data. However, as a whole, it did not favor either acceptance or rejection of a causal relation. In the lists below, the superscript letters refer to the appropriate notes in Table 1-2. The notes in Tables 1-1 and 1-2 are integral to interpretation of the findings. The committee reached the following conclusions regarding causality.

The evidence favors rejection of a causal relation between:

- diphtheria and tetanus toxoids and encephalopathy,[c] infantile spasms,[d] and death from sudden infant death syndrome (SIDS);[e,g] and
- conjugate Hib vaccines and early-onset Hib disease.

The evidence favors acceptance of a causal relation between:

- diphtheria and tetanus toxoids and Guillain-Barré syndrome[h] and hospital reentry,[b]
- measles vaccine and anaphylaxis,[d]

- oral polio vaccine and Guillain-Barré syndrome, and
- unconjugated (PRP) Hib vaccine and early-onset Hib disease in children age 18 months or older who receive their first Hib immunization with unconjugated (PRP) vaccine.

The evidence establishes a causal relation between:

- diphtheria and tetanus toxoids and anaphylaxis,[b]
- measles vaccine and death from measles vaccine-strain viral infection,[f]
- measles-mumps-rubella vaccine and thrombocytopenia and anaphylaxis,
- oral polio vaccine and poliomyelitis and death from polio-vaccine-strain viral infection,[f] and
- hepatitis B vaccine and anaphylaxis.

For the vast majority of vaccine-adverse event relations studied, the data came predominantly from uncontrolled studies and case reports. Most of the pathologic conditions studied are rare in the general population. The risk of developing these conditions because of vaccination would *seem* to be low. Without age-specific incidence rates and relative risk estimates, however, it is not possible to calculate the proportion of individuals whose condition is causally related to a vaccine. When the data permitted, such calculations (i.e., the risk difference or excess risk) were made and can be found in the conclusions in Chapters 5 through 9. Because age-specific incidence rates were not available for many of the pathologic conditions studied and because controlled epidemiologic studies of these relations are lacking, few such estimates could be made.

NEED FOR RESEARCH AND SURVEILLANCE

During its attempt to find evidence regarding causality, the committee identified needs for research and surveillance of adverse events. Work in these areas will help to ensure that all vaccines used are as free from the risk of causing adverse events as possible. Some of the needs identified are for increased surveillance of reports of demyelinating disease and arthritis following hepatitis B vaccination, better follow-up of reports of death and other serious adverse events following vaccination, increased use of large databases (currently used only on a small scale) to supplement passive surveillance reporting systems, and disease registries for the rare pathologic conditions studied by the committee.

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2

Causality and Evidence

CAUSALITY

Definitions

The concept of causality is of cardinal importance in health research, clinical practice, and public health policy. It also lies at the heart of this committee's charge: to make causal inferences about the relation between vaccines routinely administered to children in the United States and several specific adverse health outcomes. Despite its importance, however, causality is not a concept that is easy to define or understand (Kramer and Lane, 1992). Consider, for example, the relation between vaccine x and Guillain-Barré syndrome (GBS). Does the statement "Vaccine x causes GBS" mean that (1) all persons immunized with vaccine x will develop GBS, (2) all cases of GBS are caused by exposure to vaccine x, or (3) there is at least one person whose GBS was caused or will be caused by vaccine x?

The first interpretation corresponds to the notion of a *sufficient cause*; vaccine x is a sufficient cause of GBS if all vaccine x recipients develop the disease. Vaccine x is a *necessary cause* of GBS if the disease occurs only among vaccine x recipients (second interpretation above). Although the idea that a "proper" cause must be both necessary and sufficient underlies Koch's postulates of causality (see Glossary in Appendix C), it is now generally recognized that for most exposure-outcome relations, exposure (i.e., the putative cause) is neither necessary nor sufficient to cause the

A REVIEW OF SELECTED FEDERAL VACCINE AND IMMUNIZATION POLICIES

OFFICE OF TECHNOLOGY ASSESSMENT
WASHINGTON, DC

1980

NIAID (Austrian)—San Francisco (Kaiser) Trial, 1975-77

Austrian, with the cooperation of Marvin A. Fried, conducted a large clinical trial involving 13,600 subjects 45 years of age and older enrolled in the Kaiser Permanente Health Plan in San Francisco, California (Austrian, et al., 1976). A total of 6,850 subjects received a 12-valent vaccine (Types 1, 3, 4, 6, 7, 8, 9, 12, 14, 18, 19, 23) produced by Eli Lilly, and 6,750 subjects received a saline placebo.

Data from this study have not been completely analyzed, so there is as yet no conclusive evidence from this study of this vaccine's efficacy in preventing pneumococcal pneumonia. Nonetheless, two findings can be reported. First, no cases of pneumococcal bacteremia caused by the serotypes represented in the vaccine were reported among vaccine recipients, whereas four such cases were reported among controls. Second, about 60 percent of those who received pneumococcal vaccine reported no adverse reactions, about 40 percent experienced discomfort or pain at the injection site, 35 percent developed redness at the injection site, and 3.4 percent developed a mild fever (Austrian, et al., 1976).[7]

NIAID (Ammann)—San Francisco (Univ. of Calif.) Trial, 1974-76

Arthur Ammann tested the safety and efficacy of a Lilly-produced 8-valent pneumococcal polysaccharide vaccine (Types 1, 3, 6, 7, 14, 18, 19, and 23) among children believed to be at high risk of contracting pneumococcal disease (Ammann, 1977). These children, who had either sickle-cell anemia or inadequate spleen function, were vaccinated at the University of California, San Francisco Medical Center.

Ammann administered Lilly's 8-valent pneumococcal vaccine to 96 high risk children: 77 patients with sickle-cell anemia and 19 with inadequate spleen function. He then measured and compared antibody responses to the vaccine among these unhealthy children with antibody responses elicited by the vaccine among 44 healthy children.

Ammann also immunized another 38 healthy young people and observed them specifically for adverse reactions. Further, during a 2-year postimmunization period, Ammann compared the incidence of pneumococcal infection among the 77 vaccinated sickle-cell patients with that among 106 unvaccinated sickle-cell patients.

Antibody titer responses to pneumococcal vaccine among the 96 high risk children were good and did not differ significantly from the responses among the 44 healthy children. Among the 77 sickle-cell patients, the mean fold increase in indirect hemagglutination titers (i.e., the postimmunization titer divided by preimmunization titer) ranged from 1.65 (Type 19) to 12.55 (Type 3). Among the 19 asplenic children, the corresponding mean fold increase in titers ranged from 1.46 (Type 19) to 18.36 (Type 3). Among both these groups of patients, a mean fold increase of 2.00 or more was recorded 3 to 4 weeks after immunization for six of the eight types of pneumococci represented in the vaccine. A mean fold increase of 2.00 or more for six of the eight types also was recorded among both groups of patients 1 year after immunization.

The only adverse reactions Ammann found were local pain at the injection site and one case of brief fever (38° C). During a 2-year postimmunization period, he found no cases of pneumococcal infection among the 77 vaccinated sickle-cell patients and eight cases among the 106 unvaccinated sickle-cell patients who served as controls.

Based on his results, Ammann's conclusions were that 1) the 8-valent pneumococcal polysaccharide vaccine stimulates type-specific antibody formation in patients with inadequate spleen function, 2) the vaccine may help reduce the incidence of pneumococcal infection in sickle-cell patients and 3) the vaccine produces very few adverse reactions.

[7] See tables 7 and 8 in ch. 3.

Appendix 3.7
CDC'S PASSIVE, VOLUNTARY CASE REPORTING SYSTEM FOR MONITORING ADVERSE REACTIONS TO LICENSED VACCINES[1]

Introduction

Vaccinations are recommended and administered to millions of children and other individuals each year on the presumption that the benefits far outweigh the risks. The benefit side of the equation is straightforward: vaccinations can prevent serious disease. The risk side is not as straightforward, since it includes factors that are known and others that

[1] This appendix (apart from the title) is a verbatim reproduction of CDC's official written description of its system for monitoring and reporting adverse reactions to licensed vaccines.

nay exist but have not yet been discovered. It is necssary, therefore, to maintain surveillance of potential risks of vaccination to continually reevaluate whether individual vaccinations are, on balance, ;ood for people. Such surveillance is important, not nly to provide potential vaccinees with accurate information about the consequences of vaccination, ut also to stimulate improvements in the vaccination process or recommendations that will minimize r eliminate the risks.

The surveillance of these risks, or adverse reactions to vaccination, can be carried out actively or assively. In the active approach, systematic and intensive efforts are made to obtain reports of all dverse effects following vaccination. An example of his is a clinical field trial, required for licensure of a ew vaccine. In the passive approach, a mechanism s established by which individuals may voluntarily eport vaccine reactions. The active approach is comrehensive, but costly in terms of personnel time and ther resources. The passive approach is not compreensive, but it can be reasonably efficient at detecting evere and uncommon reactions without substantial xpenditures of time and resources since it makes aximum use of existing reporting mechanisms and rocedures.

The following discussion describes a passive sys:m for monitoring adverse reactions to vaccination iat should be used by all immunization projects. Included will be a form for reporting adverse reactions o the Center for Disease Control where a National dverse Reactions Monitoring System will be maintined.

ystem Description

The system description will center around these pics:

- designation of adverse reaction coordinators,
- establishment of a reporting mechanisms,
- stimulation of reporting,
- criterion for reporting, and
- submission of reaction reports to CDC.

)esignation of Adverse Reaction :oordinators

The responsibility for establishing an Adverse Re:tion Monitoring System is that of each Immuniza:on Project Office. The first step is to designate an dividual on the Immunization Project staff to serve System Coordinator. This individual will then be sponsible for establishing the system in the Project ea and for coordinating its operation.

In establishing the system, the first task of the Sysm Coordinator should be to have Adverse Reaction Coordinators designated in each local health jurisdiction within the Project area. These could be individuals in county health departments or large public clinics. In addition, Adverse Reaction Coordinators should be designated in hospital emergency rooms wherever possible and representatives of the State and local medical societies and pediatric organizations should be invited to serve as liaison people to the system to promote the reporting of reactions from the private sector. (The establishment of these contacts can be delegated to the local coordinators.)

The designation of Adverse Reaction Coordinators will create a surveillance network which can be used to collect information about vaccine reactions and channel the reports to the points at which analysis can be carried out. These local Coordinators will have the specific responsibilities of implementing a reporting mechanism in their areas, of stimulating reporting by the public and local immunization providers, and of making sure that reports are submitted promptly and correctly to the Immunization Project Office. The System Coordinator in the Central Office may be the logical person to be responsible for monitoring all phases of the operation and for submitting reaction reports to the Center for Disease Control. Copies of the reports should be forwarded to the Regional Offices.

Establishment of a Reporting Mechanism

The next task of the System Coordinator is the establishment of a mechanism through which the public and immunization providers can easily report vaccine reactions. One possibility is the installation of a toll-free telephone which can be called without charge from anywhere within the Project area. Another possibility is the designation of local telephones in each health jurisdiction for receiving reaction reports. Both methods may be used conjointly.

The telephones should be attended during regular business hours by the designated Coordinator or other health professionnal. A supply of the form, "Report of Illness Following Vaccination" (Exhibit One),[8] should be kept near the telephone(s) so that reports can be documented on it directly. Consideration should be given to the use of tape recording units to handle calls made after hours.

Telephone communication should be the primary mechanism for receiving reaction reports in a Project Area. It may be supplemented, however, by a mechanism for receiving reports through the mail, primarily from immunization providers. This can be effected by supplying providers with the report form

[8] CDC's "Report of Illness Following Vaccination" form (Exhibit One) appears in this appendix as figure 3.7A.

THE VACCINE REACTION

"When it happens to you or your child, the risks are 100%"

Vol.1, No.4 *Published bi-monthly by the National Vaccine Information Center* Sept/Oct 1995

Barbara Loe Fisher, Editor

To The Reader: Since the beginning of September, I have been engaged in a remarkable dialogue with a scientist at the University of Southern California whose work I became aware of after reading an article published in the Riverside Press on August 28. Although the content for the September-October issue of *THE VACCINE REACTION* had already been scheduled, I came to the conclusion that this story was of such importance and potentially impacts upon so many individuals suffering from unexplained neurological, psychiatric and autoimmune disorder symptoms, that the entire issue should be devoted to covering it. I do not believe the significance of this research should be underestimated or minimized and, in the interest of public health and safety, expect that the Food and Drug Administration and Centers for Disease Control officials responsible for insuring the public health and safety will take their responsibilities seriously and act quickly to support continuation of this research to confirm or disprove these scientific findings. Failure to act now could jeopardize the health and well being of every baby born and every child and adult who may already be infected with an atypical cytopathic virus they contracted through exposure to contaminated vaccines or exposure to infected blood or body fluids. - ***The Editor***

DISCOVERY OF AN ATYPICAL VIRUS INFECTING HUMANS LINKED TO VIRAL VACCINES PRODUCED ON MONKEY TISSUES

In what could be one of the most important scientific discoveries of this decade, an award-winning pathologist and immunologist at the University of Southern California, W. John Martin, M.D., Ph.D., has discovered an atypical virus infecting both children and adults who are exhibiting neurological, psychiatric and autoimmune disorder symptoms with diagnoses including chronic fatigue syndrome, fibromyalgia, depression, schizophrenia, anxiety disorder, seizures, developmental delays, autism, lupus, multiple sclerosis, Alzheimer's, Parkinson's, unexplained encephalopathy and chronic vegetative states. Martin and his colleagues at USC's Infectious Diseases and Molecular Pathology Laboratories have been meticulously culturing out stealth viruses from patients for the past eight years and, in a stunning development earlier this year, successfully identified one of the viruses as being of African green monkey origin by using DNA sequence analysis. Kidney tissues from African green monkeys have been used to make the live oral polio vaccine (OPV) as well as other viral vaccines during the past three decades.

YOU CAN BE INFECTED AND NOT BE SICK - A distinctive feature of the virus Martin and his colleagues has characterized is that it belongs to a novel class of atypical cytopathic viruses (capable of causing pathologic changes in cells), which they refer to as

it into cats. In an article to be published in the December issue of Pathobiology, they report their remarkable findings of what happens to the cats after they have been infected with the virus.

THE MONEY HAS RUN OUT - A casualty of the budget cuts that are hitting California and other localities across the country, the minimal funding that has helped USC's Infectious Diseases and Molecular Pathology Lab conduct stealth virus research has now been exhausted. The Lab has been forced to drastically cut back on its research linking the proliferation of atypical neurologic, psychiatric and immune system disorders in children and adults to the detection of an atypical cytomegalovirus whose genetic code is almost identical to that of a virus that is commonly present in the kidney tissues of the African green monkey and could have, therefore, been inadvertently transmitted to humans during the production of the oral polio vaccine. Committed to continuing their research because they know their discovery has the potential to save lives, Martin and his seven colleagues have continued to work without pay for the past month in an effort to keep USC's lab open.

AN APPEAL TO THE FDA - Dr. Martin, who is professor of pathology and director of USC's Infectious Diseases and Molecular Pathology Lab, has received numerous awards, scholarships and fellowships during his 30-year career as a distinguished scientist at Harvard, University College in London, University of Sydney in Australia, NIH, Food and Drug Administration, and the National Cancer Institute. In June, Dr. Martin and S. Zaki Salahuddin, Ph.D., Li Chang Zeng, M.D., Khalid Ahmed, M.T., Jing G. Seward, M.D., John-Carl Olsen, Inderjit Singh Seehrai, M.D., and Mark Nowicki, Ph.D., applied to the FDA for a 6-month grant to:

1) Determine the prevalence of simian cytomegalovirus derived stealth viral infection in humans;

They are proposing a simple, quick and cost-effective way to do that by performing serological, polymerase chain reaction (PCR) and viral culture testing of blood and lymphocyte samples already stored in the National Heart, Lung and Blood Institute at NIH which were obtained during the federally funded Transfusion Safety Study (TSS) conducted in the 1980's. The University of Southern California acted as the prime contractor for the TSS, a study which was conducted because of the fear that blood products were contaminated with viruses, including HIV. The goal of the Transfusion Safety Study was to try to determine the prevalence of viral infections, including HIV, in well defined populations in the U.S..

In addition to the proposal to test the TSS samples for stealth virus infection, Martin has already obtained permission from the Los Angeles County - University of Southern California Medical Center's Institutional Review Board to test blood and fluid samples stored in their archives if funding can be obtained to do it. The scientists estimate that if they tested a total of 250 blood samples from both of these sources, it would be adequate to make an initial scientific determination of the scope of stealth virus presence in the U.S. population.

2) To screen monkey colonies used for the production of viral vaccines for the presence of stealth viruses.

Serious Reports by Criteria for Selected Vaccines

	Total Reports*	Total Serious**	Life-threatening	Hospitalized	Disabled	Died***
DTP	7321	1269	133	975	72	246
OPV	5832	1015	144	759	49	229
HIB Vaccine	5059	1027	121	781	36	225
Hepatitis B	4227	383	37	241	108	17
MMR	3502	434	50	372	43	26
Td	830	46	7	36	8	1
DT	268	27	6	21	2	3
Vaccines on VIT	10,969	1,710	193	1,332	162	278
Vaccines not on VIT	10,944	1,740	218	1,308	183	288
Total Database	17,221	2,625	301	1,935	316	360

* A report may contain more than one vaccine. These columns should not be added.

** More than one serious criterion may occur concurrently on one report.

*** This column represents the reports where death was selected in item 8 on the VAERS form, and does not represent a determination that death was the direct result of vaccine administration.

When reviewing and evaluating data from VAERS, it is important to note that for any reported event, no cause and effect relationship has been established. The event may have been related to an underlying disease or condition, to drugs being taken concurrently, or may have occurred by chance at the same time the vaccine was administered.

Accumulated reported events should not be used to calculate incidence or estimates of risk. They must be carefully interpreted as reporting rates and not occurrence or incidence rates.

Reports Stating That Only One Vaccine Was Administered November 1, 1990 - July 31, 1992

	Reports	Total Serious*	Life-threat	Hosp	Disabled	Died
DTP	853	72	11	50	15	3
OPV	15	9	2	6	3	1
HIB Vaccine	404	71	9	56	6	8
Hepatitis B	3507	229	27	138	76	9

* More than one criterion for serious may occur concurrently on one report; therefore, the columns of types of serious should not be added to obtain the total number of serious reports.

When reviewing and evaluating data from VAERS, it is important to note that for any reported event, no cause and effect relationship has been established. The event may have been related to an underlying disease or condition, to drugs being taken concurrently, or may have occurred by chance at the same time the vaccine was administered.

Accumulated reported events should not be used to calculate incidence or estimates of risk. They must be carefully interpreted as reporting rates and not occurrence or incidence rates.

INSTITUTE OF MEDICINE

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EMBARGOED: NOT FOR PUBLIC RELEASE BEFORE 6 P.M. EST WEDNESDAY, MARCH 2

NEW FINDINGS SUGGEST POSSIBLE LINK BETWEEN DPT VACCINE AND CERTAIN FORMS OF BRAIN DYSFUNCTION IN RARE CASES

WASHINGTON -- A 10-year follow-up on the children involved in a British study to investigate the relationship between diphtheria-pertussis-tetanus (DPT) vaccination and brain dysfunction led an Institute of Medicine (IOM) committee to conduct a new assessment. The committee concluded that the evidence is insufficient to indicate that DPT vaccination increases the number of children with chronic brain dysfunction because the dysfunction reported by the British researchers might be related to underlying brain or metabolic abnormalities.

Nevertheless the committee concluded that the evidence suggests -- but does not prove -- a possible link between DPT and chronic brain dysfunction, or death, in some of the children who experience a serious, acute neurologic illness within seven days of vaccination. The committee only can extend its conclusions to those acute and chronic brain dysfunctions as studied by the British researchers.

Both the IOM committee and British researchers emphasized that these data refer to rare occurrences and should not alarm parents. The number of cases of acute encephalopathy, or short-term brain damage, expected to result from DPT ranges from 0 to 10.5 per million immunizations. The subsequent risk of chronic brain dysfunction, or long-term brain damage, is smaller.

(MORE)

Limited copies of the report, *DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis*, are available from the Health Promotion and Disease Prevention Division, Institute of Medicine, at the letterhead address; tel. (202) 334-3935. Reporters may obtain copies from the Office of News and Public Information, also at the letterhead address (contacts listed above).

"As a pediatrician, I would not advise parents to forego DPT vaccinations for their children," said committee chair Richard B. Johnston Jr., adjunct professor of pediatrics at the Yale University School of Medicine, New Haven, Conn., and medical director at March of Dimes, White Plains, N.Y. "Diphtheria, pertussis, and tetanus are potentially serious diseases that pose real, proven threats to unvaccinated infants and children."

In 1991 IOM issued a report that found a causal link between DPT and acute encephalopathy. The evidence was insufficient at that time to indicate a causal relationship between DPT and long-term brain dysfunction. The appearance of a single, new report -- the 10-year follow-up to Britain's National Childhood Encephalopathy Study (NCES) -- prompted IOM to re-evaluate the possibility that DPT might cause long-term brain dysfunction.

The NCES, original results of which were published in 1981, is a case-control study of serious, acute neurologic illnesses in children in Great Britain and the only systematic study of long-term dysfunctions after vaccination with DPT.

Results of follow-up assessments of the NCES children were grouped into six areas of dysfunction -- neurological, behavioral, educational, motor, sensory, and the ability to care for one's self.

The IOM study was supported by funds coordinated by the National Institute of Allergy and Infectious Diseases of the National Institutes of Health, Bethesda, Md.

The Institute of Medicine is a private, non-profit organization that provides health policy advice under a congressional charter granted to the National Academy of Sciences. A committee roster is attached.

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INSTITUTE OF MEDICINE
Division of Health Promotion and Disease Prevention

Committee to Study New Research on Vaccines

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Report of the Task Force on Pertussis and Pertussis Immunization—1988

Supplement

in a randomized, double-blind fashion, and in this study the difference between the reaction rates following the extracted vaccine varied only slightly from the comparative whole-cell vaccines. The local reactions were less frequent with extracted vaccine, although the systemic reactions were not significantly different.[320]

In addition, there are no specific data concerning efficacy or frequency of uncommon temporally related severe neurologic events with this extracted vaccine. In terms of currently identified pertussis components, the extracted vaccine was not characterized or standardized and efforts to duplicate the vaccine suggested significant product variability.

Possible Components of Acellular Vaccines

Recent studies have significantly advanced our understanding of antigenic and other biologically active pertussis components.[12,32–34,37,38,40,44–46,48,55,56,60,75,76,123,135,138,166,261,322,323] Data regarding these *B pertussis* components and their role in the pathogenesis of infection and disease have been extensively reviewed earlier in this report (see "Antigenic and Biologically Active Factors," p 939; Table 1; and "Pathogenesis of *B pertussis* Infection, p 947). This information has afforded the theoretical potential for designing vaccines that contain only relevant protective antigens, free of extraneous materials.

Development of Acellular Vaccines in Japan

In Japan, pertussis component vaccines have been developed that mainly contain LPF and FHA.[126,235] Products of six manufacturers, using slightly varying processes, have been marketed. Component vaccines produced in Japan are of two types, B type containing approximately equal amounts of LPF and FHA and T type containing a preponderance of FHA, a lesser amount of LPF, and some agglutinogens. More than 30 million doses have been administered to children, largely T type. It is the T type that has had preliminary studies of toxicity and immunogenicity in the United States and the B type that was used in the recent Swedish efficacy trials. Acellular vaccines have been used for routine immunization starting at age 24 months in Japan since October 1981. The data concerning protection and side effects are derived from immunization of 2-year-old children and may or may not be applicable to immunization of young infants.

Transient Local and Systemic Reactions

In general, transient local and systemic reactions caused by acellular vaccines were less frequent and milder when compared with Japanese conventional whole-cell vaccines. A small number of children in the United States received a Japanese T-type component vaccine and similar mild reactions were observed.[247–249] However, in Japanese clinical studies several findings of special interest were noted. It was noted that local reactions appeared at a much later time after the first dose than following subsequent doses. In one study, the mean interval between immunization and local reaction was 7.9 days following the first dose and decreased to 2.6, 2.2, and 1.9 days following the second, third, and fourth doses.[235] The observation suggested delayed hypersensitivity to the initial dose and an accelerated response to repeat doses, although its significance is unclear. Also, in one study, the frequency of local erythema and induration on the first day after vaccination increased from 6% after the initial dose to 25%, 30%, and 41% with successive doses.[235] In a few cases, following booster doses there was marked erythema and swelling of the arm from the shoulder down to the elbow, some with appearance of blisters.[243] It should be noted that in Japan these adjuvant-containing vaccines are given by deep subcutaneous injection rather than by intramuscular injection, which is the usual method for DTP vaccines that contain an adjuvant.

Temporally Related Severe Events

Following a brief suspension of immunization in 1975 in Japan, immunization was reinstituted using the same whole-cell DTP vaccines starting at 24 months rather than at 3 months of age. Cases of presumed vaccine-associated reactions decreased (Tables 7 and 8). Several years later in 1981, the new acellular pertussis vaccines were substituted, but the practice of initiating immunization at 24 months of age was continued with the acellular vaccines.

In the 5 year period from 1970 through 1974, a period when standard whole-cell DTP immunization was started routinely at 3 to 5 months, there had been a total of 57 severe temporally related events and 37 deaths (9.5 severe reactions and 6.1 deaths per year) including presumed vaccine-associated encephalopathy and other CNS diseases, as determined by claims paid by the Japanese national compensation system. When whole-cell vaccines were initiated at 24 months of age, in the six years between 1975 and 1980, there were eight severe temporally related events (average 1.6 year) and three deaths. The whole-cell DTP vaccines used in the latter period were equivalent to those in prior use. Thus, the age of starting routine immunization appears to be a far

TABLE 7. Claims Paid by Vaccine Compensation System in Japan, 1970 through 1984*

Reactions	1970–January 1975		February 1975–August 1981		September 1981–1984	
	No. of Cases	No. of Deaths	No. of Cases	No. of Deaths	No. of Cases	No. of Deaths
With sequelae	57	37	8	3	5	2
Encephalopathy	29	21	2	1	0	0
Encephalitis	2	1	0	0	2	0
Acute infectious hemiplegia	2	0	1	0	1	0
Convulsions	8	1	3	1	1	1
Infantile spasm	2	0	0	0	0	0
Sudden death	11	11	0	0	0	0
Other	3	3	2	1	1	1
Without sequelae	82		34		14	
Mild encephalopathy	14		1		0	
Acute cerebellar ataxia	0		1		1	
Convulsions	4		0		0	
Febrile seizure	27		12		1	
Mild shock	8		3		1	
Exanthem	7		3		0	
Abscess	5		3		0	
Local reactions	8		7		11	
Others	9		4		0	

* From Noble et al.[238] Reproduced with permission.

more important determinant of temporally associated reactions than the switch from conventional whole-cell vaccines to acellular vaccines.

The conclusion can be drawn that either (1) DTP prepared with whole-cell *B pertussis* is less likely to cause neurologic disease when begun at 24 months or (2) the purported reactions in infants were in large part unrelated developmental events expected commonly in that age group but attributed to vaccine because they were time related. If the former is true, one cannot assess whether the new acellular pertussis vaccines used in the period from 1981 to 1984 are in fact different from whole-cell vaccines in their encephalopathic potential because they, too, were begun at 24 months of age. The rate of severe reactions does not differ significantly between the acellular and whole-cell vaccines when used at 24 months of age (Table 8). The decrease in severe reactions is slight, if any. The category "sudden death" is also instructive in that the entity disappeared following both whole-cell and acellular vaccines, when immunization was delayed until a child was 24 months of age.

It is clear that delaying the initial vaccination until a child is 24 months, regardless of the type of vaccine, reduces most of the temporally associated severe adverse events. Furthermore, analysis of cases with paid claims in the Japanese national compensation system indicates many of the putative cases to be related to other medical conditions.[243] There are no data at this time that allow prediction of the rate of temporally related severe events that could be expected if Japanese

TABLE 8. Adverse Reactions After Pertussis Immunization, Based on Claims Paid by Compensation System of Japan*

	1970–1974	1975–1980	1981–1984
Vaccine type	Whole cell	Whole cell	Acellular
Age at initiation (mo)	3–5	24	24
No. of doses of vaccine (millions)	25.1	19.8	20.4
No. of severe reactions (deaths) with sequelae	57 (37)	8 (3)	5 (2)
Incidence (deaths)/million doses	2.27 (1.47)	0.40 (0.15)	0.25 (0.10)
No. of mild reactions without sequelae	82	34	14
Incidence of mild reactions/million doses	3.27	1.72	0.69

* From Noble et al.[238] Reproduced with permission. Whole-cell vaccines were routinely administered to infants at 3 months of age until February 1975, when the recommended age was increased to 2 years. Use of whole-cell vaccines in this group continued until September 1981, when acellular vaccines were introduced for routine use in 2-year-old children. Vaccine distribution is based on calendar year, but adverse reaction data correspond to the vaccine type and strategy used.

TONY KNOWLES, GOVERNOR

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February 19, 1996

Honorable Lyda Green
Alaska State Senate
Room 423
State Capitol
Juneau, AK 99801-1182

Dear Senator Green:

Several questions arose during committee deliberation at the recent hearing on SB 185. Among these were:

1. What are the causes of death for the children under age 7 who die each year in Alaska?
2. How many of these deaths are from unknown causes?
3. Do other states or jurisdictions operate a monitoring program similar to what is called for in SB 185?
4. Does the State participate in the Vaccine Adverse Events Reporting System (VAERS)?
5. Are there currently protocols in place that deal with the issue of defective serums?
6. How many non-fatal adverse reactions to inoculations occur in Alaska each year?

The following responds directly to the questions raised and provides additional background information that may be useful to the committee in considering the issues and questions raised during that hearing.

- Over the ten year period 1985 - 1994 an average of 151 children aged seven and under died in Alaska each year. (The number of deaths in this age range has been declining steadily from 186 in 1985 to 113 in 1994.) During this period an average of 29 deaths annually were listed as resulting from SIDS and 3 deaths annually were from unknown causes.

- Our research could find no other state with a monitoring system similar to what is called for in SB 185.