ICP-2 READINGS

SEMESTER I-II



"JUST THINK OF IT AS IF YOU'RE READING A LONG TEXT-MESSAGE."



Figure of a MEDICAL STUDENT

Physical Examination and History Taking

Sixth Edition

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Interviewing and the Health History

CHAPTER 1

The way you talk with a patient while taking a history lays the foundation for good care. By listening and responding skillfully and empathically, you learn what is bothering the patient and what symptoms he or she has experienced. You also may learn what the patient thinks the trouble may be, how or why it happened, and what outcome is hoped for or feared. As you listen to the story of an illness, moreover, you begin to formulate a range of possible diagnoses. By asking additional questions, you can fill in the gaps in the patient's initial account and test some of your diagnostic hypotheses.

This process, when successful, helps to establish a trusting relationship between you and the patient. It develops your understanding of the patient as a person and, in turn, helps the patient to feel understood. What you learn while taking a history, moreover, helps to shape the history itself, and it suggests the most relevant bodily parts or systems on which you may focus your physical examination. At a later stage of care, it will affect your explanations to the patient and your shared plan for the future.

Even if you discover that nothing can be done about the patient's disease, your discussion with the person about the experience of being ill can be therapeutic. In the example that follows, research protocol made the patient ineligible for treatment of her longstanding and severe arthritis.

> She had never talked about what the symptoms meant to her. She had never said: "This means that I can't go to the bathroom by myself, put my clothes on, even get out of bed without calling for help."
>
> When we finished [the physical assessment] I said something like: "Rheumatoid arthritis really has not been nice to you." She burst into tears, and her daughter did also, and I sat there, very close to losing it myself.
>
> She said: "You know, no one has ever talked about it as a personal thing before, no one's ever talked to me as if this were a thing that mattered, a personal event."
>
> That was the significant thing about the encounter. I didn't really have much else to offer. . . . Something really significant had happened between us, something that she valued and would carry away with her.*

* Hastings C: The lived experience of the illness: Making contact with the patient. In Benner P, Wrubel J: The Primacy of Caring: Stress and Coping in Health and Illness. Menlo Park, CA, Addison-Wesley, 1989.

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This chapter outlines the structure, purposes, and content of a health history and describes some basic techniques of interviewing. It also suggests ways to talk with patients of different ages and to approach a variety of difficult issues and problems.

The Structure and Purposes of a Health History

The traditional health history has several parts, each with a specific purpose. Together they give structure to your data collection and to your final record, but they do not dictate the sequence of the interview.

Certain introductory materials in the health history typically precede the account of the patient's story. The *date* is always important, and in rapidly changing circumstances the time should be added. *Identifying data,* such as age, sex, race or ethnic origin, birthplace, and occupation, serve not only to establish who the patient is but also to give you some tentative suggestions as to what kind of person you are talking to and what the likely problems might be. When patients do not initiate their own visits, the *source of referral* becomes important. It indicates that a written report may be necessary, and it helps you to understand the patient's possible motivations. Persons seen at the request of school authorities or an insurance company may have different goals than those who come on their own initiative. The *source of the history,* whether it be the patient, family, friends, police, a letter of referral, or the past medical record, also deserves comment. It helps you to assess the value and possible biases of the information. Under some circumstances it is also helpful to comment on the probable *reliability* of the source of your data. Reliability varies with knowledge, memory, trust, and motivation, among other factors, and is a judgment made at the end of the interaction, not at the beginning.

The main part of the history starts with the patient's *chief complaints.* These are the one or more symptoms or other concerns for which the patient is seeking care or advice. The *present illness* amplifies the chief complaints and, in its written form, gives a full, clear, chronological account of how each of the symptoms developed and what events were related to them. It also includes how the patient thinks and feels about the illness, what concerns have led to seeking attention, and how the illness has affected the patient's life and functions. The *past history* explores prior illnesses, injuries, and medical interventions, while the *current health status* focuses on the present state of health and on environmental conditions, personal habits, and health-related measures that may impinge on it.

The *family history* helps you to assess the patient's risks of developing certain diseases and may also suggest what the patient might be worrying about. Further, a pattern of familial illness may emerge that will prove useful in the care of related persons. The *psychosocial history* sometimes suggests some contributory factors in the patient's illness and helps you to evaluate the patient's sources of support, likely reactions to illness, coping

mechanisms, strengths, and concerns. It helps you in getting to know your patient as a person. In the *review of systems* you ask about common symptoms in each major body system, and thus try to identify problems that the patient has not mentioned.

The Content of a Comprehensive History

The items in a history vary with the patient's age, sex, and illness, with the clinician's specialty and available time, and with the goals of the visit. Under many circumstances the clinician's efforts are targeted on a specific complaint, such as a sore throat or burning on urination. A limited approach, tailored to the problem, is then indicated. In other circumstances, however, a comprehensive history is needed. By learning and understanding all the items in such a history you can select the ones you need. Two patterns of a comprehensive history are detailed in the next few pages: one for adults, the other for children. Technical terms for symptoms appear in these histories. Definitions of these terms, together with ways to ask about the symptoms, are included in Chapter 2.

COMPREHENSIVE HISTORY: ADULT PATIENT

Date of History

Identifying Data, including age, sex, race, place of birth, marital status, occupation, and religion

Source of Referral, if any, and the purpose of it

Source of History, such as the patient, a relative, a friend, the patient's medical record, or a referral letter

Reliability, if relevant. For example, "The patient is consistently clear about her symptoms but vague on when they began."

Chief Complaints, when possible in the patient's own words. "My stomach hurts and I feel awful." Sometimes patients have no overt complaints; ascertain their goals instead. "I have come for my regular checkup" or "I've been admitted for a thorough evaluation of my heart."

Present Illness. This section is a clear, chronological account of the problems for which the patient is seeking care. The data come from the patient but the organization is yours. The narrative should include the onset of the problem, the setting in which it developed, its manifestations, and any treatments. The principal symptoms should be described in terms of (1) location, (2) quality, (3) quantity or severity, (4) timing (i.e., onset, duration, and frequency), (5) the setting in which they occur, (6) factors that have aggravated or relieved them, and (7) associated manifestations. Also note significant negatives (the absence of certain symptoms that will aid in differential diagnosis).

A present illness should also include patients' responses to their own symptoms and incapacities. What does the patient think has caused the problem? What are the underlying worries that have led to seeking professional attention? ("I think I may have appendicitis.") And why is that a worry? ("My Uncle Charlie died of a ruptured appendix.") Further, what effects has the illness had on the patient's life? This question is especially important in understanding a patient with chronic illness. "What can't you do now that you could do before? How has the backache, shortness of breath, or whatever, affected your ability to work? . . . your life at home? . . . your social activities? . . . your role as a parent? . . . your role as a husband, or wife? . . . the way you feel about yourself as a man, or a woman?"

Past History

General State of Health as the patient perceives it

Childhood Illnesses, such as measles, rubella, mumps, whooping cough, chickenpox, rheumatic fever, scarlet fever, polio

Adult Illnesses

Psychiatric Illnesses

Accidents and Injuries

Operations

Hospitalizations not already described

Current Health Status. Although some of the variables grouped under this heading have past as well as current components, they all may affect current health.

Current Medications, including home remedies, nonprescription drugs, vitamin/mineral supplements, and medicines borrowed from family or friends. Ask about doses and frequency of use. You may need to ask patients to bring you all their medicines and show you what they take.

Allergies

Tobacco, including the type (smoked, e.g., cigarettes, or smokeless, e.g., chewing tobacco or snuff), amount, and duration of use, e.g., cigarettes, a pack a day for 12 years

Alcohol, Drugs, and Related Substances. See pp. 16–17 for suggested methods of inquiry.

Diet, including usual daily intake and any dietary restrictions or supplements. Ask about coffee, tea, cola drinks, and other caffeine-containing beverages.

Screening Tests appropriate to the patient, such as tuberculin tests, Pap smears, mammograms, stools for occult blood, and cholesterol tests, together with the results and the dates they were last performed

Immunizations, such as tetanus, pertussis, diphtheria, polio, measles, rubella, mumps, influenza, hepatitis B, *Hemophilus influenzae,* type b, and pneumococcal vaccine

Sleep Patterns, including times that the person goes to bed and awakens, daytime naps, and any difficulties in falling asleep or staying asleep

Exercise and Leisure Activities

Environmental Hazards, including those in the home, school, and workplace

Use of Safety Measures, such as seat belts, smoke detectors, and other devices related to specific hazards

Family History

The age and health, or age and cause of death, of each immediate family member (i.e., parents, siblings, spouse, and children). Data on grandparents or grandchildren may also be useful.

The occurrence within the family of any of the following conditions: diabetes, heart disease, hypercholesterolemia, high blood pressure, stroke, kidney disease, tuberculosis, cancer, arthritis, anemia, allergies, asthma, headaches, epilepsy, mental illness, alcoholism, drug addiction, and symptoms like those of the patient.

Psychosocial History. This is an outline or narrative description that captures the important and relevant information about the patient as a person:

Home Situation and Significant Others. "Who lives at home with you? Tell me a little about them . . . and about your friends." "Who helps you when you are sick, or need assistance?"

Daily Life, from the time of arising to bedtime. "What is a typical day like? What do you do first? . . . Next?"

Important Experiences, including upbringing, schooling, military service, job history, financial situation, marriage, recreation, retirement

Religious Beliefs relevant to perceptions of health, illness, and treatment

The Patient's Outlook on the present and on the future

Review of Systems

General. Usual weight, recent weight change, any clothes that fit tighter or looser than before. Weakness, fatigue, fever

Skin. Rashes, lumps, sores, itching, dryness, color change, changes in hair or nails

Head. Headache, head injury

Eyes. Vision, glasses or contact lenses, last eye examination, pain, redness, excessive tearing, double vision, blurred vision, spots, specks, flashing lights, glaucoma, cataracts

Ears. Hearing, tinnitus, vertigo, earaches, infection, discharge. If hearing is decreased, use of hearing aids

Nose and Sinuses. Frequent colds; nasal stuffiness, discharge, or itching; hay fever, nosebleeds, sinus trouble

Mouth and Throat. Condition of teeth and gums, bleeding gums, dentures, if any, and how they fit, last dental examination, sore tongue, dry mouth, frequent sore throats, hoarseness

Neck. Lumps, "swollen glands," goiter, pain or stiffness in the neck

Breasts. Lumps, pain or discomfort, nipple discharge, self-examination

Respiratory. Cough, sputum (color, quantity), hemoptysis, wheezing, asthma, bronchitis, emphysema, pneumonia, tuberculosis, pleurisy; last chest x-ray film

Cardiac. Heart trouble, high blood pressure, rheumatic fever, heart murmurs; chest pain or discomfort, palpitations; dyspnea, orthopnea, paroxysmal nocturnal dyspnea, edema; past electrocardiogram or other heart test results

Gastrointestinal. Trouble swallowing, heartburn, appetite, nausea, vomiting, regurgitation, vomiting of blood, indigestion. Frequency of bowel movements, color and size of stools, change in bowel habits, rectal bleeding or black tarry stools, hemorrhoids, constipation, diarrhea. Abdominal pain, food intolerance, excessive belching or passing of gas. Jaundice, liver or gallbladder trouble, hepatitis

Urinary. Frequency of urination, polyuria, nocturia, burning or pain on urination, hematuria, urgency, reduced caliber or force of the urinary stream, hesitancy, dribbling, incontinence; urinary infections, stones

Genital

Male. Hernias, discharge from or sores on the penis, testicular pain or masses, history of sexually transmitted diseases and their treatments. Sexual preference, interest, function, satisfaction, and problems

Female. Age at menarche; regularity, frequency, and duration of periods; amount of bleeding, bleeding between periods or after intercourse, last menstrual period; dysmenorrhea, premenstrual tension; age at meno-

pause, menopausal symptoms, postmenopausal bleeding. If the patient was born before 1971, exposure to DES (diethylstilbestrol) from maternal use during pregnancy. Discharge, itching, sores, lumps, sexually transmitted diseases and their treatments. Number of pregnancies, number of deliveries, number of abortions (spontaneous and induced); complications of pregnancy; birth control methods. Sexual preference, interest, function, satisfaction; any problems, including dyspareunia

Peripheral Vascular. Intermittent claudication, leg cramps, varicose veins, past clots in the veins

Musculoskeletal. Muscle or joint pains, stiffness, arthritis, gout, backache. If present, describe location and symptoms (e.g., swelling, redness, pain, tenderness, stiffness, weakness, limitation of motion or activity).

Neurologic. Fainting, blackouts, seizures, weakness, paralysis, numbness or loss of sensation, tingling or "pins and needles," tremors or other involuntary movements

Hematologic. Anemia, easy bruising or bleeding, past transfusions and any reactions to them

Endocrine. Thyroid trouble, heat or cold intolerance, excessive sweating; diabetes, excessive thirst or hunger, polyuria

Psychiatric. Nervousness, tension, mood including depression; memory

COMPREHENSIVE HISTORY: CHILD PATIENT

In addition to the obvious age-related differences between histories of children and those of adults, there are present and past historical data specifically pertinent to the assessment of infants, children, and adolescents. These relate particularly to the patient's chronological age and stage of development. The child's history, then, follows the same outline as the adult's history, with certain additions that are presented here.

Identifying Data. Date and place of birth. Nickname, particularly for those between 2 and 10 years of age. First names of parents (and last name of each, if different), their occupations, and where they may be reached during work hours

Chief Complaints. Make clear whether these are concerns of the patient, the parent(s), or both. In some instances a third party, such as a schoolteacher, may have expressed concerns about the child.

Present Illness. Should include how all members of the family respond to the patient's symptoms, what they think about them, and whether the patient achieves any secondary gains from the illness

Past History

Birth History. Particularly important during the first 2 years of life and for neuruologic and developmental problems. Hospital records should be reviewed if preliminary information from the parent(s) indicates significant difficulties before, during, or after delivery.

Prenatal. Maternal health before and during pregnancy, including nutrition and specific illnesses related to or complicated by pregnancy; doses and duration of all legal and illegal drugs taken during pregnancy (includes alcohol ingestion and cigarette smoking); weight gain; vaginal bleeding; duration of pregnancy; parental attitudes concerning the pregnancy and parenthood in general and this child in particular

Natal. Nature of labor and delivery, including degree of difficulty, analgesia used, and complications encountered; birth order if a multiple birth; birth weight

Neonatal. Onset of respirations; resuscitation efforts; Apgar scores (see pp. 561–562) and estimation of gestational age (see p. 406). Specific problems with feeding, respiratory distress, cyanosis, jaundice, anemia, convulsions, congenital anomalies, infection. Mother's health postpartum; separation of mother and infant and reasons for it; mother's initial reaction to her baby and the nature of bonding. Patterns of crying and sleeping, and of urination and defecation

Feeding History. Particularly important during the first 2 years of life and in dealing with problems of under- and overnutrition

Infancy. Breast feeding—frequency and duration of feeds, use of complementary or supplementary artificial feedings, difficulties encountered, timing and method of weaning. *Artificial (formula) feeding*—type, concentration, amount, and frequency of feeds, difficulties (regurgitation, colic, diarrhea) encountered, timing and method of weaning. *Vitamin and iron supplements*—type, amount given, frequency, and duration. *Solid foods*—types and amounts of baby foods given, when introduced, infant's response, introduction of table foods, self-feeding, parental and infant responses to feeding process

Childhood. Eating habits—likes and dislikes, specific types and amounts of food eaten, parental attitudes toward eating in general and toward this child's under- or overeating, parental response to feeding problems (if present). A *diet diary* kept over a 7- to 14-day period may be required for an accurate assessment of food intake in childhood feeding problems.

Growth and Developmental History. Particularly important during infancy and childhood and in dealing with problems of delayed physical growth, psychomotor and intellectual retardation, and behavioral disturbances

Physical Growth. Actual (or approximate) weight and height at birth and at 1, 2, 5, and 10 years; history of any slow or rapid gains or losses; tooth eruption and loss pattern

Developmental Milestones. Ages at which patient held up head while in a prone position, rolled over from front to back and back to front, sat with support and alone, stood with support and alone, walked with support and alone, said first word, combinations of words, and sentences, tied own shoes, dressed without help

Social Development. Sleep—amount and patterns during day and at night, bedtime routines, type of bed and its location; nightmares, terrors, and somnambulation. *Toileting*—methods of training used, when bladder and bowel control attained, occurrence of accidents or of enuresis or encopresis, parental attitudes, terms used within the family for urination and defecation (important to know when a young child is admitted to the hospital). *Speech*—hesitation, stuttering, baby talk, lisping, estimate of number of words in vocabulary. *Habits*—bed rocking, head banging, tics, thumb sucking, nail biting, pica, ritualistic behavior. *Discipline*—parental assessment of child's temperament and response to discipline; methods used, success or failure, negativism, temper tantrums, withdrawal, aggressive behavior. *Schooling*—experience with day care, nursery school, and kindergarten; age and adjustment upon entry; current parental and child satisfaction; academic achievement; school's concerns. *Sexuality*—relations with members of opposite sex; inquisitiveness regarding conception, pregnancy, and girl–boy differences; parental responses to child's questions and the sex education they have offered regarding masturbation, menstruation, nocturnal emissions, development of secondary sexual characteristics, sexual urges, and AIDS and other sexually-transmitted diseases; dating patterns. *Personality*—degree of independence; relationship with parents, siblings, and peers; group and independent activities and interests, congeniality, special friends (real or imaginary); major assets and skills; self-image

Childhood Illnesses. In addition to specific illnesses experienced, mention of any recent exposures to childhood illnesses should be made here.

Accidents and Injuries
Operations
Hospitalizations

} The reactions of the child and parents to these events should be ascertained. Age-appropriate questions about safety and injury prevention should be asked of the child.

Current Health Status

Allergies. Particular attention should be given to the allergies that are more prevalent during infancy and childhood—eczema, urticaria, perennial allergic rhinitis, asthma, food intolerance, and insect hypersensitivity.

Immunizations. Specific dates of administration of each vaccine should be recorded so that an ongoing booster program can be maintained throughout childhood and adolescence. Parents should have their own written record of their child's immunizations. Any untoward reactions to specific vaccines should also be recorded.

Screening Procedures. The dates and results of any screening tests performed should be recorded. These include blood pressure, vision, hearing, and tuberculin tests, urinalysis, hematocrits, tests for phenylketonuria, galactosemia, and other genetic–metabolic disorders, and, for certain high-risk populations, sickle cell, blood lead, cholesterol, alpha$_1$-antitrypsin deficiency, and other tests that may be indicated.

Family History. The education attained, job history, emotional health, and family background of each parent or parent substitute. The family socioeconomic circumstances, including income, type of dwelling, and neighborhood in which the family lives. Parental work schedules; family cohesiveness and interdependence; support available from relatives, friends, and neighbors; the ethnic and cultural milieu in which the family lives. Parental expectations, and attitudes toward the patient in relation to siblings. (All or portions of this information may be recorded in the present illness section, if pertinent to it, or under psychosocial history.) Consanguinity of the parents should be ascertained (by inquiring if they are "related by blood").

Once you know what kind of information to gather, you should lay that knowledge aside temporarily lest it come between you and the patient. At least at the start of the interview, and often at other times, you should be guided primarily by what the patient says and does rather than by a printed form or a rigid format.

Setting the Stage for the Interview

Reviewing the Chart. Before seeing the patient, quickly review the chart. Note the identifying data. Age, sex, race, marital status, address, occupation, and religion give you important glimpses into the patient's likely life experiences and may even guide your diagnostic hypotheses. Has the patient been referred from elsewhere? By whom? For what? Reviewing the medical chart may give you valuable information about past diagnoses and treatments, but it should not prevent you from developing new approaches or ideas.

The Environment. Although you may have to talk with the patient under difficult circumstances, such as a four-bed room or the corridor of a busy emergency department, a proper environment will improve communication. Try to make it as private and comfortable as possible. There should be places where both you and the patient can sit down in clear view of

each other, preferably at eye level. Leaning against the far wall, inching toward the door, or shifting around uncomfortably from foot to foot discourages the patient's attempts at communication. So do arrangements that indicate inequality of power or even disrespect, such as greeting and interviewing a woman while she is lying supine, positioned for a pelvic examination.

Your distance from the patient should probably be several feet, not so close as to be intimate nor too distant for easy conversation. Patients may be able to talk more easily when sitting next to your desk than when peering over it as if over a barrier. When they prefer greater social distance they are telling you something about themselves, psychologically or perhaps culturally. Lighting also makes a difference. Avoid sitting between a patient and a bright light or window. Although your view may be fine, the patient must squint uncomfortably toward your silhouette. You unwittingly conduct an interrogation, not a helping interview.

Your Demeanor and Appearance. Just as you observe the patient throughout the interview, the patient will be watching you. Consciously or not, you send messages through both your words and your behavior. You should be sensitive to those messages and control them as well as you can. Posture, gestures, eye contact, and words can all express interest, attention, acceptance, and understanding. The skilled interviewer seems calm and unhurried, even when time is limited. Reactions that betray disgust, disapproval, embarrassment, impatience, or boredom block communication, as do behaviors that condescend, stereotype, or make sport of the patient. Although negative reactions such as these are normal and understandable, they should not be expressed. Guard against them not only when talking with the patient but also when discussing the patient with your colleagues or instructors, either at the bedside or in the hall.

Your personal appearance may also affect the ease with which you establish a relationship. Cleanliness, neatness, conservative dress, and a name tag are usually desirable, but casual dress may be preferable in circumstances such as dealing with children or young people.

Note Taking. Because no one can remember all the details of a comprehensive history, you need to take notes. Most patients are accustomed to note taking, but some may seem uncomfortable with it. If so, explore their concerns and explain your desire to make an accurate record. With practice you may be able to record most of the past history, current health status, family history, and review of systems in final form as you talk with the patient, especially if you have the help of a written questionnaire. Note taking should not divert your attention from the patient, however, nor should a written form prevent you from following a patient's leads. While eliciting the present illness, the psychosocial history, or other complex portions of the patient's account, do not attempt to write your final report. Instead, jot down short phrases, words, and dates. When the patient is talking about sensitive or disturbing material it is best not to take notes at all.

Learning About the Present Illness

Greeting the Patient. You are now ready to make your approach, greet the patient by name, and give your undivided attention. Shake hands if you feel comfortable doing so. Unless you are talking with a child or adolescent or unless you already know the patient well, use the appropriate title—for example, Mr. O'Neill or Ms. Washington. Use of first names or terms of endearment with unfamiliar adults and use of "Granny" for an aged woman or "Mother" for a child's parent tend to depersonalize and demean. Introduce yourself by name. If there is any ambiguity in your role, such as your status as a student, explain your relation to the patient's care.

The Patient's Comfort. Be alert to the patient's comfort. In the office or clinic, there should be a suitable place for coats and belongings other than the patient's own lap. In the hospital, inquire how the patient is feeling and whether your visit now is convenient. Watch for indications of discomfort such as poor positioning, evidence of pain or anxiety, or signs of the need to urinate. An improved position in bed or a short delay so that the patient can say goodbye to visitors or make a trip to the bathroom may be the shortest route to a good history.

Opening Questions. You need to find out why the patient is here—the chief complaints, if any, and the present illness. (Occasionally a patient may come for a checkup or may wish to discuss a health-related matter without having either complaint or illness.) Begin your interview with a general question that allows full freedom of response—for example, "What brings you here?" or "What seems to be the trouble?" After the patient answers, inquire again, or even several times, "Anything else?" When the patient has finished, encourage further description by saying "Tell me about it," or, if there seems to be more than one problem, ask about one of them. "Tell me about the headaches" or ". . . about what bothers you most." As the patient answers, pick up the thread of the history and follow wherever it leads.

Following the Patient's Leads. Many patients want help with relatively straightforward medical problems. Others, however, have illnesses with complex psychosocial and pathophysiological causes, and may have complicated feelings about themselves, their illnesses, potential treatments, and those who are trying to help them. At the start you cannot tell one kind of patient from another. In order to do so, your interviewing technique must allow patients to recount their own stories spontaneously. If you intervene verbally too soon, if you ask specific questions prematurely, you risk trampling on the very information you are seeking. Your role, however, is not passive. You should listen actively and watch for clues to important symptoms, emotions, events, and relationships. You can then guide the patient into telling you more about these areas. Methods of helping and guiding patients without diverting them from their own accounts include facilitation, reflection, clarification, empathic responses, confrontation, interpretation, and questions that elicit feelings.

Facilitation. You use facilitation when by posture, actions, or words you encourage the patient to say more but do not specify the topic. Silence itself, when attentive yet relaxed, is facilitative. Leaning forward, making eye contact, saying "Mm-hmm" or "Go on" or "I'm listening," all help the patient to continue.

Reflection. Closely akin to facilitation is reflection, a repetition of the patient's words that encourages the patient to give you more details. Reflection may be useful in eliciting both facts and feelings, as in the following example:

Patient: The pain got worse and began to spread. (Pause)
Response: It spread?
Patient: Yes, it went to my shoulder and down my left arm to the fingers. It was so bad that I thought I was going to die. (Pause)
Response: You thought you were going to die?
Patient: Yes. It was just like the pain my father had when he had his heart attack, and I was afraid the same thing was happening to me.

This reflective technique has helped to reveal not only the location and severity of the pain, but also its meaning to the patient. It did not bias the story or interrupt the patient's train of thought.

Clarification. Sometimes the patient's words are ambiguous or the associations are unclear. If you are to understand their meaning you must request clarification, as in "Tell me what you meant by 'a cold'," or "You said you were behaving just like your mother. What did you mean?"

Empathic Responses. As patients talk with you, they may express—with or without words—feelings about which they are embarrassed, ashamed, or otherwise reticent. These feelings may well be crucial to how you understand their illnesses or plan treatment. If you can recognize and respond to them in a way that shows understanding and acceptance, you show empathy for the patients, make them feel more secure, and encourage them to continue. Empathic responses may be as simple as "I understand." Other examples include, "You must have been very upset," or "That must have been very difficult for you." Empathic responses may also be nonverbal—for example, offering a tissue to a crying patient or gently placing your hand on an arm to convey understanding. In using an empathic response, be sure that you are responding correctly to what the patient has already expressed. If you have acknowledged how upset a patient must have been at the death of a parent, when in fact the death relieved the patient from a longstanding financial and emotional burden, you have misunderstood the situation.

Confrontation. While an empathic response acknowledges expressed feelings, confrontation points out to patients something about their own words or behaviors. If you observe clues of anger, anxiety, or depression, for example, confrontation may help to bring these feelings out in the open. "Your hands are trembling whenever you talk about that," or "You

say you don't care but there are tears in your eyes." Confrontation may also be useful when the patient's story has been inconsistent. "You say you don't know what brings on your stomach pains, yet whenever you've had them you were feeling picked on."

Interpretation. Interpretation goes a step beyond confrontation. Here you make an inference, rather than a simple observation. "Nothing has been right for you today. You seem fed up with the hospital." "You are asking a lot of questions about the x-rays. Are you worried about them?" In interpreting a patient's words or behavior, you take some risk of making the wrong inference and impeding further communication. When used wisely, however, an interpretation can both demonstrate empathy and increase understanding.

Asking About Feelings. Rather than making an inference or reflecting a feeling, you may simply ask patients how they feel, or felt, about something such as symptoms or events. When you sense important but unexpressed feelings from the patient's face, voice, words, or behavior, inquire about them. Unless you let patients know that you are interested in feelings as well as in facts, you may miss important insights.

Getting More Data. Using the nondirective techniques described thus far, you will usually be able to obtain a general idea of the patient's principal problems. You can encourage a chronological account by such questions as "What then?" or "What happened next?" Most of the time, however, you will need further specific information. Fill in the details with more direct questions that ask for specific information not already offered by the patient. If the present illness involves pain, for example, you should determine the following elements:

Attributes of a Symptom

1. Its location. Where is it? Does it radiate?
2. Its quality. What is it like?
3. Its quantity or severity. How bad is it?
4. Its timing. When did (does) it start? How long does it last? How often does it come?
5. The setting in which it occurs, including environmental factors, personal activities, emotional reactions, or other circumstances that may have contributed to the illness
6. Factors that make it better or worse
7. Associated manifestations

Other symptoms should be described in similar terms. These attributes are fundamental in recognizing patterns of disease and differentiating one disease from another.

Clinical Reasoning. As you learn about a patient's symptoms and their attributes, you should start to think analytically about what bodily systems might be involved by a pathologic process. Leg pain, for example, suggests a problem in the peripheral vascular, musculoskeletal, or nervous system: An associated swollen ankle favors a venous problem. Aching joints suggest a musculoskeletal disorder, while a severe pain that shoots down the back of one leg to below the knee indicates pressure on

a nerve root. For additional data that will contribute to your analysis, use items from relevant sections of the review of systems. You can thus develop arguments for and against the various diagnostic possibilities. This kind of clinical thinking is illustrated by the tables in Chapter 2 and discussed further in Chapter 20.

Direct Questions. To gather specific items of information, direct questions are suitable. Several principles apply to their use. They should *proceed from the general to the specific.* A possible sequence, for example, might be "What was your chest pain like? Where did you feel it? Show me. Did it stay right there or did it travel anywhere? . . . to which fingers?"

Direct questions *should not be leading questions.* If a patient says yes to "Did your stools look like tar?" you must wonder if the description is the patient's or yours. A better wording is "What color were your stools?" When possible, ask questions that *require a graded response* rather than a yes or no answer. "How many stairs can you climb before stopping for breath?" is better than "Do you get short of breath climbing stairs?"

Sometimes patients seem quite unable to describe their symptoms without help. To minimize bias here, *offer multiple-choice answers.* "Is your pain aching, sharp, pressing, burning, shooting, or what?" Almost any direct question can provide at least two possible answers. "Do you bring up any phlegm with your cough, or not?"

Ask one question at a time. "Any tuberculosis, pleurisy, asthma, bronchitis, pneumonia?" may lead to a negative answer out of sheer confusion.

Finally, *use language that is understandable and appropriate* to the patient. Although you might ask a trained health professional about dyspnea, the more customary term is shortness of breath. When talking with an Appalachian coal miner, on the other hand, it may help to use the colloquial phrase "smothering spells." Appropriate words for symptoms are suggested in Chapter 2. Whenever possible, however, use the patient's words, making sure you understand their meaning.

The Rest of the Story

While the present illness is usually the single most important part of a history, important data are also discovered in subsequent parts of the interview. In most of these later sections, direct questions constitute your major technique. Stay alert, however, for important medical or emotional material, and be prepared to revert to a nondirective style wherever indicated. While taking a family history, for example, you may learn of a parent's death or a child's illness. Here is a good opportunity to find out what it meant to the patient. "How was it for you then?" or "What were your feelings at the time?" The review of systems may also uncover material that requires as full an exploration as the present illness. Keep your technique flexible.

Taking a History on Sensitive Topics. Beginning students always have difficulties in talking with patients about topics that are emotionally laden or culturally sensitive. At first the list of such subjects may be long, including sexual activities, death and dying, the financial concerns of patients, their racial and ethnic experiences, family interactions, domestic violence, psychiatric illnesses, physical deformities, and the functions of the urinary tract and bowel. Most of us will always feel a little uncomfortable in a few of these areas. Many adult patients, however, respond fairly easily to such questions, and you may thereby learn of important factors that have contributed to their illnesses.

There are several ways of becoming more comfortable in difficult areas: special courses, professional and general reading, and your own life experiences. Use them all. Further, familiarize yourself with some opening questions on sensitive topics, and learn the additional kinds of data you need in order to make the desired assessments. Whenever possible, listen to experienced clinicians as they discuss such subjects with patients, and then try some of the difficult areas yourself. The range of topics that you can explore with comfort will widen progressively, sometimes to your surprise.

Alcohol and Drugs. One difficult area for many clinicians is asking patients about their use of alcohol and illicit drugs. Yet alcohol and drugs are often directly related to a patient's symptoms, and dependence upon a substance may importantly affect future management. It is not your role to pass judgment on the use of these substances, but it is your job (if the patient is willing) to gather the data with which to make a correct assessment and plan treatment. A nonjudgmental demeanor will help patients discuss their practices with you.

Questions about alcohol and other drugs follow naturally after questions about coffee and cigarettes. "How much alcohol do you drink?" is a good opening question that avoids the easy yes or no response. It is not, however, very helpful in detecting an alcohol problem. For this purpose, try two additional questions: "Have you ever had a drinking problem?" and "When was your last drink?" An affirmative answer to the first question, along with a drink within 24 hours, has been shown in at least one study to suggest a drinking problem.†

Four other questions known as the CAGE questions are also helpful in detecting alcoholism. Their name comes from their themes of Cutting down, Annoyance by criticism, Guilty feelings, and Eye-openers. You can alter the wording of the questions to suit your style, but retain their meaning and themes.

† Cyr MG, Wartman SA: The effectiveness of routine screening questions in the detection of alcoholism. JAMA 259:51–54, 1988.

*The CAGE Questionnaire**

- Have you ever felt the need to Cut down on drinking?
- Have you ever felt Annoyed by criticism of drinking?
- Have you ever had Guilty feelings about drinking?
- Have you ever taken a drink first thing in the morning (Eye-opener) to steady your nerves or get rid of a hangover?

* Adapted from Mayfield D, McLeod G, Hall P: The CAGE questionnaire: Validation of a new alcoholism screening instrument. Am J Psychiatry 131:1121–1123, 1974.

Two or more affirmative answers suggest alcoholism. They also suggest further lines of inquiry.

If indicated, ask about blackouts (loss of memory for events during drinking), about accidents or injuries while drinking, and about alcohol-related job losses, marital problems, or arrests.

Questions about drugs take a somewhat similar pattern. "How much marijuana do you use? cocaine? heroin? other drugs like these? How about sleeping pills? diet pills? pain-killers?" And further:

How do you feel when you take it?
Have you had any bad reactions? What happened?
Any drug-related accidents, injuries, or arrests? Job or family problems?
Have you ever tried to quit?

Less directly, it may be helpful to ask first about the use of such substances by friends or family members. "A lot of college students are using drugs these days. How about your school? your friends?" After patients have found your response nonjudgmental and concerned, they may feel more comfortable telling you about their own patterns of use.

Physical Violence. Physical abuse—often not mentioned by the victim—should be considered (1) when injuries are unexplained, seem inconsistent with the patient's story, are concealed by the patient, or cause embarrassment; (2) when the patient has delayed getting treatment for trauma; (3) when there is a past history of repeated injuries or "accidents"; and (4) when the patient or a person close to the patient has a history of alcoholism or drug abuse. At times, the behavior of the abuser raises suspicion: he (she) tries to dominate the interview, will not leave the room, or seems unusually anxious or concerned.

Suitable questions relate to what the patient has told you and what you have observed:

When he comes home drunk like that, does he ever hit (beat, abuse) you, or the children? What does he do? What do you do?
You mentioned that you and your husband were having lots of arguments. Do they ever lead to physical fighting?
I notice you have some bruises on your breasts and abdomen. Can you tell me what happened? Did somebody hit you?

By suggesting that the problem is common, you may enable patients to talk about their experiences. "Many women tell me that someone at home is abusing or hurting them. How is it for you?" In cases of suspected child abuse, you might proceed as follows: "Most parents get very upset when their baby cries or their child has been naughty. How do *you* feel when *your* baby cries? What do you do when your baby won't stop crying? What sort of discipline do you use when your child has done something wrong? Are you ever afraid you might hurt your child?"

The Sexual History. Asking questions about sexual functions and practices serves at least four purposes. (1) Many patients have sex-related questions or problems that they would like to discuss with a professional if given the opportunity. Even if they choose not to discuss these questions on the first visit, they may feel free to do so at a later time if you have introduced the topic. (2) Sexual practices may be directly related to specific symptoms, and they need to be understood for diagnostic, therapeutic, and preventive reasons. (3) Sexual dysfunctions are sometimes the consequence of medications and, if recognized, may be reversible. (4) Sexual practices are obviously related to the risks of unwanted pregnancy and sexually transmitted diseases, including AIDS. Discussion may lead to preventing disease.

Questions about sexual functions or practices may be relevant at more than one point in a person's history. If a patient's chief complaint involves genitourinary symptoms, a sexual history is included in the present illness. Whenever a person has a chronic illness or serious symptoms such as pain or shortness of breath, sexual function may be affected. Asking about it in the context of other effects on the patient's life is a natural sequence of inquiry. Most commonly, a sexual history is taken during the genitourinary portion of the review of systems. This fairly late point in the history has the advantage of having given you time to establish rapport with the patient.

An introductory sentence or two is often helpful in preparing patients for what to them is sometimes an embarrassing topic. "Now, to figure out why you have this discharge and what we should do about it, I need to ask you some questions about your sexual activity." If there have been no apparent sex-related complaints, a different introduction is indicated. "I'd like to ask you some questions about your sexual health and practices. This information helps me (us) to provide better care for you. If you prefer, I won't write down your answers in the chart. May I go ahead?" If the patient does not wish to go on, accept the choice and make clear (if it is true) that you are available to discuss any such matters in the future.

If the patient assents, proceed with the following questions:

1. "Are you sexually active? That is, have you had sex with anyone in the past few months?" If the answer is yes, skip to question 3.
2. "Have you ever been sexually active?" If no, skip to question 8. If yes, proceed to questions 3, 4, 6, and 7. (Adjust to the past by changing "Do" to "Did" in questions 3, 4, and 7.) Then continue to question 8.

3. "Do you have sex with men, women, or both?"
4. "Do you have more than one partner?" or "How many partners have you had in the last two months?"
5. If the patient is a woman or girl of childbearing age and is sexually active with males, "Are you interested in getting pregnant? Are you using any contraception, or doing anything to try to prevent pregnancy?"
6. "Are you worried about the AIDS virus? Do you think your partner(s) might have had sex with other people who were using IV drugs? or who could have been exposed to the AIDS virus or other sexual infections?"
7. "Do you take any precautions to avoid infection?"
8. "Do you have any problems or concerns about your sexual function?"

Note that these questions make no assumptions about marital status, sexual preference, or attitudes toward pregnancy or contraception. Listen to each of the patient's responses, and ask additional questions as indicated. For further lines of inquiry, about sexual functions and sexually transmitted diseases, see pp. 52–55.

Transitions. As you move from one part of the history to another, it helps to orient the patient with brief transitional phrases. "Now I'd like to ask some questions about your past health," or "about other parts of your body."

The Review of Systems. The main purpose of the review of systems is to make sure that you have not missed any important symptoms, particularly in areas that you have not already thoroughly explored while discussing the present illness. A fairly general question that introduces each system, or subset of a system, is helpful. It focuses the patient's attention, allows you to move from the general to the more specific in each system, and on occasion may be all you need to ask. For example:

How are your ears and hearing?
How about your lungs and breathing?
Any trouble with your heart?
How is your digestion? How about your bowels?

The detail in which you ask additional questions within each area depends on the patient's age, complaints, and general state of health and the purpose of the visit, among other variables. An older patient, who is at greater risk of heart disease, cancer, and hearing loss, for example, needs more detailed questioning in certain areas than does an apparently healthy 20-year-old.

Some clinicians like to combine the review of systems with the physical examination, asking about the ears, for example, while looking at them. When a patient has few symptoms, this combination can be efficient. When a patient has multiple symptoms, however, the flow of both the history and the examination is disrupted and necessary note taking be-

comes awkward. If you want to try the combination, it is probably wise to wait until you master the flow of the examination.

Closing. After you have completed the history, return the initiative briefly to the patient: "Is there anything else we should talk about?" or "Have we left anything out?" You may want to recapitulate part of the present illness to be sure of a common understanding. Finally, make clear to the patient what to do or what to expect next. "Now I would like to examine you. I will step out for a few minutes. Please get completely undressed and put on this gown." By specifying whether the gown should open in the front or back, you may earn the patient's gratitude and save yourself some time.

Patients at Different Ages

As people develop, have families, and age, they provide you with special opportunities and require certain adaptations in your interviewing style.

Talking With Parents. To obtain histories on infants and children under 5 years of age, you gather all or at least most of your information from a third party, the parent(s) or legal guardian. Pediatric practitioners usually conduct interviews with both the parent and the child present. This is convenient, and it offers an opportunity to observe both parent–child interactions and the child's capacity for self-amusement. These observations may provide a clearer picture of the relationship between parent and child (and between parents if both are present) than can the answers to any number of questions. For the younger child, moreover, this interlude may help to dispel fears of the practitioner or of the visit, and it may allow for a smooth transition from the interview to the examination.

Interviewing a parent with the child present, however, has its disadvantages. The history may be incomplete and less accurate than when you interview the parent(s) alone. When sensitive areas are not fully explored because the child is present, you will need to interview the parent at a later time (often at the end of the visit when the child has left the room) to clarify certain points or to fill in missing data.

The techniques for talking with parents are much the same as those for talking with adult patients, with some special modifications. When parents describe a child's symptoms, they often do so accurately but they also have their own assumptions, perceptions, biases, and needs. For example, parents may assume that their child's chronic cough is due to a series of colds, not to bronchial asthma; they may perceive their child's poor performance in school as the fault of an overbearing teacher rather than as the result of a learning disability; or their bias toward their child as being exceptional may cause them to play down inappropriate social behaviors. Parents need to feel that they are doing a good job. When you ask a mother questions about her child's health you are, in a sense, testing her capabilities as a mother, and you should evaluate her responses in that context. There is a lot at stake for most parents as they try to cope with the problems of their children, so they need health practitioners who

are supportive rather than judgmental or critical. Comments like, "Why didn't you bring him in sooner?" or "Why, in heaven's name, did you do that?" will not improve your rapport with a worried parent whose infant or child is acutely ill.

Refer to the infant or child by name rather than by "him," "her," or "the baby." When the mother's marital status is not immediately clear, you may avoid embarrassment in asking about the father by saying "Is Jane's father in good health?" rather than "Is your husband in good health?" Address the parents as "Mr. Smith" and "Ms. Smith" rather than by their first names or, heaven forbid, "Mom" or "Dad." First names may be used with permission when you have established a reasonably long-standing relationship. On the other hand, be prepared for the parent who calls you by your first name.

In interviewing parents, open-ended questions are usually more productive than direct questions. In the realm of psychosocial issues and problems, however, you must more often than not use explicit direct questions, since parents rarely introduce these subjects spontaneously even when given the opportunity with open-ended approaches.

Finally, you need to recognize that the chief complaint may not relate at all to the real reason the parent has brought the child to see you. The complaint may serve as a "ticket of admission" to care, through which if the circumstances are right the parent may bring up another concern that by itself is not viewed as a "legitimate" reason for seeking care. Try to create an atmosphere that will allow parents to express all their concerns. If necessary, ask questions that will facilitate the process.

Are there any other problems with Johnny that you would like to tell me about?
What did you hope I would be able to do for you when you came today?
Is there anything special you would like me to explain to you about Jody?
Is there anything else bothering you about the other children, your husband (wife), or yourself that you'd like to talk about?

Talking With Children. Children of 5 years or older are able to add significantly to the history and can describe more accurately than can parents the severity of the symptoms and their own level of concern regarding them. You can sometimes improve the accuracy of your information by interviewing the child without the parent present. Usually, it is best to begin such interviews by discussing an interesting, nonthreatening subject, such as the child's T-shirt or school activities. An enthusiastic, informal, gentle style is most effective.

Following this, simple open-ended questions help to place children at ease and get them to talk about their problems:

Your mother tells me that you get a lot of stomachaches. What can you tell me about them?

What do they make you worry about?
How does it bother you when you miss going to school a lot?
What helps to make them go away?
What do you think causes them?

Questions may also be used to obtain a subjective assessment of the child's symptoms:

Show me where you get the pain. Is it like a pin prick, or does it ache?
Does it stay in the same spot, or does it move around?
Does it make you feel like you are going to throw up?

Talking With Adolescents. Many adults find talking with an adolescent difficult and frustrating because the adolescent often does not answer questions in an "adult" manner and may appear laconic and disdainful. This need not be the case. Adolescents, like most other people, will usually respond positively to anyone who demonstrates a genuine interest in them, not as "cases" but as people. That interest must be established early and then sustained if communication is to be effective. Adolescents tend to open up when the focus of the interview is on themselves and not on their problems. Thus, a good way to begin the interview with adolescents is to chat informally about their friends, school, hobbies, and family.

Adolescents seek health care on their own initiative or at the suggestion or insistence of their parents. They may come alone or with at least one parent. In the latter case, it is best to explain to both parent and adolescent that health care at this stage of one's individual development requires some degree of confidentiality. This requires speaking to the adolescent alone after obtaining past medical and social information from the parent(s). A confidential relationship is not based on "keeping secrets"; it is based on mutual respect. If it becomes necessary for the adolescent's own sake or for the sake of others to share confidential information, it is important to include the adolescent in that process.

Certain techniques of promoting good communication with an adult patient may be threatening to an adolescent. Reflection is a technique that should be avoided with the younger, cognitively immature adolescent, since it requires thinking skills not yet acquired. The use of silence in an attempt to get the patient to talk is rarely successful with adolescents, who usually do not have sufficient self-assurance to respond appropriately to this form of facilitation. Confrontation may cause an anxious adolescent to retreat into silence. Closely related to this is the technique of asking about feelings. Adolescents often find discussing their feelings with adults very difficult.

These caveats need not deter you from talking with adolescents. Most adolescents will talk with someone they respect and accept when given the opportunity in a friendly, informal atmosphere. You are more likely

to succeed as a professional if you "play it straight," act your age, and do not stretch too far in trying to bridge the generation gap.

Aging Patients. At the other end of the life cycle, aging patients also pose special problems and special opportunities. Their hearing and vision may be impaired, their responses may be slow, and they often have chronic illnesses with their associated discomforts and difficulties in getting about. For several reasons, elderly people may not report their symptoms. Some may be afraid or embarrassed to do so or are trying to avoid medical expenses or the discomforts of diagnosis and treatment. Others may think that their symptoms are merely a part of the aging process, or may simply have forgotten about them. Aging patients also may tell their histories more slowly than do younger ones.

Give an elderly person extra time to respond to your questions if needed. Speak slowly and in a lower voice. A comfortable room, free of distractions and noise, is helpful. Do not try to accomplish everything in one visit. Multiple visits may be less fatiguing and more productive.

From middle age on, people become increasingly aware of their personal aging and begin to measure their lives in terms of the years left rather than the years lived. It is normal for older people to reminisce about the past and to reflect upon previous experience, including joys, regrets, and conflicts. Listening to this process of life review can give you important insights into your patients and may help them work through some of their painful feelings.

While generalizations about elderly people are useful, they may also lead to stereotypes that block your understanding and enjoyment of their individuality. Try to determine the priorities and goals of such patients. Learn how they have handled crises in the past. Because they may pursue similar adaptive patterns in the present situation, this knowledge will help you plan with them. Find out how they perceive themselves and their situation. "Can you tell me how you feel about getting older? What kinds of things do you find most satisfying? What kinds of things worry you? What would you like to change if you could?"

Learning how elderly people (and others with chronic illness) function in their daily lives is essential to your understanding of and care for them. Establishing their level of function also provides a baseline against which to make future comparisons. Can they perform the ordinary activities of daily living independently, do they need some help, or are they entirely dependent? Inquire about walking, eating, dressing, grooming, bathing, and toileting. Are there any problems such as incontinence or falls? Inquire too about using a telephone, shopping, preparation of food, housekeeping, house repairs, laundry, driving a car or using other transportation, taking medications, and handling financial affairs such as paying the bills. Are there problems with stairs, distance from shops or the bank, and fears for personal safety? Who is available for help?

Special Challenges

Regardless of patient age, certain behaviors and special situations may particularly vex or perplex the practitioner. Your skills in handling these problems will evolve over a lifetime.

Silence. Neophyte interviewers may grow uncomfortable during periods of silence, feeling somehow obligated to keep the conversation going. They need not feel so. Silences have many meanings and many uses. When recounting their present illnesses, patients frequently fall silent for short periods in order to collect their thoughts, remember details, or decide whether or not they trust you enough to report something. An attentive silence on the interviewer's part is usually the best response here, sometimes followed by brief encouragement to continue. During periods of silence, be particularly alert to nonverbal signs of distress—evidence that the patient is having difficulty in controlling emotions. If so, these are almost invariably significant feelings that are best expressed. A gentle confrontation may help: "You seem to be having trouble talking about this." Depressed patients or those with dementia may have lost their usual spontaneity of expression, give short answers to questions, and fall silent quickly after each one. If you sense one of these problems, shift your inquiry to an exploratory mental status examination (see pp. 99–107).

At times, a patient's silence results from interviewer error or insensitivity. Are you asking too many direct questions in rapid sequence? The patient may simply have yielded the initiative to you and taken the passive role you seem to expect. Have you offended the patient in any way—for example, by signs of disapproval or criticism? Have you failed to recognize an overwhelming symptom such as pain, nausea, dyspnea, or the need to urinate or defecate? If so, you may need to interrupt or abbreviate the interview or return when the patient feels more comfortable.

Overtalkative Patients. The garrulous, rambling patient may be just as difficult as the silent one, possibly more so. Faced with limited time and a perceived need to "get the whole story," the interviewer may grow impatient, even exasperated. Although there are no perfect solutions for this problem, several techniques are helpful. First, you may need to lower your goals and accept less than a comprehensive history. It may be unobtainable. Second, give the patient free rein for the first 5 or 10 minutes of the interview. You will then have the chance to observe the patient's pattern of speech. Does the patient seem obsessively detailed or unduly anxious? Is there a flight of ideas or a disorganization of thought processes that suggests a psychotic disorder? Perhaps the patient has simply lacked a good listener for a long time and is expressing pent-up concerns that need to be aired. Third, try to focus the account on what seems to be most important. Show interest and ask questions in those areas. Interrupt if you must, but courteously. A brief summary may help you change the topic while letting the patient know that you have both heard and understood. "As I understand it, your chest pains come frequently, last a long time, and do not necessarily stay in any one place. Now tell me about

your breathing." Finally, do not let your impatience show. If you have used up the allotted time or, more likely, gone over it, explain that to the patient and arrange for a second meeting. Setting a time limit for the next appointment may be helpful. "I know we have much more to talk about. Can you come again next week? We will have a full half hour then."

Patients With Multiple Symptoms. Some patients seem to have every symptom that you mention. They have an "essentially positive review of systems." Although it is conceivable that such a patient has multiple organic illnesses, serious emotional problems are much more likely. In such cases it will profit little to explore each symptom in detail. Guide the interview into a psychosocial assessment instead.

Anxious Patients. Anxiety is a frequent and natural reaction to sickness, to therapy, and to the health-care system itself. For some patients, anxiety has importantly colored their reactions to life stress and may have contributed to their illnesses. Be sensitive to nonverbal and verbal clues. For example, anxious patients may sit tensely, fidgeting with their fingers or clothes. They may sigh frequently, lick their dry lips, sweat more than average, or actually tremble. Carotid pulsations may betray a rapid heart rate. Some anxious patients fall silent, unable to speak freely or confide. Others try to cover their feelings with words, busily avoiding their own basic problems. When you sense an underlying anxiety, encourage such patients to talk about their feelings.

Reassurance. When you are talking with anxious patients, it is tempting to reassure them: "Don't worry. Everything is going to be all right." This approach is usually counterproductive. Unless you and the patient have had a chance to explore the nature of the anxiety, you may well be giving reassurance about the wrong thing. Moreover, premature reassurance blocks further communication. Because admitting anxiety exposes a weakness, it requires encouragement, not a coverup. The first step to effective reassurance involves identifying and accepting the patient's feelings. This promotes a feeling of security. The final steps come much later in the health-care process, after you have completed the interview, the physical examination, and perhaps some laboratory studies. Then you can interpret for the patient what is happening and deal openly with the real concerns.

Anger and Hostility. Patients have reasons to be angry: they are ill, they have suffered loss, they lack their accustomed control over their own lives, they feel relatively powerless in the health-care system. They may direct this anger toward you. It is possible that you have justly earned their hostility. Were you late for your appointment, inconsiderate, insensitive, or angry yourself? If so, recognize the fact and try to make amends. More often, however, patients are displacing their anger onto the clinician as a symbol of all that is wrong. Allow them to get it off their chests. Accept their feelings without getting angry in return. Beware of joining such patients in their hostility toward another part of the clinic or hospital, even when you privately harbor similar feelings. After a patient has calmed down, you may be able to identify specific steps that will help

in the future. Rational solutions to emotional problems are not always possible, however, and people need time to resolve their angry feelings.

The Obstreperous Inebriate. Few patients can disrupt the clinic or emergency room more quickly than acutely intoxicated persons who are angry, belligerent, and uncontrolled. Before interviewing such patients, it is wise to alert the security force of the hospital. As you make your approach greet the patient by name and title, introduce yourself, and offer a handshake. In this situation it is especially important to appear accepting, not challenging. To do this, avoid all but the briefest eye contact and keep your posture relaxed and nonthreatening, your hands loosely open rather than clenched into fists. Do not try to make inebriated patients lower their voices or stop cursing at you or the staff, but listen carefully and try to understand what they are saying. Since some such persons feel trapped in small rooms it is usually best to talk with them in an open area, and you too are likely to feel more comfortable there. In addition, an offer of food or coffee may help to quiet the agitated person and bring some calm to the stormy scene.

Crying. Like anger, crying is an important clue to emotions. Rarely should it be suppressed. If the patient seems on the verge of tears, gentle confrontation or an empathic response may simply allow crying. Quiet acceptance is then appropriate. Offer a tissue; wait for recovery; perhaps make a facilitating or supportive remark: "It's good to get it out." In that kind of accepting context, most patients will soon compose themselves and will feel better and capable of continuing the discussion.

Depression. Masquerading as fatigue, weight loss, insomnia, or mysterious aches and pains, depression is one of the most common problems in clinical medicine, and is commonly missed or ignored. Be alert for it, identify it, and explore its manifestations. Be sure you know how bad it is. Just as you would evaluate the severity of chest pain, you must evaluate the severity of depression. Both are potentially lethal. You need not fear that asking about suicide will suggest it to the patient. For appropriate questions about depression, see Chapter 3.

Sexually Attractive or Seductive Patients. Clinicians of both sexes may occasionally find themselves attracted to their patients. If you become aware of such feelings, accept them as normal human responses but prevent them from affecting your behavior. Keep your relationship with the patient within professional bounds.

Occasionally patients may be frankly seductive or may make sexual advances. Calmly, but firmly, you should make clear that your relationship is professional, not personal. You may also wish to review your own image. Have you been overly warm with the patient? expressed your affection physically? sought his or her emotional support? Has your dress or demeanor been unconsciously seductive? Avoid these problems when you can.

Confusing Behaviors or Histories. At times you may find yourself baffled, frustrated, and confused in your interaction with the patient. The

history is vague and difficult to understand, ideas are poorly related to one another, and language is hard to follow. Even though you word your questions carefully, you seem unable to get clear answers. The patient's manner of relating to you may also seem peculiar: distant, aloof, inappropriate, or bizarre. Symptoms may be described in bizarre terms: "My fingernails feel too heavy," or "My stomach knots up like a snake." These characteristics should alert you to possible mental illnesses, such as schizophrenia. With the usual nondirective techniques you may be able to get more information about the unusual qualities of the symptoms. You should also include in your interview an assessment of the patient's mental status, with special attention to mood, thought, and perceptions (see pp. 101–104).

Many psychotic patients are functioning, with varying degrees of success, in the community. Such patients are frequently capable of telling you freely about their diagnoses, their symptoms, their hospitalizations, and their current medications. You should feel comfortable inquiring about these without embarrassment or circumlocution.

Schizophrenia is not the only cause of confusing histories. Some patients have disorders of cognitive function such as delirium or dementia. Be particularly alert for delirium when dealing with an acutely ill or intoxicated patient, and for dementia when dealing with an elderly patient. Patients with these problems may be unable to give clear histories. They are vague and inconsistent about symptoms or events and unable to report when and how things happened. They may be inattentive to your questions and hesitant in their answers. Occasionally such patients may confabulate, that is, make up part of their histories in order to fill in the gaps in their memories. When you suspect a cognitive disorder, such as dementia, do not spend too much time trying to get a detailed history. You will only tire and frustrate the patient as well as yourself. Shift your inquiry instead to an evaluation of mental status, checking particularly on level of consciousness, orientation, and memory (see pp. 99 and 104–106). You can work the initial questions smoothly into the interview. "When was your last appointment in the clinic? Let's see, then, that was about how long ago?" "Your address now is? . . . and your phone number?" Responses can all be checked against the chart (presuming, of course, that the chart is accurate).

Patients With Limited Intelligence. Patients of moderately limited intelligence can usually give adequate histories. You may, in fact, overlook their limitations and thereby make mistakes, such as omitting their dysfunction from a disability evaluation or giving instructions they cannot understand. If you suspect such problems, pay special attention to the patients' schooling. How far did they go in school? Why did they drop out? How were they doing at the time? What kinds of courses are (were) they taking? High school seniors of normal intelligence are not usually taking simple arithmetic. If your patient is, you can make a smooth transition into a mental status examination, including simple calculations, vocabulary, information, and tests of abstract thinking (see pp. 106–107).

When patients suffer from severe mental retardation, you will have to obtain their history from family or friends. By showing interest in the patients themselves, however, and by engaging them in simple conversation, try to establish a personal relationship. As with children, avoid "talking down" to mentally retarded patients and using affectations of speech or condescending behaviors. If the patient does not perceive these postures, family members or friends will.

Ability to Read. Before giving written instructions, it may be advisable to assess a patient's reading ability. Some people who cannot read because of a language barrier, learning disorder, or poor vision admit it when questioned. Others do not. You can check, as if testing their vision, by asking them to read some words or sentences for you. Illiterate people may try to hide their inability to read. Respond sensitively, and remember that literacy and intelligence are not synonymous.

Language Barriers. Nothing will more surely convince you that a history is essential than having to do without one. When you cannot communicate with your patient because you speak different languages, take every possible step to find a translator. A few broken words and gestures are no substitute. The ideal translator is a neutral, objective person who is familiar with both languages. When family members or friends try to help, they are more likely to distort meanings and may also present problems in confidentiality to both the patient and the interviewer. Many translators try to speed the process by telescoping a long communication into a few words. Try to make clear at the beginning that you need the translator to translate everything, not to interpret or summarize. Make your questions clear and short. You can also help the translator by outlining the goals for each segment of your history.

When available, written bilingual questionnaires are invaluable, especially for the review of systems. Before using one, however, be sure patients can read in their own language or can get help with the questionnaire.

Hearing Problems. Communicating with people whose hearing is severely impaired presents many of the problems of communicating with a patient who speaks a different language. Written questionnaires are a great help. Although very time-consuming, handwritten questions and answers may be the only solution. If the patient knows sign language, make every effort to find a translator who speaks, hears, and can use it. When patients have partial hearing impairment or can read lips, face them directly, in good light. Speak slowly and in a relatively low-pitched voice. Do not let your voice trail off at the ends of sentences, avoid covering your mouth, and use gestures to reinforce your words. If the patient has a "good" ear, arrange the seating to take advantage of it. A person who has a hearing aid should, of course, wear it, and you should check to be sure that it is working. Patients who wear glasses should use them too; visual cues may help them to understand you better. Supplement any oral instructions with written ones.

Blind Patients. When talking with a blind patient, be especially careful to announce yourself and explain who you are and why you are there. Taking the patient's hand may help to establish contact and indicate where you are. If the room is unfamiliar, orient the patient to it and explain what is there and whether anyone else is present. Remember to respond vocally to such patients when they speak, since facilitative postures and gestures will not work. At the same time guard against raising your voice unnecessarily.

Fatally Ill Patients. In communicating with fatally ill or dying patients, most interviewers face problems within themselves—their own discomforts, anxieties, and desires to avoid the subject or even the patients. With the help of reading and discussion, you will need to work through your own feelings. As in any clinical situation, it is helpful to know what reactions the patient is likely to have. Kübler-Ross has described five stages in a patient's response to impending death: denial and isolation, anger, bargaining, depression or preparatory grief, and acceptance. At each stage, your approach is basically the same. Be alert to the feelings of such patients and to cues that they want to talk about them. Help them to bring out their concerns with nondirective techniques. Make openings for them to ask questions: "I wonder if you have any concerns about the operation? . . . your illness? . . . how it will be when you go home?" Explore these concerns and provide whatever information the patients request. Be wary of inappropriate reassurance. If you can explore and accept the patients' feelings, if you can answer the patients' questions, if you can assure and demonstrate your ability to stay with the patients throughout the illness, reassurance will grow where it really matters—within the patients themselves.

Fatally ill or dying patients rarely want to talk about their illnesses all the time, nor do they wish to confide in everyone they meet. Give such patients opportunities to talk, and listen receptively, but if the patient prefers to keep the conversation on a lighter plane you need not feel like a failure. Remember that illness—even a terminal one—is only one small part of personhood. A smile, a touch, an inquiry after a family member, a comment on the day's ballgame, or even some gentle kidding all recognize and reinforce other parts of the patient's individuality and help to sustain the living person. To communicate appropriately you have to get to know the patient; that is part of the helping process.

Talking With Families or Friends. Some patients are totally unable to give their own histories. Others may be unable to describe parts of them, such as their behavior during a convulsion. Under these circumstances you must try to find a third person from whom to get the story. At times, although you may think you have a reasonably comprehensive knowledge of the patient, other sources may offer surprising and important information. A spouse, for example, may report significant family strains, depressive symptoms, or drinking habits that the patient has denied. When you suspect such discrepancies, look for opportunities to get additional information from persons other than the patient.

When seeking data from a third person, it is usually wise to get the patient's approval. Assure such patients that you will keep confidential what they have already told you, or get their permission to share certain information. Data from other persons must also be held in confidence.

The basic principles of interviewing apply to your conversations with relatives or friends. Find a private place to talk. Leaning against opposite walls of a hospital corridor is not conducive to good communication. Introduce yourself, state your purpose, inquire how they are feeling under the circumstances, and recognize and acknowledge their concerns. As you listen to their versions of the history, be alert for clues to the quality of their relationships with the patient. These may color their credibility or give you helpful ideas in planning the patient's care.

Occasionally a relative or friend insists on accompanying the patient during the history or even the physical examination. If you can, ascertain his or her reasons as well as the patient's wishes. When patients are completely unable to give their own histories, help from an informed person is essential. When patients can communicate at all, however, even just by facial expressions or gestures, it is important that they be given the chance to do so with complete confidentiality. It is usually possible to divide the interview into two parts—one with the patient alone and the other with both the patient and the second person. Each part has its own value.

Responding to Patients' Questions. Patients' questions may seek simple factual information. More often, however, they express feelings or concerns. Try to elicit these feelings or delve further, lest you offer a misguided answer.

Patient:	What are the effects of this blood pressure medicine?
Response:	There are several effects. Why do you ask?
Patient:	(Pause) Well, I was reading up on it in a friend's book. I read it could make me impotent.

Similar caution is indicated when patients seek advice for personal problems. Should the patient quit a stressful job, for example, or move to Arizona, or have an abortion? Before responding, find out what approaches he or she has considered, what pros and cons there might be to the possible solutions. A chance to talk through the problem with you is usually much more valuable than any answer you could give.

Finally, when the patient is asking for specific information about the diagnosis, progress, or treatment plan, answer when you can but be careful that your responses do not conflict with those provided by others. When you are unsure of the answer, offer to find out if you can. Alternatively, you can suggest that the patient ask Dr. X because Dr. X knows more about the case or is making that decision. Beware, however, of using this approach simply to avoid a difficult issue. If you carry the primary patient responsibility yourself, share your opinions and plans and the patient's prognosis with other members of the health team so that each in turn can communicate with the patient effectively.

Quality of the Data. Virtually all the information with which the clinician works is subject to error. Patients forget symptoms, misremember the sequence in which they occurred, hide important but embarrassing facts, and shape their stories toward what interviewers seem to want to hear. Clinicians misunderstand their patients, overlook some relevant information, fail to ask the one key question, jump to premature diagnostic conclusions, or forget to examine the genitals of a patient with asymptomatic testicular carcinoma. You can avoid some of these errors by being thorough, by keeping an open mind as you gather data, and by analyzing any mistakes that you might make. Clinical data, however, including laboratory work, are inherently imperfect. The quality of information may be judged by its reliability, validity, sensitivity, specificity, and predictive value.

- *Reliability* refers to how well an observation repeatedly gives the same result. This may be measured for one observer or for more than one. If on several occasions one clinician consistently percusses the same span of a patient's liver dullness, *intraobserver reliability* is good. If, on the other hand, several observers find quite different spans of liver dullness on the same patient, *interobserver reliability* is poor.

- *Validity* refers to a close agreement between an observation and the best possible measure of reality. The validity of blood pressures measured by a sphygmomanometer, for example, might be compared with levels obtained by intraarterial tracings.

- *Sensitivity* of an observation or test refers to the proportion of people with a disease (or other condition) who are positive for that disease on a given test (called "true positive"). When the observation or test is negative in a person who has the disease, the result is called "false negative." A highly sensitive test or observation reveals most of the people with a given condition (the true positives) and has few false negatives.

- *Specificity* of an observation or test refers to the proportion of people without a disease or condition who are negative on a given test (called "true negative"). A test that is 95% specific correctly identifies 95 out of 100 normal people. The other 5 are "false positives."

Heart murmurs provide good examples of sensitivity and specificity. The vast majority of patients with significant valvular aortic stenosis have systolic murmurs audible in the aortic area. A systolic murmur is, therefore, quite a sensitive criterion for valvular aortic stenosis. When auscultation for an aortic systolic murmur is used to detect this condition, it reveals most of the cases and misses only a few. The false negative rate is low. Such a murmur, however, sorely lacks specificity. Many other conditions, such as increased blood flow across a normal valve or the sclerotic changes associated with aging, may also produce this kind

of murmur. If you were to use an aortic systolic murmur as your sole criterion for aortic stenosis, you would falsely label many patients as having it, thus producing many false positives. In contrast, the high-pitched decrescendo diastolic murmur heard best along the left sternal border is a murmur quite specific for aortic regurgitation. Normal people virtually never have such a murmur, and other conditions that might cause a similar sound are uncommon. The specificity of this murmur is very high.

- *Predictive value* is also a useful clinical tool. In a given population of individuals, a few may have a condition or disease and probably most do not. The clinician who has made an observation or obtained a test result—either positive or negative—wants to know how well this finding predicts the presence or absence of disease.

  The *positive predictive value* of an observation or a test is the characteristic that is most relevant to the clinical setting. It refers to the proportion of "true" positive observations in a given population. In a group of women found to have suspicious breast nodules in a cancer screening program, for example, the proportion later determined to have breast cancer would constitute the positive predictive value of "suspicious nodules."

  The *negative predictive value* of an observation or test refers to the proportion of "true" negative observations in a population. In a screening program for breast cancer, the proportion of women without suspicious nodules who really have no breast cancer constitutes the negative predictive value of the observation.

  Predictive values depend in part on sensitivity and specificity but, unlike them, also depend heavily on the prevalence of the condition within the population. Despite unchanging sensitivity and specificity, the positive predictive value of an observation rises with prevalence while the negative predictive value falls.

Calculating Sensitivity, Specificity, and Predictive Values. It is helpful to arrange data from an observation or test finding in a 2 × 2 table that shows the results of an observation, either positive or negative, in a group of people with and without the disease. Always using the exact format on p. 643 will allow you to avoid errors in calculating sensitivity and specificity. Note that presence or absence of disease implies use of a "gold standard" to establish whether the disease is truly present. This is usually the best test available, such as a coronary angiogram for coronary artery disease or tissue biopsy for malignancy.

Note that the numbers related to sensitivity and specificity are located in the left and right columns, respectively, and are indicated here by vertical

red bars. Numbers related to positive and negative predictive values are found in the upper and lower rows, respectively, and are indicated by horizontal bars. The four boxes in the table are often identified by letters *a* through *d*, shown below in red.

		Disease: Present	Disease: Absent	
Observation	+	95 true positive observations (a)	10 false positive observations (b)	105 total positive observations
	−	5 false negative observations (c)	90 true negative observations (d)	95 total negative observations
		100 total persons with the disease	100 total persons without the disease	200 total persons

$$\textbf{Sensitivity} = \frac{a}{a+c} = \frac{\text{true positive observations (95)}}{\text{total persons with disease (95 + 5)}} \times 100 = 95\%$$

$$\textbf{Specificity} = \frac{d}{b+d} = \frac{\text{true negative observations (90)}}{\text{total persons without disease (90 + 10)}} \times 100 = 90\%$$

$$\textbf{Positive predictive value} = \frac{a}{a+b} = \frac{\text{true positive observations (95)}}{\text{total positive observations (95 + 10)}} \times 100 = 90.5\%$$

$$\textbf{Negative predictive value} = \frac{d}{c+d} = \frac{\text{true negative observations (90)}}{\text{total negative observations (90 + 5)}} \times 100 = 94.7\%$$

Two examples further illustrate these principles and show how predictive values vary with prevalence. Consider first an imaginary population *A* with 1000 people. The prevalence of disease X in this population is high—40%. You can quickly calculate that 400 of these people have X. You then set out to detect these cases with an observation that is 90% sensitive and 80% specific. Of the 400 people with X, the observation reveals .90 × 400, or 360 (the true positives). It misses the other 40 (400 − 360, the false negatives). Out of the 600 people without X, the observation proves negative in .80 × 600, or 480. These people are truly free of X, as the observation suggests (the true negatives). But the observation misleads you in the remaining 120 (600 − 480). These people are falsely labeled as having X when they are really free of it (the false positives). These figures are summarized on the next page:

		Disease X: Present	Disease X: Absent	
Observation	+	360 true positive observations (a)	120 false positive observations (b)	480 total positive observations
	−	40 false negative observations (c)	480 true negative observations (d)	520 total negative observations
		400 persons with X	600 persons without X	1000 total persons

As a clinician who does not have perfect knowledge of who really does or does not have disease X, you are faced with a total of 480 people with positive observations. You must try to distinguish between the true and the false positives, and will undoubtedly use additional kinds of data to help you in this task. Given only the sensitivity and specificity of your observation, however, you can determine the probability that a positive observation is a true positive, and you may wish to explain it to the concerned patient. This probability is calculated as follows:

$$\text{Positive predictive value} = \frac{\text{true positives (360)}}{\text{total positives (360 + 120)}} \times 100 = 75\%$$

Thus 3 out of 4 of the persons with positive observations really have the disease, and 1 out of 4 does not.

By a similar calculation, you can determine the probability that a negative observation is a true negative. The results here are reasonably reassuring to the involved patient:

$$\text{Negative predictive value} = \frac{\text{true negatives (480)}}{\text{total negatives (480 + 40)}} \times 100 = 92\%$$

As *prevalence* of the disease in a population diminishes, however, the predictive value of a positive observation diminishes remarkably, while the predictive value of a negative observation rises further. Consider a second population, *B*, of 1000 people, only 1% of whom have disease X. Now there are only 10 cases of X and 990 people without X. If this population is screened with the same observation, which has a 90% sensitivity and an 80% specificity, here are the results:

Observation	Disease X: Present	Disease X: Absent	
+	9 true positive observations (a)	198 false positive observations (b)	207 total positive observations
−	1 false negative observations (c)	792 true negative observations (d)	793 total negative observations
	10 persons with X	990 persons without X	1000 total persons

$$\text{Positive predictive value} = \frac{9}{207} \times 100 = 4\%$$

$$\text{Negative predictive value} = \frac{792}{793} \times 100 = 99\%$$

You are now confronted with possibly upsetting 207 people (all those with positive observations) in order to detect 9 out of the 10 real cases. The predictive value of a positive observation is only 4%. Improving the specificity of your observation without diminishing its sensitivity would be very helpful, if it were possible. For example, if you could increase the specificity of the observation from 80% to 98% (given the same prevalence of 1% and sensitivity of 90%), the positive predictive value of the observation would improve from 4% to 31%—scarcely ideal but certainly better. Good observations or tests have a sensitivity and specificity of 90%.

The Interplay of Assessment and Data Collection

The concepts of sensitivity and specificity help in both the collection and the analysis of data. They even underlie some of the basic strategies of interviewing. A question that is characterized by high sensitivity, if answered in the affirmative, may be particularly useful for screening and for gathering evidence to support a hypothesis. For example, "Have you had any discomfort or unpleasant feelings in your chest?" is a highly sensitive question for angina pectoris, and in patients with this condition would yield few false negative responses. It is a good first screening question, but because there are many other causes of chest discomfort it is not at all specific. With additional directed questions about location, quality, and duration of the discomfort, you can test further your hypothesis of angina pectoris. A pain that is retrosternal, pressing, and less than 10 minutes in duration—each a reasonably sensitive attribute of angina pectoris but not by itself specific—would add importantly to your growing evidence for

The Patient's Record

CHAPTER 21

The clinical record documents the patient's history and physical findings. It shows how clinicians assess the patient, what plans they make on the patient's behalf, what actions they take, and how the patient responds to their efforts. An accurate, clear, well organized record reflects and facilitates sound clinical thinking. It leads to good communication among the many professionals who participate in caring for the patient, and helps to coordinate their activities. It also serves to document the patient's problems and health care for medicolegal purposes.

When creating a record, you do more than simply make a list of what the patient has told you and what you have found on examination. You must review your data, organize them, evaluate the importance and relevance of each item, and construct a clear, concise, yet comprehensive report. If you are a beginner, organizing the present illness will probably constitute one of the most difficult problems because considerable knowledge is needed to cluster related symptoms and physical signs. That muscular weakness, heat intolerance, excessive sweating, diarrhea, and weight loss all constitute a present illness, for example, may not be apparent to either the patient or the student who is unfamiliar with hyperthyroidism. Until your knowledge and judgment grow, the patient's story itself and the seven key attributes of symptoms listed on page 14 are helpful guides.

Regardless of your experience, certain principles will help you to organize a good record. Order is imperative. Use it consistently and obviously so that future readers, including yourself, can easily find specific points of information. Keep items of history in the history, for example, and do not let them stray into the physical examination. Make your headings clear, use indentations and spacing to accentuate your organization, and asterisk or underline important points. Arrange the present illness in chronological order, starting with the current episode and then filling in the relevant background information. If a patient with longstanding diabetes is hospitalized in coma, for example, start with the events leading up to the coma and then summarize the past history of the diabetes.

The amount of detail to record often poses a vexing problem. As a student, you may wish (or you may be required) to be quite detailed. This helps to build your descriptive skills, vocabulary, and speed—admittedly a painful, tedious process. Pressures of time, however, will ultimately

Bates, B. A Guide to Physical Examination and History Taking, Sixth Edition.
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force some compromises. The following guidelines may be useful in choosing what to record and what to omit:

- *Record all the data*—both positive and negative—*that contribute directly to your assessment.* No diagnosis should be made, no problem identified, unless you have clearly spelled out the data upon which your assessment is based.

- *Describe specifically any pertinent negative information* (i.e., the absence of a symptom or a sign) when other portions of the history or physical examination suggest that an abnormality might exist or develop in that area. For example, if the patient has large and unexplained bruises, you should specifically note the negative history for other kinds of bleeding, for injury and physical violence, for medications and nutritional deficits that might lead to bruising, and for familial bleeding disorders. If a patient feels depressed but not suicidal, state both facts. If the patient has no emotional problems, on the other hand, a comment on suicide is clearly unnecessary.

- *Data not recorded are data lost.* No matter how vividly you can recall a detail today, you will probably not remember it in a few months. The phrase "neurologic exam negative," even in your own handwriting, may leave you wondering a few months hence: "Did I really do a sensory exam?"

- On the other hand, information can be buried in a mass of excessive detail, to be discovered by only the most persistent reader. *Omit most of your negative findings* unless they relate directly to the patient's complaints or to specific exclusions in your diagnostic assessment. Do not try to list all the abnormalities that you did *not* observe. Instead, concentrate on a few major ones (such as "no heart murmurs") and try to describe structures in a concise, positive way. "Cervix pink and smooth" indicates that you saw no redness, ulcers, nodules, masses, cysts, or other suspicious lesions, but the description is shorter and much more readable. You can even omit certain bodily structures despite the fact that you examined them. You may thus leave out normal eyebrows and eyelashes even though you looked at them.

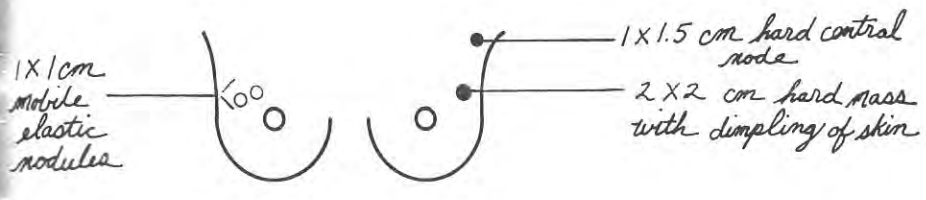
- Save valuable time and space by omitting superfluous words. *Avoid redundancies* such as those in parentheses in the following examples: pink (in color), resonant (by percussion), tender (to palpation), both (right and left) ears, (audible) murmur, and (bilaterally) symmetrical thorax. Repetitive introductory phrases such as "The patient reports no . . ." are also redundant and may be omitted. Unless you have indicated otherwise, readers will assume that the patient gave you the history. *Use short words* instead of long and probably fancier ones when they mean the same thing: "felt" for "palpated" and "heard" for "auscultated." Try to *describe what you observed, not what you did.* "Optic discs seen" may mark an exciting moment in your career when you first glimpsed them, and it may be all you can claim during your first few

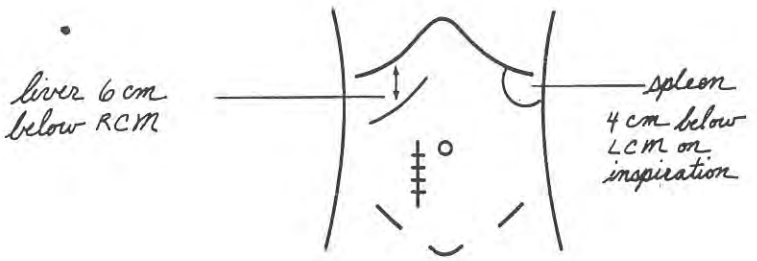
tries at an ophthalmoscopic examination. "Disc margins sharp," however, adds important information with only two additional letters.

- *Be objective.* Hostility, moralizing comments, and disapproval have no place in the patient's record, whether conveyed in words, penmanship, or punctuation. Notes such as "PATIENT DRUNK AND LATE TO CLINIC AGAIN!!" tell more about the writer than about the patient and, furthermore, might prove embarrassing in court.

Because records are scientific and legal documents, they should be understandable. Employ abbreviations and symbols only if they are commonly used and understood. Some clinicians may wish to develop an elegant style, and should certainly be encouraged to do so. Time is usually scarce, however, and style may be sacrificed in favor of concise completeness. It is common to use words and brief phrases instead of whole sentences. Legibility is essential. Otherwise, all that you have done is worthless to potential readers.

Diagrams add greatly to the clarity of the record. Two examples follow:





Make measurements in centimeters, not in fruits, vegetables, or nuts. "Pea-sized" and "walnut-sized" lesions preclude accurate evaluations and future comparisons. How big were the peas? Did the walnut have a shell?

You should write the record as soon as possible, before the data fade from your memory. In your initial attempts at interviewing, you will probably prefer just to take notes when talking with a patient. As you gain experience, however, work toward recording in final form the past medical history, family history, and review of systems during the interview. Leave

spaces for filling in later the present illness, the psychosocial history, and any other complex areas. During a physical examination it is wise to record immediately specific measurements such as the blood pressures in three positions. Recording a large number of items and descriptions interrupts the flow of the examination, however, and you will soon learn to remember your findings and record them after you have finished.

Recording the history and physical examination is simplified by printed forms. If your institution or agency provides them, you may be expected to use them. You should also, however, be able to create your own record. The example that follows offers one moderately complete guide. Although it is longer than most you may see in patients' charts, it still does not reflect every question and technique that you have learned to use.

Note the difference in the statements that introduce the history and the physical examination. The basic identifying data start the history, while a descriptive paragraph that summarizes your general survey begins the physical examination.

Unless forms are used and carefully followed, records are not exactly alike in detail. Detail varies appropriately with the patient's symptoms and signs and with the clinician's diagnostic thoughts about them. In this record, additional pertinent negatives are sometimes listed when an abnormality is described. Because of the edema and varicose veins, for example, the clinician also reported "No stasis pigmentation or ulcers." If there had been neither edema nor varicose veins, these comments would not have been necessary.

Mrs. Audrey N., 1463 Maple Blvd., Capital City
11/13/94
Mrs. N. is a 54-year-old, widowed, white saleswoman, born in the U.S.

Referral. None

Source. Self, seems reliable

Chief Complaint. Headaches

Present Illness. For about 3 mo Mrs. N. has been increasingly troubled by headaches: bifrontal, usually aching, occasionally throbbing, mild to moderately severe. She has missed work only once because of headaches, when she felt nauseated and vomited several times. Otherwise, nausea is rare. Headaches now average once a wk, usually are present on waking and last all day. They are relieved by lying down and using a cold wet towel on head. Little relief from aspirin. No other related symptoms, no local weakness, no numbness or visual symptoms

"Sick headaches" with nausea and vomiting began at age 15, recurred through her mid-20s, then diminished to one every 2 or 3 mo and almost disappeared.

Has recently had increased pressure at work from a new and demanding boss, and is also worried about her daughter (see psychosocial). Thinks her headaches may be like those in the past, but wants to be sure because her mother died of a stroke. Concerned that they make her irritable with her family

Past History

General Health. Good

Childhood Illnesses. Only measles and chickenpox

Adult Illnesses. Acute kidney infection, 1982, with fever and right flank pain; treated with ampicillin. A generalized rash with itching developed several days later. Kidney x-rays said to be normal, and infection has not recurred.

Psychiatric Illness. None

Injuries. Stepped on glass at beach, 1991, laceration, sutured, healed

Operations. Tonsillectomy, age 6; appendectomy, age 13

Current Health Status

Medications. Aspirin for headaches, multivitamins. Has taken "water pill" for ankle swelling, but none in past several mo

****Allergies.*** Ampicillin caused rash.

Tobacco. About 1 pack cigs per day from age 18 (36 pack yr)†

Alcohol/Drugs. Rare drink (wine) only, doesn't like it. No drugs

Diet. Breakfast—orange juice, 2 sweet rolls, black coffee
Mid-morning—doughnut, coffee
Lunch—hamburger and bun or fish sandwich, coffee
Dinner—meat or fish, vegetable, potato, sometimes fruit, sometimes cookies
Snacks in evening (e.g., chips, cola)
Has almost no milk or cheese

Tests. Last Pap smear 1991, "normal." No mammograms

* Asterisk or underline important points.
† (Age 54 yr − 18 yr) × (1 pack) = 36 pack yr

Immunizations. Oral polio vaccine, yr uncertain; tetanus shots × 2 in 1991, followed by a booster 1 yr later; flu vaccine 11/93, no reaction

Sleep. Generally good, average 7 hr, sometimes has trouble falling asleep, is wakened by alarm

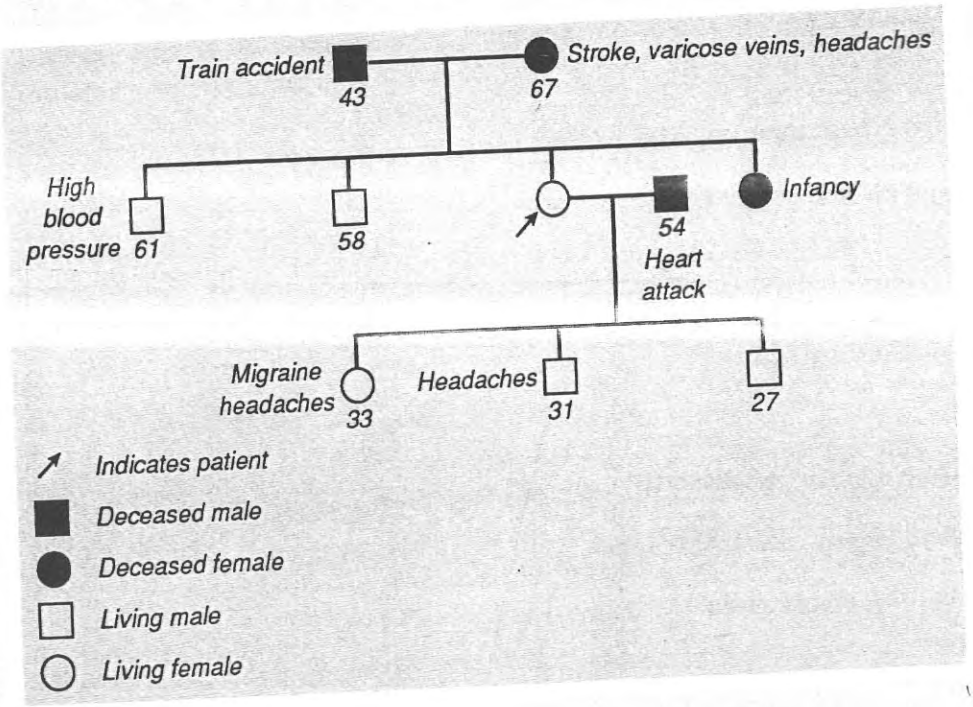
Exercise/Leisure. "No time"

* *Hazards.* Medicines kept in unlocked medicine cabinet. Cleaning solutions, furniture polish, and Drano kept in unlocked cabinet below sink. Mr. N.'s shotgun, with a box of shells, is in upstairs closet.

Safety. Seat belt regularly

Family History

(There are two methods of recording the family history. The diagrammatic format is more helpful than the narrative in tracing genetic disorders. The negative family information follows either format.)



Outline

Father died, 43, train accident
Mother died, 67, stroke, had had varicose veins, headaches
One brother, 61, has high blood pressure, otherwise well
One brother, 58, apparently well but for mild arthritis
One sister, died in infancy, ?cause
Husband died, 54, heart attack
One daughter, age 33, "migraine headaches," otherwise well
One son, 31, headaches
One son, 27, well

No family history of diabetes, tuberculosis, heart or kidney disease, cancer, anemia, epilepsy, or mental illness

**Psychosocial.* Born and raised in Lake City, finished high school, married at age 19. Worked as a clerk in store for 2 yr, then moved with husband to Capital City, had 3 children. Mr. N. had a fairly steady factory job, but to help with the family income Mrs. N. went back to work 15 yr ago. Children have all married. 4 yr ago Mr. N. died suddenly of a heart attack, leaving little savings and no insurance. Finances now tight. Has moved to small apartment to be near daughter, Dorothy. Dorothy's husband, Arthur, has a drinking problem and is verbally though not physically abusive. Mrs. N.'s apartment serves as a haven for Dorothy and her 2 children, Kevin, 6 yr, and Linda, 3 yr. Mrs. N. feels responsible for helping them, is tense and nervous, but denies depression. She has a few good friends but doesn't like to bother them with her family's trouble. "I'd rather keep it to myself. I don't like gossip." No church or other organizational support

Typically up at 7:00 a.m., works 9:00 to 5:30, eats dinner alone. Dorothy or the children visit most evenings and weekends. Moderate number of squabbles and considerable strain

Review of Systems

**General.* Has gained about 10 lb in the past 4 yr

Skin. No rashes or other changes

Head. See present illness. No head injury

Eyes. Reading glasses for 5 yr, last checked 1 yr ago. No symptoms

Ears. Hearing good. No tinnitus, vertigo, infections

Nose, Sinuses. Occasional mild cold. No hay fever, sinus trouble

Mouth and Throat. Some *bleeding of gums* recently. Last to dentist 2 yr ago. Occasional canker sore, has had one for 4 days

Neck. No lumps, goiter, pain

Breasts. No lumps, pain, discharge. Does breast self-exams sporadically

Respiratory. No cough, wheezing, pneumonia, tuberculosis. Last chest x-ray 1982, St. Mary's Hospital, normal

Cardiac. No known heart disease or high blood pressure; last blood pressure taken in 1987. No dyspnea, orthopnea, chest pain, palpitations. No ECG

**GI.* Appetite good; no nausea, vomiting, indigestion. Bowel movement about once daily though sometimes has hard stools for 2–3 d when espe-

cially tense; no diarrhea or bleeding. No pain, jaundice, gallbladder or liver trouble

**Urinary.* No frequency, dysuria, hematuria or recent flank pain; nocturia × 1, large volume. Occasionally loses some urine when coughs hard

Genital. Menarche at 13, regular periods, tapered off in late 40s and stopped at 49; no bleeding since; mild hot flashes and sweats then, none now

Gravida 3, para 3, living children 3. Prolonged labor during first pregnancy, otherwise normal. Little sexual interest now, not sexually active

**Musculoskeletal.* Mild aching low back pain often after a long day's work; no radiation down legs; used to do back exercises, but not now. No other joint pain

**Peripheral Vascular.* Varicose veins appeared in both legs during first pregnancy. Has had swollen ankles after prolonged standing for 10 yr; wears light elastic pantyhose; tried "water pill" 5 mo ago but it didn't help much; no history of phlebitis or leg pain

Neurologic. No faints, seizures, motor or sensory loss. Memory good

Hematologic. Except for bleeding gums, no easy bleeding. No anemia

Endocrine. No known thyroid trouble, temperature intolerance. Sweating average. No symptoms or history of diabetes

Psychiatric. See present illness and psychosocial

Physical Examination

Mrs. N. is a short, moderately obese, middle-aged woman who walks and moves easily and responds quickly to questions. She wears no makeup but her hair is fixed neatly and her clothes are immaculate. Although her ankles are swollen, her color is good and she lies flat without discomfort. She talks freely but is somewhat tense, with moist, cold hands.

P 94, regular R 18 Temp 37.1°C (oral)
BP164/98 right arm, lying
160/96 left arm, lying
152/88 right arm, lying (wide cuff)
Ht (without shoes) 157 cm (5'2")
Wt (dressed) 65 kg (143 lb)

Skin. Palms cold and moist, but color good. Scattered cherry angiomas over the upper trunk

Head. Hair of average texture. Scalp and skull normal

Eyes. Vision 20/30 in each eye. Visual fields full by confrontation. Conjunctiva pink. Sclera clear. Pupils round, regular, equal, react to light. Extraocular movements intact. Disc margins sharp. No arterial narrowing, A–V nicking

Ears. Wax partially obscures right drum. Left canal clear and drum negative. Acuity good (to whispered voice). Weber midline. AC > BC

Nose. Mucosa pink, septum midline. No sinus tenderness

**Mouth.* Mucosa pink. Several interdental papillae red and slightly swollen. Teeth in good repair. Tongue midline, with a (3 × 4 mm) shallow, white ulcer on a red base, located on the undersurface near the tip; it is slightly tender but not indurated. Tonsils absent. Pharynx negative

Neck. Trachea midline. Thyroid isthmus barely palpable, lobes not felt

Lymph Nodes. Small (less than 1 cm), soft, nontender, and mobile tonsillar and posterior cervical nodes bilaterally. No axillary or epitrochlear nodes. Several small inguinal nodes bilaterally—soft and nontender

Thorax and Lungs. Thorax symmetrical. Good expansion. Lungs resonant. Breath sounds normal with no added sounds

**Cardiovascular.* Jugular venous pressure 1 cm above the sternal angle, with head of bed raised to 30°. Carotid pulses normal and symmetrical. Apical impulse barely palpable in the 5th left interspace 8 cm from the midsternal line. Physiologic split of S_2. No S_3 or S_4. A 2/6 medium-pitched midsystolic murmur at the 2nd right interspace; does not radiate to the neck. Diastole clear

Breasts. Large, pendulous, symmetrical. No masses. Nipples erect and without discharge

Abdomen. Obese, but symmetrical. Well healed right lower quadrant scar. Bowel sounds normal. Sigmoid colon slightly tender, no other masses or tenderness. Liver span 7 cm in right midclavicular line. Splenic percussion sign negative. Liver, spleen, and kidneys not felt. No CVA tenderness

**Genitalia.* Vulva normal. Mild cystocele on straining. Vaginal mucosa pink. Cervix parous, pink, without discharge. Uterus anterior, midline, smooth, not enlarged. Adnexa difficult to feel because of obesity and poor relaxation. No cervical or adnexal tenderness. Pap smears taken. Rectovaginal exam unremarkable

Rectal. No masses. Brown stool, negative for occult blood

**Peripheral Vascular*

2+ edema of feet and ankles with 1+ edema extending up to just below knees. Moderate varicosities of saphenous veins bilaterally from mid-

thigh to ankles, with spider veins on both lower legs. No stasis pigmentation or ulcers. No calf tenderness

Pulses:

	Radial	Femoral	Popliteal	Dorsalis Pedis	Posterior Tibial
RT	N	N	N	↓	N
LT	N	N	N	0	N

Musculoskeletal. No joint deformities. Good range of motion, in hands, wrists, elbows, shoulders, spine, hips, knees, ankles

Neurologic

Mental Status. Tense but alert and cooperative. Thought coherent. Oriented. Cognitive testing not done in detail

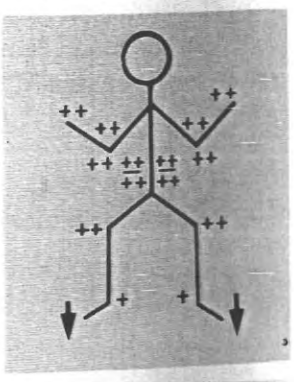
Cranial Nerves. See head and neck. Also—

I—Not tested
V—Sensation intact, strength good
VII—Facial movement good
XI—Sternomastoids and trapezii strong

Motor. Normal muscle bulk and tone. Strength 5/5 throughout. Rapid alternating movements and point-to-point movements intact. Gait normal. No pronator drift

Sensory. Romberg negative. Pinprick, light touch, position, vibration, and stereognosis intact

Reflexes. (Two methods of recording may be used, depending upon personal preference: a tabular form or a stick figure diagram, as shown below and at right.)



	Biceps	Triceps	Sup	Abd	Knee	Ankle	Pl
RT	2+	2+	2+	2+/2+	2+	1+	↓
LT	2+	2+	2+	2+/2+	2+	1+	↓

Before reading farther, assess Mrs. N.'s symptoms and physical findings. Then construct your own problem list for Mrs. N., as suggested in Chapter 20.

One way to organize Mrs. N.'s problem list is shown below. The clinician constructed the following problem list for Mrs. N. and placed it at the front of the chart. When a new assessment indicates changing the name of a problem, the original name is crossed out and a new name is given to the old number.

Date Problem Entered	No.	Active Problems	Inactive Problems
11/13/94	1	Migraine headaches	
11/13/94	2		Acute kidney infection
11/13/94	3	Allergy to ampicillin	
11/13/94	4	Tensions secondary to family situation, finances, and stress at work	
11/13/94	5	Gingivitis	
11/13/94	6	Low back pain	
11/13/94	7	Varicose veins with venous insufficiency	
11/13/94	8	Cystocele with occasional stress incontinence	
11/13/94	9	Possible high blood pressure	
11/13/94	10	Diet high in calories, fat, and carbohydrates, low in calcium	
11/13/94	11	Home hazards: kitchen supplies, medicines, gun	

Different clinicians often organize somewhat different problem lists for the same patient, and yours probably does not agree exactly with this one. Good lists vary in their emphases, length, and detail according to many factors, including clinicians' philosophies, specialties, and perceptions of their role in the care of the patient. The list illustrated here includes problems that need some attention now (such as the headaches) or may need further observation or possible future attention (such as the blood pressure and cystocele). The allergy is listed as an active problem to warn against inadvertent future prescriptions of penicillins.

A few items noted in the history and physical examination, such as canker sores and hard stools, do not appear in this problem list because they are relatively common phenomena that do not seem to demand attention. Such judgments may be wrong. Problem lists that are cluttered with relatively insignificant items, however, diminish in value. Some clinicians would undoubtedly judge this list too long; others would bring greater explicitness to problems such as "tensions," "diet," and "gingivitis."

The patient's record included notes on two of Mrs. N.'s problems:

1. Migraine headaches

Assessment. Supporting this diagnosis are "sick headaches" in earlier life, recurrent course of headaches, their duration, their relief by cold and quiet, associated nausea and vomiting (once at least), and positive family history. Further, no related neurologic symptoms or signs. Headaches may be somewhat more frequent than typical migraine headaches, pain is usually aching rather than throbbing, and there are obvious tensions at work and at home. Tension headaches should also be considered, therefore, but the headaches fit this pattern less well.

Plan

Diagnostic. Observation only. Mrs. N. to look for possible precipitating factors.

Therapeutic. Continue aspirin as needed.

Education. Nature of migraine discussed. Patient pleased and relieved

9. Possible high blood pressure

Assessment. Some of apparent elevation clearly related to obese arms, and some may be related to anxiety of a first visit. No evidence of target organ damage

Plan

Diagnostic. Repeat BP in one month. Use wide cuff. Urinalysis

Therapeutic. None now. Consider diet change on next visit.

Education. Need for BP checks explained

A month later Mrs. N. returned for a second visit. Part of the progress notes read as follows:

1. Migraine headaches

Subjective (S). Has had only 2 headaches, both mild, without associated symptoms. No longer worried about them. Cannot detect any precipitating factors

Objective (O). Not reexamined

Assessment (A). Improved

Plan (P). Return as needed.

4. Tensions

S. Dorothy is now attending Al-Anon meetings and tensions at home seem somewhat better.
O. Mrs. N. is more relaxed today.
A. Somewhat improved
P. Encouraged to discuss situation with me as needed

9. Possible high blood pressure

S. None
O. BP 146/84 right arm, lying (wide cuff). Urinalysis normal
A. If systolic pressure is high next time, it will indicate isolated systolic hypertension.
P. Repeat BP in 6 months.

Although you have insufficient information about most of Mrs. N.'s other problems, including her own priorities, try to develop an approach to them. What further data do you need?

What information do you need and how do you obtain it? These questions appear implicitly in Chapter 1 and continue throughout the book—and long afterward. The process of learning about a patient continues far beyond the first encounter, and understanding grows in depth, complexity, and fascination. Although your knowledge of Mrs. N. is incomplete, you know a great deal about her and have the tools with which to expand your knowledge further. Needed now is repetitive practice, with supervision, in using your newly acquired tools.

ICP - Introduction to Clinical Practice

ICP-IntCL page 1/2

Source	Mode
☐ Tutor	☐ Video
☐ Peer	☐ Audio
☐ Self	☐ Live

ICP - Interview Check List

Student Name:	*Simulated Patient Case Name:*	*Date:*				
		Assessment				
ITEM	DEFINITION	Excellent 5	Satisfactory 4 3	Marginal 2	Unsatisfactory 1	Not Observed 0
OPENING						
1. Initial Greeting: a. verbal introduction b. shake hands c. address patient as: Mr., Mrs., Ms	States name and role on team: "2nd year student" Greets warmly					
2. Puts patient at ease	Minimizes distractions. Attends to patient's comfort and privacy					
3. States goals for interview	Teaching exercise, consult, etc. Corrects misunderstanding.					
4. Calibration	A brief chat to assess potential barriers/level of communication					
INFORMATION GATHERING						
5. Questioning: Uses open- to- closed cone	Focuses by starting with open questions and ending with closed questions. Avoids multiple and leading questions. Avoids the use of jargon/ technical language					
6. Negotiates priorities for problems to be discussed.	Sets agenda and verifies it with patient, if appropriate.					
7. Establishes a narrative thread	Maintains a chronological account *Lets patient tell story without interrupting and listens carefully(3)* Follows significant leads					
8. Re- directs and /or interrupts (if necessary)	Recognizes when patient is rambling (circumstantial and/ or tangential)					
9. Problem Survey	Asks, "What else?" until all major concerns are expressed					
10. Segment Summaries	Restates the content and/ or feelings (paraphrases patient's answers and clarifies unclear statements)					
11. Clarification	Restates content and feelings expressed and checks for accuracy, i. e., "Let me see if I have this right."					
12. Transitional statements between interview sections	Avoids abrupt changes in content areas					

*from Loyola University Chicago Interview Check List (LUCICL) & ABIM Patient Perception Questionnaire

ICP - Introduction to Clinical Practice

ICP-IntCL page 2/2

Source	Mode
☐ Tutor	☐ Video
☐ Peer	☐ Audio
☐ Self	☐ Live

Student Name:	*Simulated Patient Case Name:*	*Date:*				
		Assessment				
ITEM	DEFINITION	Needs Work	Satisfactory	Good	Excellent	Not Observed
CLOSING						
13. Encourages patient's questions or invites comments	Does not avoid questions and answers clearly					
14. States appreciation for patient's efforts.						
15. Specifies follow- up (if necessary)						
FACILITATION SKILLS						
16. Eye contact	Conveys interest and attentiveness. Positive body language					
17. Open posture						
18. Invites/ reinforces patient's responses with nods, "umhmm" and repeating patient's last statement.						
19. Uses silences appropriately to facilitate expression	Silences must be at least 3 seconds long.					
RELATIONSHIP SKILLS						
20. Reflection	Restating an expressed emotion					
21. Legitimation	Expresses understandability of patient's emotions					
22. Respect	Expresses respect for patient's coping efforts. Treats patient at same level					
23. Support/ partnership (if appropriate)	Willingness to be helpful, to work together					
PATIENT EDUCATION						
24. Delivers diagnostic and instructional statements in simple language	Explains what patient needs to know and what to expect.					
25. Checks patient's understanding.						
26. Involves patients in process						
FLOW						
27. Overall feeling is that the interview moves smoothly from one component to another, with key points summarized and ending with a smooth closure.						

ICP - INTRODUCTION TO CLINICAL PRACTICE

ICP-OI-Hx

Student Name:

No:

Source	Mode
☐ Tutor	☐ Video
☐ Peer	☐ Audio
☐ Self	☐ Live

Outline of Medical History

A. **Chief Complaint :** .....

B. **History of Present Illness**
1. Characteristics of Symptoms
   a. ☐ Location
   b. ☐ Radiation
   c. ☐ Quality
   d. ☐ Severity/ Intensity
   e. ☐ Timing (onset, duration)
      i. ☐ Sudden, gradual
      ii. ☐ Acute, chronic
   f. ☐ Frequency/ Pattern (intermittent, continuous, progressive)
   g. ☐ Setting
   h. ☐ Aggravating/ Exacerbating factors
   i. ☐ Alleviating factors
   j. ☐ Associated manifestations
2. ☐ Associated **active medical, surgical or psychiatric problems** which may impact the Chief Complaint
3. ☐ **Past experience** with symptom(s)
   a. ☐ Prior Treatment? Response? Data from past charts?
   b. ☐ What has patient done about the symptom(s)
4. ☐ Significant positives and negatives
5. ☐ What was the psychosocial **context** of the onset of the symptoms?
6. ☐ Patient's **understanding** of the disease? Especially causes/ implications/ fears
7. ☐ **Impact** of the disease and/ or its treatment on the patient's life, work, relationships
8. ☐ Patient **expectations**
9. ☐ Patient's **reason** for visit
10. ☐ Preferences for end- of- life care (if appropriate)

C. **Past Medical History**
1. ☐ Childhood illnesses
2. ☐ Immunizations
3. ☐ Adult illnesses/ hospitalizations
4. ☐ Operations
5. ☐ Injuries/ Accidents
6. ☐ Obstetric History
7. ☐ Past psychiatric history? Mood changes?
7. ☐ Transfusions
8. ☐ Medications
9. ☐ Allergies and Drug Reactions
10. ☐ Health Screening (prior exams, cholesterol, etc.)
11. ☐ Diet, Sleep, Exercise
12. ☐ Tobacco, Alcohol, Drugs

D. **Psychosocial History**
1. ☐ Marital status
2. ☐ Living arrangements/ Family structure
   How are things at home?
3. ☐ Support/ Secondary Gains: are there people you can rely on for help? How have family or friends responded to the illness?
4. ☐ Employment history/ job satisfaction
5. ☐ Sexual history/ function
6. ☐ Significant life events

E. **Family History**
1. ☐ Current health of parents, siblings, children
2. ☐ History of significant illnesses (branching diagram if appropriate)
3. ☐ Deaths: dates and ages at death

F. ☐ **Review of Systems**

G. ☐ **General Comments** *(Use back for additional space)*

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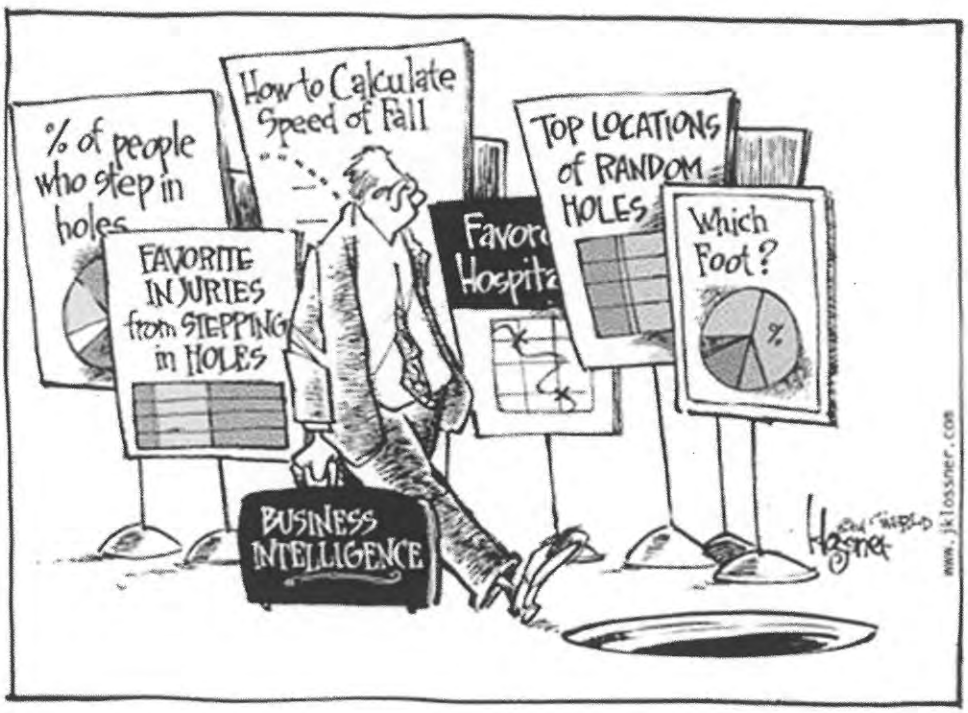
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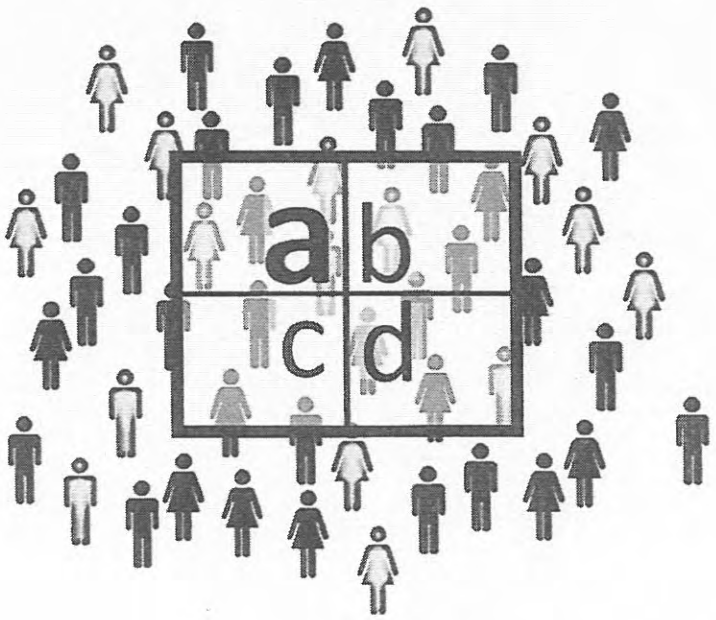
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*Adapted from Loyola U. Chicago


% of people who step in holes
How to Calculate Speed of Fall
TOP LOCATIONS of RANDOM HOLES
Which Foot?
FAVORITE INJURIES from STEPPING in HOLES
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SAĞLIKTA ARAŞTIRMA ve ÇÖZÜMLEME

Gazanfer Aksakoğlu



Üçüncü Yazım

VI. ARAŞTIRMA PLANLAMA

'verba volant, skripta manent'

(söz uçar, yazı kalır)

Araştırma öncesinde ve sırasında araştırmacı konuyu ve yöntemini ayrıntıları ile düşünür, danışır, okur, tartışır, yeniden düşünür, değiştirir, yeniden tartışır,.. Düşüncenin oluşumu için bu sürecin yaşanması gerekir. Ancak tüm bu düşünce ve tasarılar duman gibi oluşur ve yine duman gibi dağılır. Geliştirilebilmeleri için somut bir nitelik kazanmaları, bunun için de yazıya dökülmeleri gerekir. Yazılı olmadıkça düşünüleni geliştirmek ve yenilemek olanaklı değildir, çünkü nerede başlayıp nerede bitiği kestirilemez. Bu nedenle araştırmacı, araştırmanın her aşamasında geliştirdiği düşünceleri yazıya dökmeli ve yeri geldikçe yeni notlara dönüştürmelidir. Çalışması ilerledikçe tuttuğu notların yıprandığını, eskidiğini, aşıldığını ve içinden alınan bir özsu dışında, artık atılma aşamasına geldiğini görecektir. Sonra yeni notlar, yeni düzenlemeler, yeni düşünceler,.. birbirini izleyerek gelir, çünkü araştırmacı hızlı ve kaçınılmaz bir gelişme sürecine girmiştir.

Araştırmanın planlanması ve yürütülmesi belirli bir dizgesellik gerektirir. Dizgesel gidiş göz ardı edilerek araştırma yapmak olanaklı değildir, çünkü bilimin tarihsel birikimi araştırma için bir düzenek getirmiştir. Araştırmacı kişisel deneyimi ve birikimini araştırmanın her aşamasına uyarlayarak özgün yapıtını ortaya koyar, ancak bunun için uymakla yükümlü olduğu bir evrensel kurallar düzeni vardır. Düzen araştırmacının araştırmanın sonuç ve yorumlarını kullanacağı alana göre esneklik içinde yorumlanabilir ve uygulanabilir, ancak aşamaları gelişigüzel atlanamaz ve değiştirilemez.

Uyulması gereken aşamalar

'istim arkadan gelsin'
Sultan II. Abdülhamit

Demiryolu hattı tamamlanınca Sultan trenle hacca gitmeye karar verir. Haydarpaşa'ya gelir, adımını vagona atar, 'Sultanım, istim (buhar) gelmedi' derler. Sultan vagona biner, 'istim arkadan gelsin' der.

Araştırmada uyulması beklenen aşamalar ana hatlarıyla aşağıda özetlenmiştir:

- *Konu seçimi*: Öncelikle hangi konuda araştırma yapılacağı belirlenmelidir. Seçilen konu tanımlayıcı ve/ya da nedensel nitelikleriyle tasarlanır. İlerleyen aşamalarda bir başlık ya da ***Ad*** biçiminde netleştirilir.
- *Amaçların saptanması*: Araştırmanın hangi hedeflere ulaşmaya çalışacağı belirlenir. Araştırmanın yürütülmesi süresince, araştırma bulgu ve sonuçlarının nerede ve niçin kullanılacağı dikkate alınarak düzenlenir. ***Amaç*** ya da Amaçlar alt başlığıyla somutlaştırılır.
- *Hazırlık işlemleri*: Tüm araştırma sürecinin hazırlığını içermesine karşın, daha çok araştırmanın en önemli bölümü olan yöntem üzerinde yoğunlaşılması beklenir. Aynı, benzer ve karşıt araştırmaların gözden geçirilmesi, konuya ilişkin kaynak kitapların ilgili bölümlerinin okunması gibi bilgilenme çalışmaları ile başlar. Edinilen bilgilerden yola çıkılarak ***Yöntem*** netleştirilir. Finans kaynağı sağlanması, kit alımı, araç ve yakıt bulunması, personel eğitimi gibi temel gereksinmeler saptanır ve gerçekleştirilir. Araştırma evreni, seçilecek örnek, bağımsız ve bağımlı değişkenler, her aşamada yararlanılacak personel, veri ölçümünde kullanılacak aygıtlar ve ölçütler, veri değerlendirilmesinde yararlanılacak çözümleme teknikleri gibi özellikler ayrıntıları ile belirlenir. Verinin toplanmasında uygulanacak standartlar saptandıktan sonra verinin çözümlemesinde kullanılacak taslak tablolar oluşturulur ve bu tablolarda veri çözümlemesini sağlayacak yöntemler seçilir. Araştırmanın en uzun sürmesi ve en çok özen gösterilmesi gereken aşamasıdır. Hazırlık dönemi ne denli uzun tutulur ve verimli kullanılırsa, veri toplanması ve değerlendirilmesi o denli kısa sürede ve başarılı olarak tamamlanır. Altı ay süren başarılı bir hazırlık dönemi altı günde kolaylıkla güvenilir veri toplanmasını sağlayabilir, altı güne sıkıştırılmış bir hazırlık aşaması altı ayda bile uygun verinin toplanmasıyla sonlanmayabilir. 'İstim' arkadan gelmez, hazırlık dönemi lokomotifin istim tutması gibidir, istim tuttuktan sonra yola çıkılırsa gidiş sorunsuz olur.
- *Veri toplama*: Önceden netleştirilmiş örnekte, saptanmış teknikler ve ölçütlerle, sağlıklı bilginin alınması işlemidir. Hiçbir uygulama ve seçenek şansa bırakılmamış, karşılaşılabilecek her olasılık göz önünde bulundurulmuş ve önlemler alınmış olmalıdır. Veri, *Bulgular* başlığıyla sunuma hazırlanacak biçimde elde edilmelidir.
- *Veri çözümleme*: Toplanan verinin derlenmesi ve değerlendirilmesi dönemidir. Amacın net, yöntemin ayrıntılı olarak saptandığı durumlarda veri kolay toplanabileceği gibi, çözümleme de çabuk ve sağlıklı yapılabilir. Daha önce hazırlık işlemleri sırasında tablo taslakları çizilmiş ve kullanılacak hesaplama yöntemleri belirlenmişse, önemli bir güçlükle karşılaşılmaksızın tamamlanır. Veri toplanması sürecinde beklenmeyen, dikkat çekici, şaşırtıcı görünen,.. sonuçlar alındıysa özenle değerlendirilmeli ve amaçlara aykırı bulunsa bile çözümlenmelidir. Çözümleme işlemi, verinin *Bulgular* başlığıyla sunulmasıyla sonlanır.
- *Araştırma sunumu*: Amaç, yöntem ve izleyen aşamalarda elde edilenlerin okuyucuya iletilmesidir. Sırası geldiğinde veri, *Bulgular* başlığıyla sunulur. Bulgular tam anlamıyla nesnel olarak sunulmalı, sunuma hiçbir öznellik katılmamalıdır. Okuyucu ya da dinleyici, veriyi kendi algıları ve yorumu çerçevesinde değerlendirmelidir. Araştırmacının çok olumlu bulduğu veriyi okuyucu çok olumsuz bulabilir ve bulma hakkına sahip olmalıdır.

Nesnelliğin karşıtı olan öznel yaklaşım, yorumlamada gündeme gelir. Araştırmacının kendi bulgularını yine kendi bulgularıyla dikey ve başka araştırmacıların bulgularıyla yatay olarak yorumlaması beklenir. Yorum, *Tartışma* başlığı altında ve öznel olarak yapılır. Araştırmanın okuyucuya sunumu *Araştırmanın Yazımı* başlığıyla ayrıca sunulmuştur.

Araştırmanın her aşamasında ***Ad, Amaç*** ve ***Yöntem*** özel bir önem taşır. Bu üç öge her zaman akılda tutulmalı, tüm araştırma süresince birbirleriyle uyumlarına özen gösterilmelidir. Ad, amacı ve yöntemi içermeli; amaç, ad ve yöntemi yönlendirmeli; yöntem ad ve amacı açıklamalıdır. Üç öge birbiriyle uyumlu değilse her aşamada yeniden gözden geçirilmeli ve her biri her gerektiği noktada düzeltilmelidir. *Yöntem* araştırmanın amaçlarına nasıl ulaşılacağını açıklayan, *Ad* ise araştırmanın temel amaçlarını yöntemin en kısa tanıtımıyla birlikte açıklayan bölümlerdir. Böylece araştırmanın *Amaç* çevresinde yoğunlaştığını kabul etmek yerinde olur.

Taşıdıkları özel önem nedeniyle *Ad, Amaç* ve *Yöntem* ayrı başlıklarla ve daha ayrıntılı olarak aşağıda açıklanmıştır.

AD

> *Yaşlı adam, balık satıcısının önünden dalgın bakışlarla geçer. Birkaç dakika sonra geri döner ve dükkanın önündeki minik karatahtaya tebeşirle yazılı 'burada taze balık satılır' yazısını göstererek balıkçıya sorar: 'Balığı başka yerde mi satıyorsun?'. Balıkçı uyarıyı anlar, 'burada' sözcüğünü siler. Yaşlı adam birkaç dakika sonra yine gelir, 'taze balık satılır' yazısını gösterip 'balığın bayatı satılır mı?' der. Balıkçı kalkar, utanarak 'taze' sözcüğünü de siler. Yaşlı adam yine geri döner, 'balık satılır' yazısı için 'balık kiraya verilir mi?' diye sorar bu kez. Balıkçı sıkılır, 'satılır' sözcüğünü de siler. Yine gelir yaşlı adam, 'balık zaten tezgahta görülüyor, bir de ne olduğunu yazmaya gerek var mı?' der. Balıkçı yine kalkar yerinden...*

Araştırmanın adını seçmek ve yazmak çok güçtür. Ad araştırmanın etiketi ve sunum biçimidir. Hiç görmemiş ya da içini okumamış olanlar, bir kaynak listesinde rastlayan ya da konuya ilişkin kaynak arayanlar için, araştırmanın tanıtıcısıdır. Bu nedenle kısa, öz, anlaşılır olmalı, ancak içermesi gereken ana ögeleri dışarıda bırakmamalıdır. Yukarıda özetlenen öykü araştırma başlığı için abartılı bir örnektir, ancak araştırmaya Ad konurken bu öyküdeki denli titiz olmak gerekir.

Ad, araştırmanın amaç ve yöntemini en can alıcı noktalarıyla özetlemelidir. Can alıcı bulunmayan noktalara hiç değinilmemesi gerekir, Ad'ın bulgu ve yorum içermesi ise hiç beklenmez.

Ad, araştırmanın hem ilk hem son yazılan bölümüdür. Araştırmanın başlangıcında, konudan yola çıkılarak öncelikle yazılır. Araştırmanın bitiminde yeniden gözden geçirilir ve bir daha yazılır. Önce yazmanın nedeni araştırma süresince yönlendirici olmasının sağlanabilmesidir. Sonra düzeltilerek yeniden yazılmasının iki nedeni vardır: Birincisi, araştırma bitiminde araştırmacı -tüm araştırmayı olduğu gibi- başlığı da beğenmemelidir. Diğer kısımları değiştirme şansı artık yoktur, sözgelimi örneği baştan seçemez, ancak Ad'ı daha iyi yazma olanağına sahiptir ve bu olanağı

kullanmalıdır. İkincisi, araştırmacı kimi kendine bağlı olan ya da çoğunlukla kendi istemi dışında gelişen nedenlerle araştırmanın amacı ve yönteminin başlangıçta beklediğinden farklı geliştiğine tanık olabilir. Finans sağlanamamıştır, sıçanlar oda sıcaklığında tutulamamıştır, beklenen sayıda hastaya ulaşılamamıştır, laboratuvar desteği kesilmiştir, laboratuvar çalışanı doğum iznine ayrılmıştır, idrar örnekleri derin dondurucunun dışında unutulmuştur,.. ya da akla gelmeyen bir yığın başka sorun oluşmuştur. Ya da tersine, her şey yolunda gitmiş, üstelik ek olarak daha önce umulmayan bir enzimatik reaksiyonu gösterme olanağı da doğmuş ya da ankete verilen yanıtlar beklenmedik yeni ve önemli bulgular sunmaya başlamıştır. Olumlu ya da olumsuz değişiklikleri gizlemek uygun olmayacağından, araştırmanın adını ve -olanaklıysa ve dürüstlükle bağdaşıyorsa- amaç ve yöntemi de yeniden düzenlemek ve yazmak gerekli ve yararlı olabilir.

Araştırma adının kısa ve öz olması, anlaşılırlığını artırır. Ad kısaltılırsa anlamını yitirmez, ayrıca araştırmacının gözünde eksik kaldığı düşünülen ayrıntı Amaç'ta ve Yöntem'de açıklanabilir. 'Sağlık Hizmetlerinin Sosyalleştirildiği Bir Bölgede Halkın İyileştirici Hizmetler İçin Seçtiği Sağlık Kuruluşları ve Bu Seçimi Etkileyen Etmenler Üzerine Bir İnceleme' olarak yazılan bir tez adı 'Sosyalleştirmede İyileştirme İçin Seçilen Kuruluşlar ve Seçimi Etkileyen Etmenler'e dönüştürülürse yarıdan fazla kısaltılmış olur, anlamını da yitirmez. 'Çocuklarda Tükürük Akım Oranı, pH'ı, İnorganik Elementleri (Sodyum, Potasyum, Kalsiyum, Magnezyum, İnorganik Fosfat) ile Çürük Arasındaki İlişkinin Karşılaştırmalı İncelemesi' başlığı kolaylıkla 'Çocuklarda Tükürük Özellikleri ile Çürük İlişkisi'ne indirgenebilir ve daha anlaşılır olması sağlanır. Tükürüğün hangi özelliklerinin incelendiği Amaç'ta kısaca belirtilir, Yöntem'de inceleme ölçütleri ve teknikleri ile açıklanır.

AMAÇ

Konusu belirlenen ve adı konulan bir araştırmanın ilk aşamada amacının net olarak ortaya konması gerekir. Amaç, araştırmanın bitiminde ulaşılmak istenen kazanımları çok kısaca özetlemelidir. Çoğunlukla birden fazla olur ve sıklıkla 'amaçlar' olarak adlandırılır. Araştırmanın amacı ya da amaçları 'Yöntem'den hemen önce ve ayrı bir bölüm olarak yazılmalıdır, araştırmacı sıralamaya daha uygun bulursa 'Yöntem'in başında da yer alabilir. Amaç çok net, açık, anlaşılır ve kısa olarak yazılmalı, birden fazla amaç varsa kesinlikle maddeler halinde dizilmelidir.

Amaç araştırma sonucunda elde edilmesi hedeflenen kazanımları göstermelidir. Tüm araştırmanın bitiminde, elde edilen sonuçlar ne olursa olsun, araştırmanın hedeflediği bir ileti vardır. İleti geniş bir yelpaze içinde, çok özelleşmiş bir konu ya da oldukça genel bir kavram olabilir. 'Endoskopik cerrahinin açık cerrahiye göre olumlulukları'nı ya da 'Beden boşluklarının görüntülenmesinde Manyetik Rezonans Görüntüleme'nin BT'ye tanı üstünlüğü'nü' ya da 'Lökosit filtresi kullanımının anti-HLA antikorlarının oluşumuna etkisi'ni ortaya koymak, 'AIDS ölümlerinin Afrika'da yol açacağı bebek ölümlerini gündemde tutmak' ya da 'İzmit Körfezi'nin kimyasal kirliliğine dikkat çekmek' amaç olabilecek kavramlardır.

Amaç iki temel özellik içermelidir:

1. *Ölçülebilir* olmalıdır: Araştırmanın amacı somut ve net olarak ölçülebilir olmalıdır. Bunu sağlamak için, kullanılan ölçütlerin genel, yuvarlak ve soyut olmamasına özen gösterilmelidir. Amacı tanımlayacak ölçüt 'iyi' değil, '%23.4 daha iyi'; 'oksijen doyumu artımı' değil, 'oksijen doyumunun yüzde 88'den 96'ya çıkması'; 'bebek ölümünün azaltılması' değil, 'bebek ölümünün binde 12'ye düşürülmesi' olmalıdır. Ölçümle belirtilemeyen hiçbir amaç incelemeye alınmamalıdır.
2. *Ulaşılabilir* olmalıdır: Araştırmanın olanakları ile ulaşılabilen en uygun verinin toplanması amaçlanmalıdır. Amaç 'kardiyovasküler bulguları saptamak' olarak belirlenirse ulaşılabilir hedefleri netleştirme olanağı azalır. Aynı amacı 'Adana-Balcalı'da 40 yaş üzeri toplumda koroner arter hastalığı belirtileri sıklığının saptanması' biçiminde netleştirmekle daha somut ve elde edilebilir hedefler ortaya konmuş olur. Benzer biçimde 'klorheksidin verniklerinin dental floraya etkisi' başlıklı bir araştırmada 'klorheksidin verniklerinin mutans streptokoklar üzerindeki antibakteriyel etkisinin saptanması' amaç olarak yerleştirilirse ulaşılmak istenen hedeflerde netlik sağlanmış olur ve konan ölçütlerle bu hedeflere ulaşılabilir.

Araştırmanın ulaşması istenen hedeflerin ölçülebilir ve ulaşılabilir olması sağlanabilirse, iyi tanımlanmış ve sınırları iyi çizilmiş amaç(lar) oluşturulabilir.

Amacın özlü ve çok kısa yazılması araştırmacının düşünce yalınlığını ve konusuna odaklanmasını da araştırmadan yararlananların algılama kolaylığını elde etmesini de sağlar.

Amacı abartılı ölçüde ya da ölçüsüz olarak genellemek doğru değildir. Amaç 'bundan sonra yapılacak çalışmalara ışık tutmak' ya da 'bilim dünyasındaki gelişmelere katkıda bulunmak' olamaz, çünkü zaten her araştırma kendiliğinden böyle bir görev üstlenmiş durumdadır ve bilim dünyasının içindeki alçakgönüllü yerini bu görev nedeniyle almıştır. Görevin yerine getirilip getirilmediği ya da çalışmanın böyle bir katkıya ulaşıp ulaşamadığı araştırmacının kendi değerlendirmesi ile değil, bilim tarihinin şaşmaz süzgeciyle belirlenecektir.

Araştırmanın amacı topluma yarar sağlayacak ipuçları elde etmek, ayrıca süreç içinde araştırmacı yetiştirilmesine katkıda bulunmaktır. Yayın araştırmanın amacı değil, sonuçları topluma ileten aracıdır.

YÖNTEM

Araştırma Tipi

Araştırmacı öncelikle araştırmasının ne tipte olacağına karar vermeli, ileriye ya da geriye yönelik ya da kesitsel bir yöntem seçerek bunu açıklamalıdır. Daha sonra araştırmanın tipine göre oluşturacağı grupları ve onlardan toplayacağı verinin özelliklerini ortaya koymalıdır.

Bir araştırmanın en önemli özelliği, araştırmacının kendine özgü koşullarda ve öznel kimliğiyle yöntem uygulaması ve topladığı veriyi çözümleyerek yorumlamasıdır.

Konuya ilişkin araştırmalar özenle seçilerek incelenmeli, danışılmalı, tartışılmalı, içlerinde örnek olabilecek yaklaşımlardan yararlanılmalı, ancak yöntem ve uygulamaları bire bir kopyalanmamalıdır. Araştırmacılar uluslararası yayınlardan bilgi ve deneyim edinme amacıyla yararlanmaları dışında, bazı durumlarda okudukları bir araştırmanın yöntemini tıpatıp uygulama yolunu da seçebilmektedir. Yabancı bir yayında, uluslararası saygınlığı olan bir dergide basılmış bile olsa, eksik ve yanlışların sıklıkla görülebildiği, bu nedenle yöntemin aynen uygulanmasının sakıncalı olabileceği akılda tutulmalıdır. Her araştırmacının ülke, laboratuvar, bilgi, deneyim, vb. özgün koşulları olduğu ve araştırmasını kendi koşullarına göre planlamasının uygun olacağı da anımsanmalıdır.

Evren ve Örnek Seçimi

Araştırmanın en önemli bölümü yöntem, onun en önemli kısmı ise örnek seçimidir. Tez ya da yayın değerlendirilmesinde örnek seçimi uygun bilimsel yöntemlerle yapıldıysa, araştırmanın diğer bölümlerini hoş görme ve geliştirme eğilimi geçerlidir. Örnek seçimi bilimsel yapılmadıysa araştırmanın kabul edilme olasılığı sıfıra yakındır.

Evren sağlık olgularının oluştuğu ve yaşandığı canlılar toplumunun tümüdür. Olgu, hastalık, sakatlık, ölüm gibi sağlık olgu ve olaylarına değinildiğinde yerkürede var olan tüm canlılardan söz edilir. 'Doğurgan çağdaki kadınlar' dendiğinde yerkürede var olan ve yapılan tanıma uygun olarak doğurgan özellikleri bulunan tüm kadınlar, 'HIV bulaşına yol açan maymunlar' dendiğinde Orta Afrika'nın (ya da tüm Afrika'nın ya da Güneydoğu Asya'nın) tüm maymunları akla gelmelidir. Araştırmalarda gerçek ve doğru sonuca ulaşmak için evreni oluşturan bu bireylerin tümünün ölçüm ve değerlendirmelerinin yapılması gerekir. İnsanlarda kan basıncı ortalamasını elde etmek için yeryüzünde yaşayan tüm insanların kan basıncı ölçümleri yapılmalı, sıçanlarda koledok kanalının tıkanması ile karaciğerde oluşacak yıkımı saptamak için yerkürede var olan tüm sıçanların kanalı bağlanmalı ve karaciğer kesit incelemeleri yapılmalıdır. İstatistik çözümlemelerin temelinde yatan ve mantığını oluşturan kavramlar ve hesaplamalar bu çerçevede oluşturulmuştur. Sözgelimi evren ortalaması 'μ' böyle bir ideal ölçüm yapılmışçasına varsayılmış, 'standart (ideal) normal dağılım' böyle düşsel bir veri varmışçasına ortaya konmuştur. Kuramsal açıdan bu varsayımların tümü doğru ve geçerlidir. Deney planlama aşamasına geçildiğinde ise kuramın dayandırıldığı varsayımsal veriyi uygulamaya kalkışmak doğal olarak gerçekçi olamaz. Evrenin tümünü değerlendirmek için zaman da yeterli değildir, para, kimyasal malzeme, araç-gereç ve özellikle çalışan sayısı da. Üstelik toplumun kendisi değişkendir, inceleme süresince ölür, doğar, göçer, hastalanır...

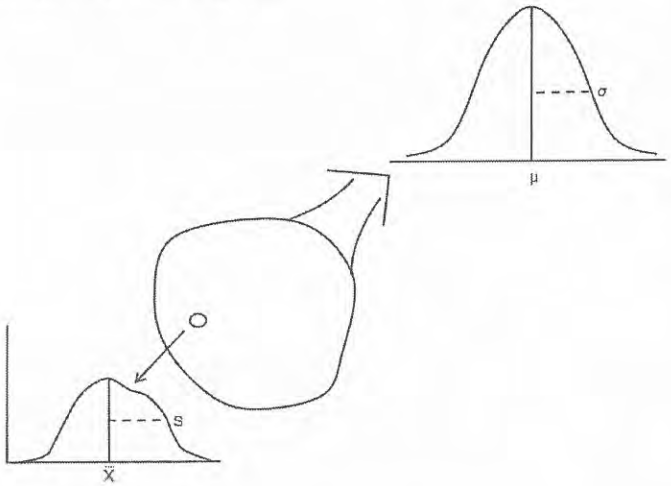
Yukarıdaki kuramsal yapı araştırma düzenlenmesinde ve çözümleme düzeneğinin oluşturulmasında temel alınan kavramları açıklar. Günlük yaşamda çalışılırken ve araştırma için örnek seçilirken evren kavramına farklı yaklaşmak gerekir. Sağlık alanındaki uygulamada evren, üzerinde çalışma yapılması düşünülen ve amaçların düzenlenmesinde hedef alınan kitledir. Sözgelimi 'Narlıdere Grup Başkanlığı'nda doğurgan çağdaki kadınlar' hedefinde aynı bölgede 2005 yıl ortasında yaşayan 15–44 yaş grubundaki '11,615 kadın', 'yoğun bakım hastaları' hedefinde 2012 yılında Dokuz Eylül Üniversite Hastanesi Anesteziyoloji yoğun bakımında sağaltıma alınan hastalardan oluşan '767 kişilik hasta grubu' ve 'koledok kanalının bağlanması sonucu alkalen fosfataz düzeyi yükselen sıçanlar' hedefinde laboratuvar olanakları ile ulaşılabilen '42 adet sıçan' toplumu, birer evren olarak görülmelidir.

Uygulamada gerçekçi ve geçerli yöntemi sağlamak ve yaşama geçirmek için, evrende sürmekte olan sağlık olgularını aynı ya da benzer biçimde yaşayan ve taşıdığı özelliklerle evreni temsil eden bir örnek bulmak gerekir. Bu örnekte araştırma ve araştırmacının ulaşabileceği büyüklükte birey ya da denek sayılarıyla çalışmak zorunludur.

Örnek evrenin içinden gelen, nicel ve nitel yönden evreni temsil eden, evrenden daha küçük modeldir. Her evrenin en iyi örneği yine kendisidir. Örnek küçüldükçe, nicelik ve nitelik yönünden evreni temsil etme özelliği azalır, büyüdükçe evrenin yapısına daha yakın konuma geleceği için temsil etme gücü artar.

Evren sonsuz derinliktedir. Evrenin içinde bulunan sonsuz sayıda eleman sonsuz sayıda değişken için sonsuz sayıda dağılım oluşturur. Bu dağılımların her biri sonsuz sayıda elemandan oluşmuştur ve değerleri eksi sonsuzla artı sonsuz arasındadır. Böyle bir yapıya ulaşmanın ve veri toplamanın olanaksızlığı nedeniyle evrenden örnek almak gerekir.

Evrenden alınabilecek sonsuz sayıda örnek sonsuz sayıda değişkenin tanımlanmasına olanak verir. Her bir değişkenin evrende yer alan sonsuz sayıda dağılımı ve bu dağılımların birer ortalaması (myu [μ]) ile standart sapması (sigma [σ]) vardır. μ ve σ araştırma ile hiçbir zaman ulaşılamayacak değerlerdir. Evrenden alınacak örneklerin her birinde o örneğe özgü birer ortalama ($\bar{x}$) ile onun standart sapması (S) yer alır (Şekil 25). Her örnekte bulunacak ortalama ve standart sapma birbirinden ve evrende bulunan ortalama ve standart sapmadan farklıdır. Örneğin ortalama ve standart sapması ile evreni temsil edebilmesi yani araştırma sonunda elde edilen değerlerin evrene genellenebilmesi için aşağıda açıklanan ilkelerin olabildiğince yerine getirilmesi gerekir.



Şekil 25. Evren ve örnekte ortalama ve standart sapma

Günlük yaşamda bilinçsiz ya da bilinçli olarak örnek alımı yaygın olarak uygulanır. Yarım kilo peynir satın almadan önce peynirden tadımlık bir parça alınarak sertliği, tadı ve tuzu konusunda karar vermek, kamyona yüklü buğday ürününü siloya kabul etmeden önce çeşitli yer ve derinliklerden özel örnek çubuğu ile bir kaç yüz gram buğday alarak niteliğini değerlendirmek tipik örnek alma işlemleridir. Bu satırlarda konuyu açıklama amacıyla sunulan örnekler de örnek seçme mantığının birer örneğidir. Araştırma amacıyla örnek alımı günlük yaşamdakine benzer mantıkla yapılır, ancak bilimsel kurallar çerçevesinde uygulanır.

Evrenin tümü incelenemeyeceğinden, araştırma ve deney için örnek almak zorunludur. Ender olarak, 'evren'in küçük ve güç ulaşılabilir olarak tanımlandığı koşullarda tüm evren örnek olarak alınabilir. Sözgelimi özelliği olan bir yöntemin, yeni bir cerrahi ya da greft tekniğinin uygulandığı hastalar biriktiğinde ya da istenmeyen bir etkilenme sonucu bir kimyasal ya da kanserojenle karşılaşmış gruplar oluştuğunda, örnek seçmeye gerek kalmaksızın tüm evren çalışmaya alınabilir. 'Yanık merkezine bir yılda kabul edilmiş olan iç yanıklar' planlanabilir bir örnek olarak düşünülemeyecek bir gruptur. Bu grup, hasta sayısı ve nitelikleriyle önceden bilinemez ve belirlenemez. Ancak bu grubun varlığı ve bilimsel yaklaşımla değerlendirilme gereği de göz ardı edilemez. Kliniğe iç yanık hastaları geldikçe tanıma uyan bir evren oluşur, o zaman da tümünü örnek olarak almak gerekir. Bu grup oluştuğunda bile, örnek olarak incelenen bu evrenin, gerçekte yeryüzünde var olan benzer hastaların ya da ileride oluşabilecek hastalar toplamının küçük bir örneğini oluşturduğu akılda tutulmalıdır.

Örnek almada uyulması gereken ilkeler

1. *En az örnek büyüklüğünün hesaplanması:* Örnek seçiminde alınması gereken birey sayısı çok önemlidir. Araştırmanın tipine, evrenin büyüklüğüne, sağlık olgusunun görülme sıklığına, yöntemin gücüne, kabul edilen olasılık düzeyine, beklenen hızdan sapmaya birçok öge, seçilecek örneğin büyüklüğünü etkiler. Bu nedenle, yukarıdaki ögeler dikkate alınarak, seçilecek en az birey sayısı kesinlikle belirlenmeli, bunun altında kalan sayıda örnek ile yetinilmemelidir. Alınacak en az birey sayısını belirlemek için Dünya Sağlık Örgütü'nün örnek sayısı belirlemeye yönelik kitabından (Lwanga SK, 1991) ya da EpiInfo Statcalc ya da PASS programlarından yararlanılmalıdır. Kitap ve programdaki sayıların belirlenmesinde evrensel formüllerden yararlanılmıştır. Ancak araştırmacıların bu formülleri kullanmaması; zaman, para, malzeme gibi olanaklar nedeniyle görülmesi gereken seçeneklerin görülmesini sağlayacak tablolara ulaşmaları uygun olur. Formüller tek bir sayı sunarak seçeneklerin görülmesini engeller ve araştırmacının öznel koşullarına göre en az örnek büyüklüğü seçme özgürlüğünü ortadan kaldırır. Programda araştırma tiplerine göre örnek büyüklüğüne karar vermeyi sağlayacak bilgi yer alır. Kitap ya da bilgisayar programlarındaki tablolarda araştırma tipi, beklenen olası prevalans, güven aralığı, kabul edilebilen sapma, göreli risk, güç gibi araştırmacı tarafından belirlenen ölçütler yerleştirilerek örnek büyüklüğü hesaplanır. Ölçütler yazılırken gerçekte olması gereken nesnel değerler kullanılmalı, istenen büyüklüğü sağlamaya yönelik düzenleme yapılmamalıdır.

Araştırmacı tüm olanaklarını kullansa da en az örnek sayısına ulaşamayacağını önceden algılıyorsa, veri çözümlemesini gerçekleştirebileceği en yüksek sayıda bireyi alarak araştırmaya başlayabilir. Hesapladığı en az örnek büyüklüğünü yönteme yazmalı, karşılaştığı açmazı ve niçin kurala uyamadığını yöntem ve kısıtlılıklar

bölümünde açıklamalıdır. Yine de böyle bir yaklaşımın tek amacı eğitim olan- tez için kabul edilebilir olabileceği, ancak yayın için geçerli olmayacağı akılda bulundurulmalıdır.

'Tüm öğrencileri incelemek' ya da 'kliniğe bir yılda başvuran tüm patella kırıklarını değerlendirmek' gerekli ya da kaçınılmaz olabilir, ancak 'en az örnek büyüklüğü' hesaplanmadan bu eylemin yapılması, elde edilecek sonuçların evrene genellenmesini engeller. Okuldaki 857 öğrencinin tümü örnek olarak alınmış ve belirli bir standartla 832'sine ulaşılmış olabilir, ancak 'en az örnek büyüklüğü' hesaplanmadıysa yapılan bir 'araştırma' sayılamaz. Hem kurala uyulmamıştır hem belki hesaplanmayan 'en az örnek büyüklüğü' 3,216 ya da 525+525 gibi çok farklı bir sayıdır.

Formülle en az örnek büyüklüğü hesaplanması

İşlemin tablolar aracılığıyla yapılması tarafımızca önerilmesine karşın araştırmacı en az örnek büyüklüğünü elle hesaplamak isteyebilir. Bu durumda kullanılacak en uygun ve anlaşılır formüller ilgili biyoistatistik kitabında bulunabilir (Sullivan LM, 2012). Bağımlı grupta yapılacak iki ayrı ölçüm için, gösterilen kaynaktan yararlanılması özellikle önerilir.

2. *Belirlenenden fazla sayıda örnek alınması:* En küçük örnek büyüklüğü araştırmacıya evreni temsil eden veriye ulaşması için en az kaç bireyle çalışması gerektiği konusunda ipucu verir. Öncelikle bu nedenle, 'en az' sayının üzerinde bireyle çalışılmalıdır. Araştırma sürecinde bireylerin bir kısmının tam verisine de ölüm, tüp kırılması, devam etmeme gibi nedenlerle ulaşılamayabilir. Öyleyse 'en az' sayının üzerine çıkmak için, saptanandan daha yüksek sayıda birey alınmasına özen gösterilmelidir.

3. *Yedek örnek grubu alınması:* Örneğe çıkan tüm bireylere ulaşılamayacağı dikkate alınarak ve deneyimlerden yararlanılarak %10 ya da %20 gibi sayıda birey yedek örnek olarak alınır. Alınacak yedek grubun büyüklüğünü belirlemek için ulaşılması düşünülen örnek sayısını beklenen ulaşma oranı ile çarpmak yeterlidir. Sözgelimi örneğe en az 187 kişi alınması gerektiği belirlendi ve ulaşılamaması beklenen kişi sayısı bunun yüzde onu ise 187 kişi 0.90'la çarpılır. Elde edilen 168.3 ya da ondan biraz daha büyük sayıda kişi örnekte ulaşılabilecek toplam sayı olarak düşünülür. Bu durumda en az 187–169=18 birey yedek olarak örneğe katılmalıdır. İstenirse (187+18=) 205 (ya da daha çok) kişiye doğrudan örnek olarak ulaşılmaya çalışılabilir. Ya da önce 187 birey izlenir, bunların sözgelimi 15'ine ulaşılamazsa 18 kişilik (ya da fazla sayıdaki) yedek gruptan 15'i sırayla alınmaya çalışılır. 18 yedekten yalnızca 13'üne ulaşılabilirse, toplam ulaşılan sayısı 187'de 185, ulaşma oranı %98.9, yani ulaşılması gereken en az örnek büyüklüğünden düşük olacaktır. Öyleyse örneğe alınacak kişi ve yedek sayısı daha yüksek, örneğin 220+40 tutulmalıdır. Verilen örnek ulaşılması gereken *'en az'* örnek büyüklüğü içindir. Bunun üzerinde sayıda örnek alınması araştırmacının elini güçlendirir.

Elde olmayan nedenlerle en az örnek sayısına ulaşılmasının olanaksız olduğu biliniyor ve bu nedenle başvuranlar ya da var olanların tümü alınmak zorunda kalınıyor olsa bile en az örnek büyüklüğü hesaplanmak ve araştırmaya -hesap yöntemiyle birlikte- yazılmak zorundadır.

4. *Anlamlılık düzeyinin seçilmesi:* Araştırma verisi toplanmaya başlanmadan önce anlamlılık düzeyi seçilmelidir. Seçilen düzey çoğu zaman p=0.05 olur. Özel durumlarda gerekçesi açıklanarak 0.05'in altında ya da üstünde bir düzey belirlenebilir. Gerekçe açıklanmadan p=0.01, p=0.02, p=0.001 gibi farklı sınır değerler seçilmemeli, seçilme gereksinmesi duyuluyorsa nedeni açıklanmalıdır. Araştırmacılar bazı durumlarda anlamlılık düzeyini ve en küçük örnek büyüklüğünü belirledikten sonra veri toplar, bir nedenle bekledikleri en az birey sayısına ulaşamadıklarında sayıyı düzeltme amacıyla önceden belirledikleri anlamlılık düzeyini değiştirirler. Bu uygulama bilimsel dürüstlük anlayışına aykırıdır.

5. *Sapmanın kestirilmesi:* Örnek büyüklüğünün hesaplanmasında etkenle karşılaşmayan grupta -coğrafya, yaş, cins, vb. nedenlerle- olgu görülme olasılığının, ayrıca bundan sapma oranının ne ölçüde beklendiği istenir. Patoloji sözgelimi %20 ve sapma oranı %5 kadar bekleniyorsa prevalans %20, beklenen sapma değeri alt sınırı %15 ve üst sınırı %25 olarak alınmalıdır.

6. *Dışlanma ölçütü konmaması:* Örnek seçiminde dışlanma ölçütü koymamak gerekir. Bunun bir nedeni nedensellik ilişkisinde eksikler oluşmasını engellemektir. Araştırmalarda yaygın olarak *'dışlanma kriteri'* adı altında konan bu tür sınırlamalar çoğunlukla nedenlerin ortadan kaldırılması anlamına gelebilir. Bağımlı değişkeni böbrek yetmezliği olarak konan bir araştırmada bağımsız değişkenler yerleştirilirken diyabet, streptokok enfeksiyonu geçirmiş olma, hipertansiyon gibi temel nedenlerin dışlanması, risk grubundaki bağımsız değişkenleri yok saymak anlamına gelir ve araştırmayı mantık boyutundan saptırır. Bir diğer neden yan tutmaya yol açmamaktır. İlaç intoksikasyonu olgularını değerlendiren bir araştırmada yalnızca sağ kalanlar inceleniyor ve ölenler dışlanıyorsa yüksek dozla karşılaşanlar, beden yüzeyi düşük olanlar, bebekler, yaşlılar,.. bilinçli olarak kapsam dışında tutuluyor demektir. Dışlama, değişkenler değil, yalnızca tanı ölçütleri yani standartlar dikkate alınarak uygulanabilir, kararı yalnızca ilgili klinik ya da laboratuvarca alınabilir. Yapılacaksa bu dışlama da kesinlikle örnek seçiminden önce, evreni oluşturma aşamasında yapılmalı, evren uygun biçimde tanımlanmalıdır. Örneğin acil servise başvuranlarda miyokard infarktüsü belirtisi olan göğüs ağrısı ile yıkım enzimleri arasında ilişki aranan bir araştırmada, enzim değerini yükselterek kafa karıştıracak olan trafik kazası sonucu başvuru dışlanmalıdır. Dışlama evreni tanımlama aşamasında yapılmalı, evren tanımlanırken genel beden travmasının araştırmaya kabul edilmeyeceği, gerekçesiyle birlikte açıklanmalıdır.

7. *Alınma ölçütü konması:* Dışlanma ölçütü yerine *'alınma ölçütü'* kullanılması uygun olur. Böylece evren araştırmacı tarafından daha açık tanımlanabilir ve örnek seçimi çok daha 'anlaşılmış' olarak yapılır. Örneğe ulaştıktan sonra konan tüm ayrıntılı ulaşma standartlarına karşın ulaşılamayanlar, ayrıca örneğe girmeyi kesinlikle kabul etmeyenler olacaktır. Bazı kişiler de koşullara uygun olmadıkları için, sözgelimi sağ kolu ampute bir birey örnekteki diğer bireylerde olduğu gibi sağ brakial arter basıncı ölçülemeyeceği için dışlanmak zorunda kalınacaktır. Sayılan durumlar ortaya çıktığında yedek örnek grubundan yararlanılacaktır. Alınma ölçütü uygulanması dışlanma ölçütü uygulanmasına kıyasla çok daha bilinçli ve yan tutmayı engelleyici bir davranıştır.

8. *Örneğin tümüne ulaşılması:* Seçilen örnek sayısı evren verisi konusunda bilgi verecek 'en az' sayıda bireyden oluşmaktadır. Araştırma sürecinde örnek grubunun tümüne ve daha fazlasına ulaşılmaya çalışılmalı, ulaşılamayan varsa eksiklik yedek

listeden giderilmelidir. Veri toplama aşamasında her bir bireye niçin ulaşılamadığının özenle not edilmesi unutulmamalıdır.

Veri toplanma sürecinde yapılan yaygın bir yanlış, araştırmada ulaşılan kişi sayısının 'en az' örnek sayısının altında kalmasıdır. 'En az' örnek sayısı, en az kaç kişiye ulaşıldığında örneğin evreni temsil edeceğinin göstergesidir. Örneğin toplumda %25 görülen bir sağlık olgusunu elde etmek için yapılan bir araştırmada %20–30 arasında olgu saptanacağı düşünülerek 0.95 olasılık ve %80 güç için bakılan örnek büyüklüğü tablosunda en az 117+117 (=234) kişiye ulaşılması gerektiği belirlendiğinde, ulaşılamayacaklar da dikkate alınarak 260 kişilik örnek ve 26 kişilik yedek liste oluşturulabilir. Yedek listeden de yararlanılmasına karşın 234 yerine 230 kişiye ulaşılabildiğinde 'en az' sayının altına inilmiş ve yapılan çalışmada evreni temsil etme olanağı ortadan kalkmış demektir.

Örneğe ulaşma konusunda bilinçli olarak yapılan bir yanlışlık, veri toplama sürecinde edinilen sonucu yeterli bularak kalan bireylere ulaşma gereği duyulmamasıdır. Bu yanlış hemen her zaman çözümlemede anlamlılık bulma kaygısı ile yapılır. Uygun örnek alımı yöntemiyle seçilen kişilerin verisi toplanırken araştırmacı salt merak nedeniyle belli bir sayıda kişiye ulaştığında elde ettiği verinin anlamlılığı için çözümlemeye yönelirse, salt veri toplanmış kişilerde sonuca varmış olacaktır. Bu bir araştırma yanılgısıdır, çünkü henüz saptanmış olan en az örnek büyüklüğüne ulaşılmamıştır. Ayrıca evren verisini açıklayacak sayı elde edilmemiş, üstelik örneğin gerçek dağılımına da ulaşılmamıştır. Bu aşamayı izleyen yaklaşım yanlışı daha da artırmaktadır: Araştırmacı 'anlamlı fark bulamadım, biraz daha veri toplayayım' derse yan tutmuş olacaktır. 'Anlamlı sonuca ulaştım, veri toplamayı keseyim' derse, evren verisini açıklayacak 'en az' sayıyı elde etmediği için yorumu evren açısından açıklayıcı olamayacak, üstelik daha da önemli bir yan tutma uygulamış olacaktır. Yapılması gereken, her kesitte hangi anlamlılık düzeyine ulaşıldığı hiç dikkate alınmaksızın veri toplamanın en az hedeflenen kişi sayısına (yukarıda 234) ulaşılıncaya dek sürdürülmesi, gerektiğinde yedek listesinden yararlanılması, varılabilen en yüksek ulaşılabilirlik düzeyine erişildiğinde araştırmayı tamamlayarak, anlamlılığın veri çözümlemesi için planlanan aşamasında hesaplanmasıdır.

Ulaşılamayan kişilerin tümüne aynı standartla yeniden ulaşılmaya çalışılmalı, yine de ulaşılamayanların her birinin ulaşılamama nedeni ayrı ayrı kaydedilmelidir. Araştırma sunulurken ulaşılma oranı belirtilecek, ulaşılamama nedenleri açıklanacak, gerekirse istek üzerine liste olarak gösterilebilecektir.

> Araştırmada örneğin evreni temsil etmesi gerektiği dikkate alınarak önceden belirlenen 'en az' kişi sayısının hesaplanması ve bunlara ulaşılması gerekir. Örneğe alınacak 'en az' kişi sayısı hesaplanmamış ya da tümüne ulaşılması bilerek durdurulmuş bir araştırma tamamlanmamış ve yan tutmuş sayılır.

Örnek almanın kaçınılmaz olumsuzlukları

Örnek almak zorunda kalmanın kaçınılmaz bazı sakıncaları vardır:

1. *Az sayıda kişiye ulaşılması*: Örnek seçmenin doğal gereği olarak örneği oluşturan bireylerin sayısı evrenin sayısından küçüktür. Sayının küçülmesiyle evrenin özelliklerinin örneğe aynen yansıması olasılığı azalır. Çok ender de olsa, 'Yineli Tek Olgu' (n of 1) çalışmalarında olduğu gibi, tek birey bile örnek olarak alınabilir. Örneğe giren birey sayısı çok azalınca örneğin evreni temsil etmesi söz konusu olamaz. Sayının küçülmesinin sakıncalarından birincisi, evrende beklenen niteliklerin örneğe yansımama olasılığıdır. Sözgelimi örnekte bulunan kadınların çoğunluğu çok çocuklu ise, az çocuklu ya da çocuksuz kadınlar yeterince temsil edilemeyebilir. Diğer sakınca, az sayıda bireyle yapılan çözümlemelerin aritmetik uygunluğunun getirdiği kuşkulu durumdur. Sekiz-on kişilik bir örnekte elde edilen bir ortalama, on binlerce kişiden elde edilecek ortalamanın karşılığı olamaz. Bu sakıncayı gidermek için örnekte bulunan bireylerin sayısı olanaklar elverdiğince yüksek tutulmaya çalışılır. Gosset'in çalışmaları ile oluşturulan t dağılımı mantığı gereği, örnek dağılımının evren dağılımına uygun olması için, seçilen her bir örnek grubundaki sayının en az 30 olması beklenir. Parametrik (ölçümsel) olmayan çözümlemelerde n=30 sayısı daha da düşürülebilir, başka bir deyişle örneğin büyüklüğü 30'un altına düştüğünde parametrik olmayan testler kullanma zorunluluğu doğar.

2. *Özelliklerin kaybolması*: Alınan örneğin özellikleri hiç bir zaman evrenin özelliklerini tam olarak yansıtamaz. Örnek, nitel yönden evrenin aynısı olamaz. 'Yaş' değişkeni dikkate alındığında nicel özellik korunmuş olur, ancak aranan değişken gerçekte 'deneyim' ise, yaş her zaman deneyimin yerini tutamaz. Örnek ne denli dikkatle seçilirse seçilsin, yaş, cins, sık görülen sağlık sorunları gibi temel özelliklerde bile evrenin tam karşılığı değildir. Nitel yönden evreni temsil etmesi ise daha da güçtür. Ender görülen özelliklerde ve hastalıklarda sayı küçüleceğinden, olasılık mantığı gereği, nitelik farkı giderek daha belirgin biçimde öne çıkar. Örneğin evreni temsil eder duruma getirilebilmesi için salt nicel değil, nitel açıdan da özen gösterilmesi, bu nedenle evrenin özelliklerinin önceden belirlenmesi gerekir. Evren içinde araştırma konusunu ilgilendiren ögelerin değişkenler aracılığıyla belirlenmesi örnek seçimini daha sağlıklı kılar. Değişkenler arasında yaştan sonra ilk akla gelen ve toplanacak veriyi en çok etkileyecek olan unsur cinstir. Evren içinde yaş ve cins dağılımı özellikleri ve diğer temel nitel özellikler önceden belirlenirse örnek seçimi buna göre planlanır, gerekirse tabakalama ya da standartlaştırma teknikleri ile örneğin evreni temsil etmesi sağlanır.

3. *Yan tutma*: Uluslararası kaynaklarda *bias* olarak geçen, Priene'li ünlü düşünür Bias'ın adından kaynaklandığı düşünülen kavram, araştırmanın değişik aşamalarında görülen -ya da daha kötüsü görülemeyen- ve onarılması güç ya da olanaksız yaralar açan bir yanılgıdır. Araştırmacının araştırma sürecinde karşılaşabileceği en önemli sorun yan tutmadır. Yan tutma çoğunlukla bilmeden ve fark etmeden yapılır, fark edildiğinde onarılması hemen hemen olanaksızdır. Klinik araştırmalar genellikle kliniğe başvuranlardan örnek alınarak yapılır, başvuranların sağlığına ve hastalıklarının sağaltımına düşkün kişiler olması, bu kişileri genel toplumdan farklılaştırır. Alan araştırmalarında toplumsal açıdan en riskli kişilerin ulaşılması en güç yerleşimlerde oturması, örneğe katılmalarını neredeyse

olanaksız kılar ve elde edilen verinin toplumu temsil etmesini engeller. Toprak yeme ortaya çıkmadan çocukların anneleri tarafından sağlık kurumuna getirilmemeleri, anemi tanısını geç almalarına ya da hiç alamamalarına yol açar. Acil servislerde yapılan çalışmalarda akut risklerle karşılaşan kişilerin çabuk eksitus olmaları nedeniyle araştırmaya katılamaması, yalnızca sağ kalabilme özelliklerini taşıyanların, yani 'daha sağlam' olanların araştırmaya alınmalarına yol açar. Bunlar ve benzeri durumlar, istemeden yan tutmanın en sık görülen nedenleridir. Yan tutma olasılığını en aza indirmenin yolu araştırmanın planlanması aşamasında çok dikkatli davranmak ve örnek seçerken kesinlikle araştırma konusunda bilgili ve deneyimli kişilere danışmaktır. Yine de yan tutma gerçekleşir ve ileri aşamalarda fark edilirse hemen geriye dönülmeli ve olabildiğince erken düzeltilmelidir.

Örnek Alma Yöntemleri

Örnek alma işlemi bilimsel bir yöntem gerektirir, gelişigüzel yapılamaz. Bilimsel yöntemle yapılan örnek seçim tekniklerine *Olasılıklı Örnek Seçimi* denir. Genellikle *gelişigüzel* olarak adlandırılan uygulama, bilimsel örnek seçimi yöntemlerinden sayılmaz. Gelişigüzel örnek almada kliniğe gelen, otobüs bekleyen, telefonla arayıp görüş bildiren kişiler, kafeste bulunan deney hayvanlarından el atılınca yakalananlar,.. hiçbir ilkeye uymaksızın çalışmaya katılır. Çoğunlukla böyle bir yaklaşımla örnek seçimi sonucu fark edilmeksizin varlıklılar, yakınması olanlar, yaşlılar, emekliler, kaçamayacak denli bitkin hayvanlar,.. gibi özelliği olan gruplar seçilmiş olabilir ve istenmeden bir yan tutma oluşur. Ender koşullarda, olasılıklı olmayan yöntemlerle de örnek almak zorunda kalınabilir. Ancak yöntem ne olursa olsun, hiçbir zaman gelişigüzel bir seçim uygulanmamalıdır.

Olasılıklı Örnek Seçimi Yöntemleri

- Sistematik Örnekleme

Düşünce olarak temel örnek seçimi yöntemidir. Bir liste ile sıralanabilen ve numaralanabilen her grup, sistematik örnekleme için gerekli evreni oluşturur. Sağlık Ocağı ya da Hastane kaydı, okul öğrencileri gibi sıralı kaydı bulunan gruplar ya da listelenebilen insan ya da deneklerde kullanılır. İlk ya da tek olarak uygulanan örnek seçimi yöntemi olabileceği gibi, küme örnekleme başta olmak üzere diğer örnek seçimi yöntemlerini izleyen ikinci aşama örneklemede de en çok kullanılan tekniktir. Temel özelliği yalın ve az yanılgıyla uygulanır olmasıdır. Uluslararası kaynaklarda *systematic sampling* olarak geçer.

Önceden listelenmiş gruplar ya da kliniğe başvuran hastalar homojen özellik göstermeyebilir, çoğunlukla da göstermez. Bir köy yaşayanlarının büyük çoğunluğu gençlerin dışa göçü nedeniyle yaşlı nüfustan oluşabilir. Kliniğe baş ağrısı yakınmasıyla başvuranlar arasında çalışan erkekler ya da evde bakması gereken çocukları bulunan kadınlar ya da kocasının tek başına evden çıkmasına kızacak olması nedeniyle gelemeyen yeni evli genç bayanlar bulunmayabilir. Böyle özelliği olan gruplarda ilk karşılaşılan kişiler ya da listede en üstte ya da ortada bulunanlar alınırsa, örnek evreni temsil etmeyebilir. Kliniğe sabah ilk gelenler emekliler gibi sevk alma gereği duymayanlar olabilir, sınıf listesinde en başta iki yıllık öğrenciler ya da kızlar yer alabilir. Homojenliği bozan benzer durumları olabildiğince en aza

indirgemek için kişileri tüm bireyler arasından eşit aralıklarla seçerek her özellikte birey almaya çabalamak gerekir.

Sistematik örneklemeyi yapmak için önce kişiler ya da denekler numara sırasıyla kaydedilir. Oluşan liste, örnek büyüklüğüne göre oranlanır. Sözgelimi 40 kişi örnek alınacak ve listede 280 kişi varsa 1/7 oranı uygulanacak demektir. Listenin başından ya da başka bir yerinden blok halinde bir grup örnek alınmaz. Kalem ucuyla körlemesine bir numara saptanarak ya da konuyla ilgisi olmayan bir kişiden 'bir sayı söyle'mesi istenerek başlangıç noktası seçilir. Sözgelimi 167 den başlandıysa 7şer atlayarak 174, 182,.. sıralı kişiler seçilir, liste bitince başa dönerek en baştaki sayı son sayıyı izliyormuş gibi devam edilir. 40 kişi tamamlandıktan sonra benzer düzenle yüzde beş, on (ya da en çok yüzde yirmilik) bir yedek liste seçilir. Ana listedeki her birey aynı standartlarla aranmalarına karşın (ölüm, taşınma, iki kez evde bulunamama gibi nedenlerle) kendilerine ulaşılamazsa yedek listedeki kişilerden sırayla yararlanılacaktır. Bundan sonraki işlemlerde bu liste ile hiçbir koşulda ve biçimde oynanamaz. Gerek görülüyorsa, yani yedek listedeki kişiler katıldıktan sonra da başta amaçlanan kişi sayısına ulaşılamıyorsa, ulaşılabilenlerle yetinilir, örneğe ulaşma oranı hesaplanarak yazılır. Listedeki 40 kişiden yalnızca 35 ine ulaşılabildiyse yedek listeden yararlanılır, oradan da ancak 3 kişiye ulaşıldıysa toplam ulaşılan kişi sayısı 38, örneğe ulaşma oranı (38 / 40) × 100 = %95.0 olarak belirtilir.

Kliniğe başvuran kişilerde de aynı ilkelerle ve yine bir liste mantığı ile örnek seçimi yapılır.

- Rasgele Sayılar Tablosu ile Örnekleme

Araştırma sistematiğinde en güvenilir ve bilimsel örnek seçimi Rasgele Sayılar Tablosu kullanılarak alınır. Uluslararası kaynaklarda *random sampling* olarak geçer. İstatistikte ve yayınlarda sıkça kullanılan *random* teriminin kaynaklandığı bu liste, *Table of Random Numbers* olarak tanınır. Bu nedenle hem yabancı dillerde hem Türkçe'de 'random' ya da 'randomize' *(randomized değil!)* sözcüğünün geçmesi bu tablodan örnek seçildiğinin göstergesi ve güvencesidir. Liste günümüzde bilgisayarla hazırlanmaktadır ve değişik örnekleri vardır. Her biri olasılık yönünden bağımsız olarak seçilmiş binlerce sayıdan oluşan bu liste dizilişi nedeniyle sonsuz sayıda ve bağımsız bireyin yan tutmaksızın seçilebilmesini sağlar.

765 kişiden oluşan bir evrenden 360 kişilik örnek seçileceğini varsayalım. Rasgele Sayılar Tablosu dizisindeki herhangi bir sayıya körlemesine kalem ucuyla gidilir (bak. *Rasgele Sayılar Tablosu*). Evren üç basamaklı olduğundan üç kolonda yan yana dizili sayılardan örnek alınacaktır. Kalemin ucundaki sayı başlangıç alınarak ve yanındaki kolonlarda onu izleyen yeterli sayı eklenerek 'örnek'in ilk bireyine ulaşılır. Sözgelimi kalemin ucu on altıncı satır ve on dördüncü kolondaki 2 sayısını gösterdiyse ve 360 kişilik bir örnek grubu seçilecekse, sağındaki 1 ve 0 sayıları ile oluşan 210 uncu birey 'örnek'in ilk kişisi olarak seçilir. Altında yer alan 948'e geçilir, 765 kişilik evrende bu sayı olmadığı için atlanır. Altında yer alan 819 da aynı nedenle atlanır, altındaki 226 alınır,.. Satırlar bitince kalemin ucundaki sayının bulunduğu kolonun sağındaki kolonda en üstteki ilk sayı olan 7'ye (birinci satır, on beşinci kolon) geçilir. Onu izleyen sayılar olan 2 ve 5 ile yine üç basamaklı bir sayı olan 725'e ulaşılır. Aşağı doğru 743 ve 436 ile devam edilir. 360 birey tamamlanıncaya ve ek yüzde beş ya da on yedek oluşuncaya dek örnek almaya devam edilir.

- Tabakalı Örnekleme

Yukarıdaki iki örnek seçimi yönteminde evrenin ya homojen olduğu varsayılmış ya da ne ölçüde heterojen olduğu bilinmeyen evrende heterojenlik bir ölçüde giderilmeye çalışılmıştır. Evrenin temel özellikleri biliniyor ve homojen olmadığı veriyle belirleniyorsa, yukarıdaki yöntemleri bile bile kullanmak bağışlanmaz bir yanılgı olur. Sistematik ya da rasgele örnek seçiminde her birey için bağımsız olasılıkla seçme işlemi yapıldığından, örneğe seçilen bireyler içinden geldikleri evrenin bireylerini bağımsız olarak yansıtır, ancak nitelik açısından tam olarak yansıtmıyor olabilir. Evrenin yüzde seksenini az öğrenim görenler oluşturuyorsa, örnekte bu kişilerin temsil oranı yüzde altmış, kırk ya da yirmi bile olabilir, çünkü evrende bu denli dengesizlik varsa sistematik ya da rasgele yöntemlerle alınacak önlemler dengesizliğin örneğe yansımasını önlemek için yeterli olmayabilir. O zaman evrendeki oransızlığın ya da farklı oranların, örneğe de olabildiğince yansıması için çaba harcanır. *Standartlaştırma* evrenin örneğe en iyi biçimde yansımasını sağlayacak temel yöntemdir. *Tabakalama* daha yalın ve uygulanabilir bir seçenek olarak örnek seçiminde daha sık ve rahat kullanılır. Uluslararası kaynaklarda *stratified sampling* olarak geçer

Evren içinde bireylerin belirli bir değişken yönünden eşit olmayan dağılım göstermeleri durumunda tabakalama uygulanmalıdır. Evren içinde öğrenim düzeyi farklı olan gruplar varsa, bu farklılığın örneğe yansıtılmaması, istemeden yan tutmaya yol açar. Evrende öğrenim düzeyi düşük olanlar çoğunlukta, yüksek olanlar azınlıkta ise, örnekte de bu dağılım benzer biçimde görülmelidir. Tabakalama işleminin kolay anlaşılabilmesi için Tablo 6 düzenlenmiştir.

Tablo 6. Öğrenim düzeyi farklı bireylerden oluşan evrenden örnek seçimi

(1) Öğrenim Durumu	(2) Sayı (**Evren**)	(3) Oran	(4) Sayı (**Örnek**)
Yok	40	40/500= 0.08	75×0.08= **6**
İlk ve ortaöğretim	360	360/500=0.72	75×0.72= **54**
Yüksek öğretim	90	90/500= 0.18	75×0.18= **13**
Lisansüstü	10	10/500= 0.02	75×0.02= **2**
Toplam	**500**	0.15	**75**

Tablo 6'da görüldüğü gibi 500 kişilik evrenden 75 kişilik ya da %15 örnek alınacaktır. Evren, öğrenim düzeyi açısından ileri derecede heterojen bir dağılım göstermektedir. İlk ve ortaöğrenim görenler çok fazla, lisansüstü öğrenim görenler çok azdır. Sistematik ya da rasgele örnek alınırsa evren içinde az oranda bulunanların fazla sayıda, fazla sayıda bulunanların az sayıda temsil edilmesi riski vardır. Tersi de olabilir, ilk ve ortaöğrenim görenler çok fazla sayıda temsil edilirken, lisansüstü öğrenim görenler örneğe hiç çıkmayabilir. Evrende bulunan her öğrenim düzeyindeki bireylerin, örneğe de evrende bulundukları oranda yansımalarını sağlamak için

tabakalanmaları gerekir. Önce tabaka adları düzenlenir (1), her bir tabakadaki birey sayısı saptanır (2), tabakaların evren içinde oluşturduğu oran belirlenir (3), alınacak örnek büyüklüğü ile oran çarpılarak her tabakadan alınacak örnek sayısı bulunur (4). Bu örnekte ilk iki tabaka için elde edilen sonuçlar tam sayıdır. Son iki tabaka için elde edilen sonuçlar ise buçukludur, sırasıyla 13.5 ve 1.5 elde edilmektedir. İkisi de tam sayıya yuvarlanırsa toplamda 76 kişi, yani 1 kişi fazla seçmek gerekecektir. Bu nedenle tam sayıya yuvarlama işlemi az kişiden oluşan tabaka yararına kullanılmış, biri 13, diğeri 2 olarak alınmıştır. Benzer durumlarda seçme hakkı araştırmacınındır. İkinci aşamada tabakaların her biri bağımsız kabul edilerek örneğe gireceği hesaplanan sayıda kişi sistematik örnekleme ile seçilir. Örneğin 40 kişilik 'Yok' grubundan 6 kişi sistematik olarak alınır. Her bir tabakadan sistematik ya da rasgele örnekleme ile seçilen kişiler toplanarak 6+54+13+2 = 75 kişiye ulaşılmış olur. Bu örnekte her tabakada genel orana uygun olarak %15 oranında örnek alındığına dikkat edilmelidir. Öğrenim durumuna göre evrenin örnekte temsil edilmesi şansa bırakılmamış, her tabaka örnekte olması gereken sayıda temsil edilmiştir.

- Küme Örnekleme

Daha çok alan araştırmalarında ve prevalans çalışmalarında kullanılır. Benzer özellikler taşıyan bireyler arasından örnek almak yerine, bunların kümeler halinde seçilmesi temeline dayanır. Zaman, yakıt, vb. kısıtlılığı olduğunda her yerleşim yerinden tek tek birey seçmek ve her birine ayrı ayrı ulaşmak güç olabilir. Uluslararası kaynaklarda *cluster sampling* olarak geçer. Ancak bu terim

Amerikancada farklı bir anlam taşır, önce üç-dört eyaletin rasgele sonra bunların içinden -sözgelimi- sistematik seçilmesi anlamına gelir.

Alan çalışmalarında bir başka güçlük sosyal etmenlerdir. Birçok ev arasında bir evin ya da bir kişinin seçilerek bakı yapılması, kan basıncı ölçülmesi, kan örneği alınması gibi uygulamalar ulaşılmayanlarda 'bize niçin bakmıyorlar?' ya da ulaşılanlarda 'bize gelirlerse komşular evde hastalık olduğunu sanacak' sıkıntısı yaratabilir. Bu nedenlerle örnek alınırken kişiler değil, kümeler örnek seçilir. Evreni oluşturan bireyler özelliklerine göre farklı gruplara ayrılır, aynı özelliği taşıyan gruptan bir ya da daha fazla sayıda küme, içindeki tüm bireylerle birlikte örneğe alınır. Böylece bir apartman, sokak, köy ya da mahallenin tamamı örnek grubuna katılabilir. Küme örnekleme ile yakın çevredeki herkes değerlendirmeye alındığı için araştırmacı yönünden rahatlık sağlar.

Guatrın sıklığı konusunda bir prevalans araştırması yapılacaksa ve nedensel ilişkide toprak erozyonu düşünülüyorsa iki tür yerleşim yerine gereksinme vardır: Erozyon olan ve olmayan. Erozyon olan bölgede benzer özellikler taşıyan beş köy varsa bunlardan örnek büyüklüğüne göre bir ya da ikisi, erozyon olmayan bölgede yine beş köy varsa bir ya da ikisi örneğe alınır. Benzer seçim hipertansiyon araştırması ya da antihipertansif uygulaması için bir ya da birkaç sokak ya da blok apartman alınması ile de yapılabilir. Örnek olarak alınan kümelerde kayıtlı herkes, gelişigüzel olmayan bir yöntemle izlenir ve değerlendirmeleri yapılır.

Klinik araştırmalarda da küme örnekleme sistemi uygulanabilir. Araştırmanın veri toplama aşaması net olarak belirlendikten sonra, saptanan hafta(lar) içinde başvuran herkes ya da önceden tanımlanmış kişiler örneğe alınır. Sözgelimi '1–14 Kasım 2005

tarihleri arasında sağlık ocağına başvuranların tümü' ya da 'üreteç kliniğine son bir yılda hematüri yakınması ile başvuranların tümü' birer küme örneğidir. Aynı kliniğe bir hafta süresince herhangi bir yakınma ile başvuran kişilerde kanser belirteci incelemesi yapmak da küme alımına bir örnektir.

Küme örnekleme prevalans araştırmalarında, dolayısıyla kesitsel araştırmalarda daha sık kullanılır. Kesitsel araştırmalarda küme örnekleme ile elde edilen ilk veri toplandıktan sonra, ikinci aşamada bir olgu-kontrol araştırması uygulanmasına olanaklı duruma getirilir. Artık araştırmacının elinde 'olgu' ve 'kontrol' olarak ayrılacak iki grup vardır. Araştırmaya devam ederken ikinci aşamada örnek seçiminde bu kez gruplar bağımsız düşünülmeli, sistematik ya da rasgele yöntemlerle örnek alınarak çalışmaya devam edilmelidir.

Küme örnekleme yönteminin gerçek -ve özellikle de bireysel- anlamda rasgele bir seçim olmadığı açıktır. Rasgele yöntemle yapılacak bir seçimin, toplanacak veride ulaşılacak hızlar açısından, küme örneklemeden daha sağlıklı sonuçlar vereceği varsayılır. Farklılığı gidermek ve küme örnekleme yapıldığında rasgele örneğe göre oluşan sapmayı giderecek bir düzeltme olması amacıyla, **tasarım etkisi** (*design effect)* adı verilen yaklaşımdan yararlanılabilir. Yalın bir formül aracılığıyla, rasgele örnek alındığında ulaşılacağı düşünülen hız dikkate alınarak, seçilecek kişi sayıları artırılmış olur. Artış genellikle rasgele örneklemede beklenen birey sayısının birkaç kat fazlasına ulaşılmasına yol açar. Yaklaşım aynı zamanda 'rasgele yöntemle seçilseydi, örnek birkaç kat küçük tutulabilirdi' mantığını da içerir. Tasarım etkisi DEFF = 1 + δ (n–1) yoluyla hesaplanır. δ, aynı kümedeki bireylerin aynı ölçüm değerini verecekleri ve birbirinden farklı değer verme olasılıklarının %5'den fazla olmayacağı mantığıyla, 0.05 olarak kullanılır. n kümenin ortalama büyüklüğüdür. Tasarım etkisi uygulandığında ortalama küme büyüklüğü 20 olan bir grupta 1 + 0.05 (20–1) = 1.95 elde edilir. Küme örnekleme yapılacaksa, rasgele örnekten 1.95 kat fazla sayıda örnekle çalışmak gerekecektir.

Küme örneklemenin İngilizce karşılığı olan '*cluster*' terimi ve uygulaması ABD kaynaklarında Türkçe'den oldukça farklı anlamda kullanılır. *Cluster* deyince önce rasgele yöntemle eyalet seçimi, sonra onun içinden sistematik ya da yine rasgele olarak bir dizi örnek seçimi,.. gibi karmaşık aşamalar ve yöntemler tanımlanır ve anlaşılır. Araştırmacının Türkçe'de küme örnekleme dendiğinde yalın bir yöntemin tanımlandığını anımsaması gerekir.

Olasılıklı Olmayan Örnek Seçimi Yöntemleri

- Olgu Grubu İncelemesi

Klinik araştırmalarda evren içinden örnek seçimi bilinçli olarak istenmeyebilir, çünkü bazı olgu türleri örnek seçilemeyecek denli az olabilir ya da klinik uygulamanın özelliği nedeniyle elde çok az sayıda olgu bulunabilir. Bir yılda kliniğe yatan multipl myeloma'lı, Wilms tümörlü, hipotiroidi'li ya da böbrek transplantasyonu uygulanan olguların sayısı seçme yapma olanağı vermeyecek denli az olabilir. Bu durumda örnek seçiminin klasik kurallarını uygulama olanağı kalmaz, olguların tümü örnek grubu olarak alınır. Artık bir örneklemeden çok, bir olgu grubunun incelenmesinden söz edilmelidir. Oluşan olgu grubu sayıca çok düşük olacağından, kontrol grubu olarak seçilen grup tam tersine, olabildiğince büyük tutulmaya çalışılır. Kontrol

grubunun büyük olması, n'in büyütülmesiyle grubun normal dağılıma daha fazla yaklaştırılmasını sağlar.

- Kartopu Yöntemi

Alan araştırmalarında, olgunun çok seyrek olduğu ve nerede görüldüğünün bilinemediği koşullarda uygulanır. *Anne ölümü* buna örnektir. İyi tanınmayan toplumlarda evler gelişigüzel ziyaret edilerek iyi tanımlanmış sorularla anne ölümü öyküsü aranır. 'Yakın çevrenizde duyduğunuz başka anne ölümü var mı?', 'kızkardeşleriniz arasında gebelik ve doğum nedeniyle ölen oldu mu?' gibi sorularla diğer yerleşim birimlerine ve hanelere uzanarak olgu aranır. Yeğlenmeyen, zorunlu olmadıkça başvurulmayan bir yöntemdir.

- Tek Olgu Seçimi

Yineli Tek Olgu (n of 1) çalışmalarında izlenecek olan tek bir örnek hastanın seçimidir. Yöntemin uygulanma nedeni olgunun özellikli olmasıdır, uygun yöntemle seçilince yan tutma kaygısı duyulmadan özel bir olgudan yola çıkılır (Fidan D, 2001).

- Hizmet Seçimi

Sistem çözümlemelerinde, yürütülmekte olan bir hizmet modelinin değerlendirilmesi ve iyileştirilmesi için yapılır. Seçilen model tek bir hizmet örneği, yani tek bir kurumdur. Modelin kullanımı, geliştirilme ve yaygınlaştırılma olanakları değerlendirilebilir (Fidan D, 2001).

Aşamalı Örnekleme Uygulaması

Bazı araştırmalarda örnek aşamalı olarak seçilir. İstenen örneğe ulaşmak için ardı sıra birden fazla örnek seçimi yöntemi uygulanabileceği gibi, küme örneklemede görüldüğü üzere, birinci örneğin seçimiyle ulaşılan amaçtan sonra, yeni bir amaç için farklı bir örnekleme yöntemine daha başvurulabilir. Her koşulda, amaçlara uygun olarak aşamaların önceden planlanması ve örnek seçimi ilkelerinin önceden saptanması gerekir. Birinci aşama tamamlandıktan sonra başlangıçta beklenenden farklı bulgular elde edildiyse izleyen aşamalardaki örnek seçimlerinde esnek davranılabilir ve yukarıda tanımlanan yöntemlerden birinden diğerine kayılarak örnek seçilebilir.

Alanda prevalans çalışmaları sonrasında ya da klinik çalışmalarında olgular elde edildikten sonra yeniden örnek almayla devam eden araştırmalar aşamalı uygulamaya örnektir. Alanda ilk aşamada hipertansiyon prevalansını saptamak, elde edilen hipertansiyonluların bir kısmında ikinci aşamada anjiyotensin konverting enzim (ACE) inhibitörü etkisini incelemeyi amaçlayan bir çalışmada iki aşamalı örnek seçilir. Sözgelimi prevalans çalışması için küme örnekleme uygulanır, hipertansiyonlular ve hipertansiyonu olmayanlar belirlenir. Birinci amaç gerçekleşmiştir. Rasgele sayılar tablosu aracılığıyla (ya da sistematik olarak) hipertansiyonlular iki gruba ayrılır, birine ACE inhibitörü, diğerine başka bir etken verilir, iki grup arasındaki iyileşme sonuçları kıyaslanarak ileriye yönelik çözümlenir. Ya da hipertansiyonlular tümüyle bir grup olarak alınabilir, hipertansiyonu olmayanlar arasından da benzer başka bir grup seçilerek iki grup kalp yetmezliği gelişimi yönünden ileriye yönelik olarak incelenir.

Araştırmanın ikinci aşama amaçlarına göre, hipertansiyonu olmayanlar arasından seçilecek olan grup sistematik ya da rasgele ya da *birebir eşleştirme* ile alınabilir ve geriye yönelik olarak, örneğin, aile öyküsü ya da geçirilmiş nefropati ya da var olan proteinüri,.. aranabilir. İkinci amaç aşaması tamamlandıktan sonra, varsa diğer aşamalara da benzer biçimde geçilebilir. Klinik araştırmalarda da örneğin ilk aşamada olgu belirlenmesine yönelik sistematik örnekleme ya da rasgele sayılar tablosu ile hipertansiyon olguları saptanır, ikinci aşamada ya olgular yine sistematik ya da rasgele sayılar tablosu aracılığıyla örnekleme ile ikiye ayrılarak ya da aynı örnekleme yöntemleri ile sağlamlar arasından örnek seçilip hipertansiyonlularla kıyaslanarak benzer aşamalar uygulanabilir.

Olasılıklı örnek seçimi yöntemleri bir araştırma içinde birbirini izleyen aşamalarla, birlikte kullanılabilir. Çok özel düzenekler dışında araştırmacı her aşamayı ayrı bir araştırma gibi ele almalı, her aşamada bağımsız bir örnek seçimi yöntemi kullanmada kendini özgür duyumsamalıdır.

Örnek Alımında Püf Noktaları

> *Çömlekçi ustasının yanına çırak giren çocuk, 'usta ben işi öğrendim, artık kendi dükkanımı açacağım' demeye başlar. Ustası her kez 'evladım, daha püf noktasını öğrenmedin' derse de çırak aldırmaz, ustadan ayrılarak kendi dükkanını kurar. Güzel çömlekler yapar, ancak fırından çıkardığı çömleklerin tümünü parçalanmış bulur. Dayanamayıp ustasına gider, durumu anlatır. Usta 'sana püf noktasını öğrenmedin dediydim ya, bak şimdi göstereyim' der, bir çömlek yapar, içinde oluşan her bir hava kabarcığını 'püf, püf,..' üfleyerek söndürür, sonra fırına yerleştirir.*

- *'100'e dikkat*: Örnek alırken örneğe giren toplam kişi sayısının 50+50=100 ya da 100+100=200 olmamasına dikkat edilmelidir. Bu denli yuvarlanmış bir örnek büyüklüğünü görenler sayının budandığını, yüzde almak için kolaya kaçıldığını, daha örnek alırken kolaycılığı düşünen bir araştırmacının ileriki aşamalarda kimbilir daha ne kolaylıklar(!) yapabileceğini dikkate alarak araştırmacıyı yan tutma ile suçlayabilir.
- *'Temsil' aranmalı*: Örnek seçimi bittikten sonra, örnek grubunun yaş ve cins gibi temel özellikler açısından evreni temsil edip etmediği çok gözlü ki-kare ya da Kolmogorov-Smirnov gibi uygun bir yöntemle sınanmalıdır.
- *Yeniden aranmalı*: Örneğe çıkan kişiler ilk aramada bulunamadıysa hemen yedek listeden yararlanılarak yeni bir birey seçilmemeli, kişi önceden saptanan kurallara göre en az bir ya da iki kez daha aranmalıdır.
- *'Denek'e dikkat*: Üzerinde çalışılan hayvanlar için kullanılan 'denek' sözcüğü insanlar için kullanılmamalı, insanlar için 'kişi', 'birey' ya da 'insan' sözcükleri yeğlenmelidir. 'Kobay' sözcüğü de gelişigüzel kullanılmamalı, kobayın İngilizce'deki 'guinea pig'e karşılık gelen özel bir hayvan türü olduğu anımsanmalıdır.
- *'Kafkasyalı' değil* ! : İngilizce yayınlardan yapılan alıntılarda bazen örneğin *Kafkasyalı*lardan oluştuğu yazılır. İngilizce'de *Caucasian* sözcüğünün aynı zamanda *beyaz ırktan* anlamına geldiği, söylenmek istenenin örneğin beyaz ırktan kişilerden oluştuğu, bilinmelidir. Özgün Türkçe bir yapıtta kullanılırsa, araştırmanın İngilizce bir kaynaktan aynen aktarıldığı sanılabilir!

- *'Gine domuzu' da değil* ! Benzer bir yanlış anlama, İngilizce'de 'kobay' karşılığı olan *Guinea pig*'in *Gine domuzu* olarak çevrilmesi ile de başa gelebilir!

Kontrol Grubu

İki ya da daha fazla grubun karşılaştırılmasında gruplardan birinin kontrol olarak kullanılması gerekebilir. İlke olarak kontrol grubu, çalışma grubu ile ölçülebilen tüm değişkenler açısından aynı özellikleri taşıyan, çalışma grubunda yer alan yalnızca tek bir neden ya da sonuç açısından farklı olan gruptur. Ölçülebilen değişkenler yaş grubu, cins, kültürel yapı, beslenme alışkanlığı ya da benzeri olabilir. Tüm bu değişkenler iki grupta da aynı olmalı, ancak incelenen neden ya da sonuç farklı olmalıdır (Şekil 2). Sözgelimi, ileriye yönelik araştırmada çalışma grubunda neden yani bağımsız değişken oral kontraseptif kullanımı ise kontrol grubunda oral kontraseptif kullanılmıyor olmalı, geriye yönelik araştırmada olgu grubunda sonuç yani yine bağımsız değişken meme kanseri ise kontrol grubunda saptanabilmiş meme kanseri bulunmuyor olmalıdır. Bunun dışında iki grubun da aynı özellikleri taşıması istenir, başka bir farklılık varsa, bu kez neden-sonuç etkileşiminde var olan diğer ögelerin rol almış olabileceğinden kuşku duyulur.

Araştırmalarda bağımlı grup kullanılmasının en önemli yararı, kontrol grubu olarak daha önce aynı grubun, yani aynı bireylerin ölçülmüş olmasıdır.

Grup özelliği

İki grubun ölçülebilir tüm özellikler açısından tam uygun olması beklenemez. Eş yumurta ikizlerinde bile teklerin birbirinden küçük de olsa farkları bulunur. Bu nedenle değişkenlerin etkileşiminde anlamlı etkisi olabileceği düşünülen ögelerin eş olmasına çalışılır, diğer 'yan' ögeler eşit varsayılır. Varsayımda genel bilgilerden ve başka araştırmaların sonuçlarından yararlanılır. Sözgelimi bir sonuç oluşumunda göz renginin anlamlı etkisi olmayacağı düşünülüyor ya da anlamlı olmadığı başka bir güvenilir araştırmada kanıtlanmış ise, araştırmanın yönü ne olursa olsun gruplardaki göz rengi yok sayılabilir. Ancak göz renginin ırk özellikleri, buna bağlı alışkanlıklar, bunlara bağlı kan biyokimya değerleri farklılıkları,.. yansıttığı düşünülüyorsa, yok sayma olanaklı değildir. Gerçekte hangi değişkenin var, hangi değişkenin yok sayılacağı çoklu çözümlemelerde elde edilecek regresyon katsayılarının anlamlılığı ile belirlenebilir: Çoklu çözümlemede temel alınan $[y=a+b_1x_1+b_2x_2+b_3x_3+...]$ denklemindeki b değerlerinin anlamlılığının hesaplanması ile seçilecek değişkenler saptanabilir, ancak böyle bir olanak çok az araştırmada ve çok ender koşullarda elde edilebilir.

Araştırmada çalışma ya da olgu grubunun sayısı kontrol grubunun sayısını belirleyici değildir. Araştırmada kaç grup kullanılırsa kullanılsın, her zaman tek kontrol grubu seçilir. Çalışma ya da olgu grubunun da tek olarak seçilmesi araştırmanın net ve düzgün yapılmasını kolaylaştırır, ancak bazen birden fazla grubun incelenmesi, özellikle yineleyen ölçümlerde gerekir. Bu durumda çalışma grubu, örneğin birkaç bağımsız grupta farklı girişimler ya da bağımlı bir grupta ardışık ölçümler nedeniyle, çok sayıda oluşabilir. Böyle bir oluşumda bile kontrol grubu tek alınmalı, diğer grupların ölçüm değerleri kontrol grubuyla birer birer ya da tümü bir arada değerlendirilmelidir.

Grup sayısı

Çözümlemeye yönelik kuramsal düzenlemeler iki grubun karşılaştırılması temeline dayalıdır. İki ayrı grubun birbiriyle karşılaştırılması ya da bir grupta iki kez değerlendirme yapılması, çözümleme kuramsal yaklaşımı açısından en doğru ve güvenilir sonucu verir. Birer grupta iki ayrı uygulama yapılacak, örneğin iki hasta grubunda iki ayrı iyileştirici yöntemin uygulanmasının sonuçları incelenecekse, ayrıca üçüncü bir kontrol grubunun alınmasına gerek yoktur. İki grup, seçimleri iyi yapıldıysa ve eş olmaları sağlandıysa, incelenen iki farklı uygulama etkileşimi yönünden birbirlerinin kontrolu işlevini görürler. Araştırmalarda 'sham' ya da 'plasebo' olarak üçüncü bir grubun kontrol grubu olarak kullanılması yanlış, gereksiz ve etik dışıdır (*bak. Fark Ettirmeme*). Plasebo kullanımı etik dışıdır. Ayrıca üçüncü bir grubun kontrol grubu olarak eklenmesi hem araştırma sürecini güçleştirecek hem çözümleme yönünden kavramların altüst olmasına yol açacaktır. Yabancı kaynaklarda sıkça görülen bu tür uygulamalar daha çok bilgisayar programlarının kullanılmasını özendirici tecimsel kaygılara dayalıdır. Araştırma planlanmasında zorunlu olmadıkça iki grubun üzerinde grup oluşmamasına, bağımlı bir grupta ise ikiden fazla ölçüm yapılmamasına özen gösterilmelidir.

Grup büyüklüğü

Kontrol grubunun büyüklüğü ideal olarak çalışma ya da olgu grubuna eş düşünülür. Ancak bu bir zorunluluk değildir. Özellikle gruptaki birey sayısının 30'un altında kaldığı durumlarda, kontrol grubunun olabildiğince büyük alınması, böylece iki grup birlikte değerlendirildiğinde normal dağılıma yaklaşma olanağının artırılması sağlanmaya çalışılır. Kesitsel ya da geriye yönelik araştırmalarda elde edilen olgu sayısı 7 ise, sayı azlığının getirdiği olumsuzluğu gidermek için kontrol grubuna 70, 170, 700, 7,000 kişi örnek alınabilir. Kontrol grubunun seçiminde çok daha fazla sayıda bireyden oluşan bir gruptan örnek seçilerek de yine oldukça büyük bir kontrol grubu oluşturulabilir. Örneğin bir hastanede bir yıl içinde 630,425 kan örneğinde trombosit yapısı incelenmiş ve bunların 12 sinde İdiyopatik Trombositopenik Purpura (İTP) tanısı konabilmişse, İTP olgularının araştırılması amacıyla yapılan bir çalışmada 12 olgunun yanına kontrol grubu olarak geriye kalan 630,413 kan örneğinin tümü ya da bunlardan sistematik örnekleme ile seçilecek 1/10, 1/100, 1/1,000 sayıda kan örneği kullanılabilir. Böyle bir örnekte üst sınır koymak doğru değildir. Araştırma olanaklarına göre, bilimsel ölçütlerle kontrol grubu ne denli büyütülebilirse evreni temsil etme olanağı da o ölçüde artar.

Kontrol grubundaki birey sayısının inceleme grubuna göre daha az sayıda tutulması kabul edilemez. Böyle bir durumda ancak araştırmacının fazla sayıda bireyle çalışmaya 'üşendiği' yorumu yapılabilir. Gruplardan birinde az sayıda birey bulunmasının nedeni ancak kanserojen etkenle karşılaşanların sayısının az olması ya da bulunabilen kanser tanısının çok az sayıda olguda görülebilmesi gibi zorunluluklarla açıklanabilir. Yani çalışma ya da olgu grupları elde olmayan nedenlerle çok küçük kalabilir. Kontrol grubunun az sayıda seçilmesini hoş görmeyi sağlayacak bir neden bulmak ise olanaksızdır.

Kontrol grubu seçiminde daha ayrıntılı bilgi için *'Kontrol Kullanma'* ve *'Örnek Büyüklüğü'* bölümlerine bakılmalıdır.

Değişkenler

Araştırma yönteminin dayanak noktalarındandır. Neden(ler) ve sonuç(lar) arasında var olduğu düşünülen nedensellik bağıntısını netleştirmeyi amaçlar. Nedenler kavramlar durumunda peş peşe sıralanır, daha sonra bağımsız değişkenler olarak sunulur. Sonuç(lar) da bağımlı değişken(ler)e dönüştürülerek yerleştirilir.

Araştırmacıların, deneyimli de olsalar atladıkları bir aşama, bağımsız ve bağımlı değişkenlerin belirlenmesidir. Araştırmanın nedensel özü, bilinmeyen bir verinin soru ve kuşkularını içerir. Uygun aracı bulunamazsa, veri nedenselliğin sorularını ve gizemini çözemez. Çözümü sağlayacak olan aracı ya da anahtar, değişkenlerdir. Araştırmacı ancak değişkenleri biçimlendirdiğinde veriye ulaşma ve çözme olanağı bulur. Bu nedenle araştırma sürecinde kafasına değişkenleri yerleştirme ve araştırma bütününe onlar aracılığıyla bakma becerisine ulaşmış olmalıdır. Yoksa doğru veriye ulaşamayacağı gibi, topladığı veriyi de derleyip yorumlayamaz.

Bağımsız ve bağımlı değişkenleri, bunların elde edilmesinde yararlanılan soru ve ölçütlerden ayırmak gerekir. Sorular ve ölçütler değişkenleri saptayabilmek amacıyla kullanılır, değişkenlerin yerine kullanılamazlar. Değişkenleri saptamadan soru ya da ölçütleri kullanmak çok yaygın olarak yapılan bir yanlıştır. Yöntem içinde her biri birer kavram olan değişkenler belirtilir, sonra bunların hangi ayrıntı ile, yani hangi tür sorular ve ölçütlerle elde edileceği açıklanır.

Koroner arter hastalığına hangi etmenlerin yol açtığı konusunda bir araştırma yapılacaksa, bu ilişkiyi açıklayan sonuç ve nedenler seçilir. Açıklamadan, araştırmanın sonuçtan nedene, yani geriye yönelik planlanacağı anlaşılmaktadır. Sözgelimi 'koroner arter hastalığına doymuş yağ alımı, tütün kullanımı ve şişmanlığın yol açtığını' göstermesi planlanan bir araştırma yapılacaksa, ilk ögenin sonuç, son üç ögenin neden olduğu düşünülüyor demektir. Sonucu bağımlı, nedenleri bağımsız değişken olarak adlandırmak ve düzenlemek gerekir. İlk tanımlanacak olan bağımlı değişken olmalıdır. Bağımlı değişken açık ve belirgin olarak *'koroner arter hastalığı'*dır. İlk bağımsız değişken *'doymuş yağ alımı'* olmalıdır. İkinci bağımsız değişken olarak *'tütün kullanımı'* alınacaktır. Son bağımsız değişken ise *'şişmanlık'*tır. Böylece nedenselliğin bağımsız değişken ögeleri de saptanmıştır. Bağımlı ve bağımsız değişkenler belirlendikten sonra sıra bunların tanımlanmasındadır. Sırasıyla 'hastalığı'nın, 'doymuş'un, 'yağ'ın, 'alım'ın,.. ne oldukları tanımlanır, sınırları konur. Birden fazla görevlinin veri toplayabileceği ve veri toplayan herkesin farklı algılayabileceği dikkate alınarak, tanımlanan değişkenler standart bir anahtar olarak yazı duruma getirilir.

Sıra tanımlanan değişkenlerin elde edilme ölçütlerinin belirlenmesine gelmiştir. Bağımlı ve bağımsız değişkenlerin hangi ögelerle belirleneceği açıkça ve standart olarak saptanır. Ölçütlerin gösterdiği maddelerin açık saptanması ve herkese kesinlikle aynı biçimde yöneltilmesi gerekir. Bağımlı değişken için standart olarak ve bir protokol çerçevesinde kullanılacak olan anjinal ağrı, EKG'de ST değişiklikleri, anjiyografide darlık yüzdesi,.. yalın ve kimsenin kuşkusuna yol açmayacak biçimde açıklanacaktır. Daha sonra bağımsız değişkenlerin standart ölçütleri konacaktır. Yağ alımı için (örneğin) günde alınan tereyağı, iç ve kuyruk yağı, zeytinyağı, vb. belli bir ölçüm birimi ile saptanacak, içinde doymuş ve doymamış olanlar ayrılacak ve hesaplanacak, hangisinin ne kadar kaloriye ya da biriken yağ dokusuna karşılık

geldiği ayrı ayrı belirlenecektir. Benzer biçimde tütünün günde kaç adet, kaç yıldan bu yana, sigara mı yoksa başka bir ürün olarak mı tüketildiği verisi elde edilecek; sigara, puro ya da pipo içiminde belirlenen zararlı maddeler dönüştürme açıklamaları ile birlikte saptanacaktır. Şişmanlık değerlendirmesi için kullanılan ölçütler kilogram olarak ağırlık ya da deri altı yağ dokusu kalınlığı ya da beden kütle indeksi olacak ve hangi cins ve yaş gruplarında nasıl elde edilecekleri belirlenecektir.

Bağımsız ve bağımlı değişkenleri belirtilmemiş bir araştırma, yürütücüsü açısından yöntemi netleşmemiş bir çalışmadır. Araştırmacı için net olmayan bir araştırmayı okuyucunun anlaması hiç beklenemez. Değişkenler konusunda ayrıntılı bilgi için '*Nedensel Araştırmalar*' başlığına bakılmalıdır.

Veri Özellikleri ve Çözümlemesi

Araştırmanın verisi, araştırma tipine göre özellik gösterir. İleriye yönelik araştırmalarda insidans ya da insidans hızı belirlenirken, kesitsel araştırmalarda prevalans saptanır. Ayrıca araştırmanın veri toplama yöntemine göre, verinin ölçümle mi yoksa sayımla mı elde edileceği ortaya çıkar. Verinin sayım ya da ölçümle elde edilmesi, iki ya da daha fazla grup alınması, grupların bağımsız ya da bağımlı olması, bağımsız ve bağımlı değişkenlerin sayısı,.. çözümleme yöntemini önceden belirleyecek unsurlardır. Sayılan nitelikler belli olunca çözümleme yöntemleri kendini gösterir. Verinin özellikleri, veri çözümlemesi yöntemini de belirleyecektir.

Veri ancak çözümleme yöntemi önceden bilinirse sağlıklı toplanabilir. Araştırmaya başlamadan önce veri çözümlemesinde hangi yöntemlerin kullanılacağı kesin olarak saptanmalıdır. Araştırmanın amacı, verinin neyi ve niçin göstereceğini önceden belirlemiş ve açıklamıştır. Amaca uygun olarak veri toplanır ve çözümlenirse, verinin de neyi ve niçin göstereceği -amaca uygun olarak- netleştirilmiş olur. Hangi değişkenlerin karşılaştırılacağı saptanır, buna göre çapraz tablolar önceden hazırlanır, veri sunumu ve olası tartışma kapsamı araştırmanın başında belirlenir. Daha sonra verinin özelliklerine göre kullanılacak çözümleme teknikleri saptanır ve *Yöntem*'de belirtilir. Düşük bir olasılıkla toplanan veri beklenenden farklı oluşursa, veri sunumu ve çözümleme yöntemlerini değiştirmek gerekebilir. Ancak iyi planlanmış bir araştırmada veri önemli ölçüde beklenen niteliklerle ortaya çıkarılabileceğinden, çözümleme yöntemleri ve bunların sonucunda oluşturulacak yorumların amaçlarla örtüşür olması beklenir.

Verinin çözümleme teknikleri veri toplanmadan önce belirlenmeli ve buna yönelik boş tablolar da veri toplanmaya başlanmadan önce hazırlanmalıdır.

Veri Toplama

Veri toplama işleminin dizgesel düzenlenmesine özen gösterilmelidir. Her bireyden ya da denekten alınacak verinin nesnel ölçütlerle ve standart alınmasına dikkat edilmelidir. Laboratuvar ve klinik çalışmalarda ölçme, kan alma, derecelendirme, vb. işlemlerin her bireyde olabildiğince tıpatıp aynı uygulanması gerekir. Alan çalışmalarında bu daha güç olur, bireylere ulaşmada sıkıntılar yaşanabilir. Bu durumda standart bir akış şeması oluşturulur, 'saat 21.00'den sonra iki kez daha aranacak', 'üçüncü kez telefon edildiğinde de evde bulunamazsa örnek dışında bırakılacak' gibi herkes için aynı olan yöntemler uygulanır. 'Çalışabilir engellilerde

'işyeri ortamına uyum' incelenecekse, hem 'çalışabilir engelliler'in, hem 'işyeri'nin hem 'uyum'un tanımlanmasında yararlanılacak ölçütlerin aynı olmasına ve kesinlikle her engelli, her işyeri ve uyum ölçütü için aynı biçimde uygulanmasına çok özen gösterilmesi gerekir. Belirtilen noktalardaki en küçük açıklama eksiği, belirsizlik, standart dışı uygulama, araştırma verisinin kabul edilemez biçimde farklı ölçüler ve ölçütlerle toplanmasına ve kabul edilemez konuma düşmesine yol açar.

Dizgesel düşünme savruk ve derbeder çalışmayı önler, disiplinli bir veri toplama düzeni getirir. Disiplinli düşünce içinde kusursuz bir akış şeması oluşturmaya çalışılmalı, ancak nerede ve ne denli esnek davranılabileceği de önceden belirlenmelidir. Dizgesel yapı veri toplamaya düzen getirmeli, ancak veri toplamayı engelleyici olmamalıdır.

Veri toplamanın hangi yöntemlerle yapılacağı ayrıntılı olarak anlatılmalıdır. Soru yöneltilecekse anketin örneği eklerde yer alacağından anket konusunda ayrıntılı bilgi vermeye gerek olmayabilir. Sorular sunulmaz, ancak içinden geldikleri değişkenler kesinlikle gösterilir. Veri ölçümle toplanacaksa ayrıntılı bilgi verilmelidir. Boy ölçümü yerde mi ayakta mı yapılacak, kan basıncı kaç dakika dinlendirmeden sonra hangi koldan ve kaç dakika arayla alınacak, kan örneklerini ölçecek aygıtın cinsi, modeli, markası nedir, açıklanmalıdır. Ölçümler arasında istenmeyen farlılıklar bekleniyorsa net olarak bildirilmelidir: Alınacak kan örneklerinin aç ya da tok iken alınacak olanları, kişilere yöneltilen soruların çalışma saatlerinde ya da dinlenme sürecinde yöneltilecek olanları, ayrı günlerde kullanılacak kitlerin seri numaraları,.. açık olarak belirtilmelidir. Böylece hem standartları koyma kaygısı açıklanmış olacak hem -varsa- veri içinde istenmeden oluşacak farklılıklara ipucu verilecektir.

Eğitim

Veri toplayacak personelin seçimi ve eğitimi planlanmalıdır. İşlemi bilen personelin, aynı standartta veri toplayabilmesi için aynı nitelikte kişilerle çalışılması ve bu kişilerin ön eğitimi çok önemlidir. Anket uygulanması yapılacaksa soruların yöneltilmesi, soruların yönlendirici sorulmaması ve benzer biçimde kaydedilmesi için benzer nitelikte personel seçilir ve aynı düzeyde eğitimden geçirilir. Veri toplanmasından önce sorular araştırmaya katılmayacak bir grupta denenir ve soruluş biçimleri standartlaştırılır. Kan ve benzeri örneklerde inceleme yapılacaksa standartlaştırma daha da önem kazanır. Personel aynı aygıtları benzer değerlendirme yöntemleri ile kullanabilmeli, aralarında fark varsa belirlenmeli ve giderilmelidir. Ölçmeyi aygıtın değil, personelin yaptığı durumlarda, sözgelimi Thoma lamıyla hücre sayımı, kalın damlada Plasmodium seçilmesi, ekstremitede ekstansiyon açısının ölçülmesi gibi tanı yöntemlerinde bu özellik daha da önem kazanır. Eğitim ve standartlaştırmanın yapılmadığı durumlarda geriye dönüşü olmayan yanılgılarla karşılaşılması kaçınılmazdır.

Zaman Çizelgesi

Araştırmanın yapılma süreci bir takvim düzeneği ile araştırma öncesinde belirlenmeli ve sergilenmelidir. Konu seçimi, kaynak inceleme, hazırlık, veri toplama, çözümleme ve değerlendirme, rapor yazımı gibi işlemlerin süreleri olası yanılgı payları ile birlikte planlanarak o araştırmaya özgü bir zaman çizelgesine geçirilir (Şekil 26).

Zaman çizelgesi araştırmayı izlemekle yükümlü başta danışman olmak üzere eğitici ve yöneticiler için uygun bir yol göstericidir. Zaman çizelgesinden yararlanarak araştırmacıyı denetleme ve yönlendirme olanağı bulurlar. En önemli yararı ise araştırmacının kendisinedir. Araştırmacının ayrıntıda boğulduğu anlarda zaman çizelgesine dönüp başvurması, yeniden araştırmaya genel bakışı sağlamada yardımcı olur. Özellikle deneyimsiz araştırmacıların iş planlamasında ve uygulamasında uyarıcı ve yol gösterici katkı sağlar.

	2013								2014						
	N	M	H	T	A	E	E	K	A	O	Ş	M	N	M	H
Konu seçimi															
Kaynak inceleme															
Hazırlık															
Ön çalışma															
Veri toplama															
Değerlendirme															
Çözümleme															
Yazım															

Şekil 26. Araştırma zaman çizelgesi

Araştırma Taslağı Sunumu

Her araştırmanın, başlangıcından başlayarak, kesinlikle bir danışmanı olacaktır. Danışman bilgi birikimi ve deneyimi ile her aşamada araştırmacının destekleyicisi ve yönlendiricisidir. Danışmanın dışındaki birim ve kişilerin de araştırma taslağının eleştirilmesinde katkıları olması beklenir. Araştırma bir kurum içinde ya da kurum için yapılacaksa, bir değerlendirme kurulu önünde sunulmalı, tartışılmalı ve eleştiriler doğrultusunda düzeltilmelidir. Örneğin bir tez taslağı bilim dalı ya da klinik sorumluları ve çalışanlarına, olabilirse tartışmalı bir toplantıyla danışılmalıdır. Danışma sonunda yapılabilirliği kuşkulu bulunan araştırmaların salt ayrıntıları değil, konusu bile değiştirilebilir. Bağımsız olarak yapılacak araştırmalarda da ilgili kurumların ve bireylerin görüşleri alınmalıdır.

Genellikle genç araştırmacılar planlama aşamasında konuyu ve amaçlarını daraltmayı düşünemez, araştırmayı ne denli geniş tutarsa o denli başarılı sonuçlar elde edeceğini savlar ve engin bir denize yönelirler. Hazırlık aşamasında farklı kişilerden görüş almaları, konunun özüne yönelmelerini sağlar ve 'dağılmalarını' önler. Sunumun bu yönüyle de yarar ve katkısı olacak, benzer olumsuz deneyimler yaşamış kişiler gerekli uyarılarda bulunacaklardır.

Değişkenleri oluşturma gereğini yerine getirememe, veri toplama öncesi sıklıkla bir yanılgı ile ortaya çıkar. Genç araştırmacılar veri anketle toplanacaksa anketi hazırladıktan sonra daha iyi bilen birine danışır ve görüş isterler. Oysa öncelikle sunulması gereken anket değil, araştırmanın başlığı, amacı, yöntemi ve onun içinde değişkenleridir; anket bunların tümünden sonra, bunlar doğru belirlendikten sonra hazırlanacaktır. Doğrudan anketini hazırlayan, ondan önce değişkenlerini belirlemeyi düşünemeyen bir araştırmacının geriye dönerek doğru aşamalara ulaşması neredeyse olanaksızdır. Bazı durumlarda da araştırmacılar soru ya da ölçümle topladıkları veriyi elde ettikten sonra danışmayı yeğlerler. Anketi hazırlanmış ya da verisi toplanmış bir araştırma için görüş ve değerlendirme olanağı kalmamış, işlem çok ilerlemiş ya da neredeyse tamamlanmış demektir. Taslak düzeyine getirilmeden önce danışılması, araştırmanın sağlıklı düzenlenmesi için ön koşuldur. Özellikle çözümlemelerin araştırmanın hazırlık döneminde planlanması gerekir. Anketini hazırlamış ve hele verisini toplamış bir araştırmacıya eleştiri sunma olanağı çok azdır, çözümleme yöntemi seçeneği sunma şansı ise hiç kalmamıştır. Toplanmış veri ile getirilen araştırmada ancak verinin izin verdiği ölçüde çözümleme yöntemleri önerilebilir, bunlar da çok kısıtlı ve zorlama yöntemler olur ve çözümlemeden çok 'veriyi kurtarma' amacına yönelik olabilir.

Araştırmanın temel amacı toplum gelişimine katkıda bulunmak, süreç içinde araştırmacı yetiştirmektir. Yayın yapmak araştırmanın amacı değil, bulguları bilim ortamına ve topluma sunan bir araçtır.

Fourth Edition

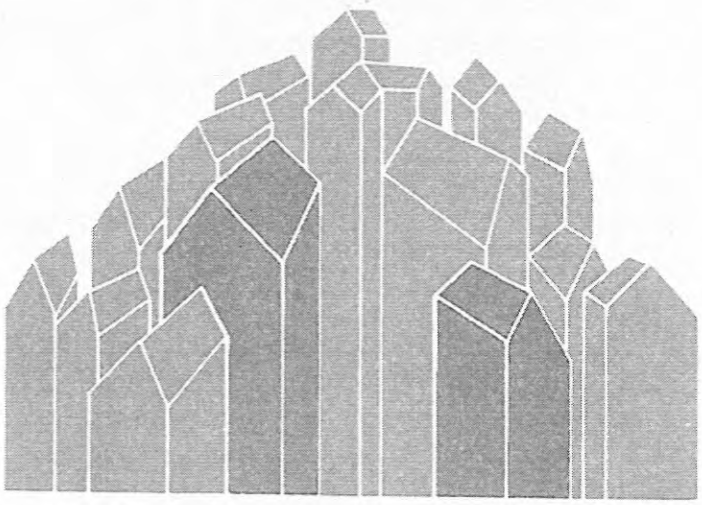
SURVEY METHODS IN COMMUNITY MEDICINE

Epidemiological Studies

Programme Evaluation

Clinical Trials

J. H. Abramson



Churchill Livingstone

STUDYING ASSOCIATIONS BETWEEN VARIABLES

Information about associations between variables—that is, about whether and how different characteristics 'hang together'[10]—may be sought both for practical purposes and because of interest in processes affecting health and disease. Analytic surveys, both those that aim to explain the health status of a specific population and those that seek new knowledge about aetiology and natural history, have the examination of associations between variables as their main function, as do many methodological studies—e.g. those that test the value of screening and diagnostic tests and risk markers—and all experiments.

Possible formulations of the study objective, when an association is to be investigated, include 'To examine the association between infant mortality rates and region', 'To determine whether there is a difference between the rates in regions A and B', and 'To test the hypothesis that the rates in regions A and B differ'. *Hypotheses* are suppositions that are tested by collecting facts that lead to their acceptance or rejection. They are not assumptions that are to be taken for granted, neither are they beliefs that the investigator sets out to prove. They are 'refutable predictions' (T H Huxley wrote of 'the great tragedy of Science—the slaying of a beautiful hypothesis by an ugly fact').

A hypothesis may be stated as a positive declaration (sometimes called the *research hypothesis*), e.g. 'The infant mortality rates in regions A and B are different' or 'The rate is higher in region A than in region B', or as a negative declaration (null hypothesis), e.g. 'There is no difference between the rates' or 'The rate is not higher in region A than in region B'. Statistical testing of an association requires the formulation of a null hypothesis, which is tested against a specific alternative;[11] this alternative ('that there is a difference between the two regions', or 'that the rate is higher in region A') is the 'research hypothesis'. If statistical testing is intended it is advisable to make the hypotheses as specific as possible at this stage, and not to leave them implicit (as in 'to study the association between mortality and region').

In a retrospective survey designed to examine a possible causal relationship between smoking and a disease, typical specific hypotheses might be that the proportion of smokers is higher among cases than among controls, that the proportion of heavy smokers is higher among cases than among controls, that the average age at starting smoking is earlier among cases than among controls, etc. In a prospective study set up for the same purpose the hypotheses would relate to the incidence of the disease among persons with different smoking habits. The value of epidemiological hypotheses is enhanced if they deal not only with the combined occurrence of the postulated cause and effect (i.e. when one is present, does the other tend to be present?), but also with the quantitative *dose–response* relationship between cause and effect (e.g. when there is more intensive exposure to the cause, is the disease more frequent or more severe?) or with the *time–response* relationship (the relationship to the time interval since exposure).

As will be seen later (in Ch. 27), if we want to know *why* there is an association between two variables, we will usually need analyses that take account of the way the association is influenced by other characteristics. The selection of these other variables will be discussed on pages 94–96. If the investigator wishes he may make mention of them when formulating the study objectives, e.g. by saying that the association will be tested 'holding sex and ethnic group constant' or 'controlling for' these variables, or that the hypothesis will be tested separately in each sex and ethnic group, or by listing the 'modifying' and 'confounding' variables that he will take into account (these terms will become clearer later). Remember there is still lots of time for these decisions; the planning of the study is still in its early stages, and study objectives can be rethought and reformulated as often as we wish. Remember too that these complications are of course unnecessary in a simple descriptive survey.

Study objectives

1. Do they meet the purpose of the study?
2. Are they clear?
3. Are they expressed in measurable terms?

It is usually helpful to formulate the study objectives explicitly in writing. For convenience they are often first given in fairly general terms, e.g. 'to measure smoking habits' or 'to examine the association between smoking and a (specified) disease', and each of these general objectives is followed by an explicit statement of the relevant specific objectives, including the testing of specific hypotheses. The stated objectives should satisfy three requirements. First, they must meet the purpose of the study. This is usually easily achieved in a descriptive survey, but in planning an analytic survey or experiment there may

be considerable difficulty in the formulation of a hypothesis; this is where the creative researcher comes into his own. Secondly, the objectives should be phrased clearly—unambiguously and very specifically—leaving no doubt as to precisely what has to be measured. Thirdly, they should be phrased in measurable terms. That is, the objectives should be realistic (answerable questions, testable hypotheses) and formulated in operational terms, which can be applied in practice. 'Any fool can ask a question; the trick is to ask one that can be answered.'[12]

A few imaginary and actual examples follow.

1. A survey of diabetes was conducted in an English community. Its first objective was '1. To establish exactly the number of diabetics'. This is a clear statement; but the formulation is incomplete, since the investigators also measured the prevalence *rate* of diabetes and established the age and sex distribution of cases. The second objective was '2. To discover the undiagnosed cases of diabetes'. This is not a complete statement, as the investigators also wanted to answer questions about the hitherto unknown cases. It should go on: 'and to compare their age and sex distribution with that of known cases'. The next objective was '3. To investigate the possible hereditary factors'. This is far too non-specific to be helpful as a blueprint in planning the study. Did the investigators intend to examine familial clustering among the people they examined? Did they want to see if prevalence was higher among the offspring of consanguineous marriages? Did they want to look for an association with the occurrence of genetic markers, such as human leucocyte antigens? Or (as was actually the case) did they want to compare the frequency of positive family histories of diabetes among known diabetics, newly discovered diabetics, and non-diabetics, controlling for age and sex? One last example from this study: '6. To repeat the whole survey at a future date'. This is hardly a study objective.
2. A report on a national study of cerebral palsy in adolescence and adulthood[13] states: 'The primary objectives of the study were: 1. To learn about the extent and nature [of the problem] and the specific needs of cerebral palsied youngsters and adults through a sociomedical study. 2. To collect epidemiological data on the cerebral palsied'. These formulations may be useful as starting points in planning a study, or as summary statements in a report, but would not be very useful as blueprints. Much further detail is needed for this purpose. (The study itself is a good one, and it is clear that the investigators actually did have specific and well thought out objectives.) Another stated objective, 'To evoke the interest of local communities and public agencies in the problems and needs of the cerebral palsied', is a laudable *purpose* for a study, but not what we have called a study objective. It might be stated as an objective of an action programme.
3. The objective of a study was stated to be 'to study the effects of vaccination against measles'. This formulation is completely non-specific, and could have given the investigator little help in the planning of his study. Was he interested in the development of serological changes, or in differences in antibody titre between groups of vaccinated and non-vaccinated children, or in differences in the subsequent incidence of measles? In fact, and to this reader's surprise, the study turned out to be a descriptive survey of the incidence of fever, pain at the injection site, and other manifestations immediately after vaccination.
4. A hypothesis including the word 'cause', such as one that the habitual drinking of coffee is a cause of cancer of the bladder, must be made more specific before it can be tested. Is it proposed to determine whether the incidence rate of the disease in different countries or at different times is correlated with the average consumption of coffee per head (group-based analytic surveys), or to determine whether patients drink more coffee than controls (a cross-sectional or retrospective survey), or to determine whether the incidence of new cases is higher among persons who drink much coffee than among those who take less coffee, and lowest among those who drink no coffee at all (a prospective survey or a rather unlikely experiment)? 'Controlling for age, sex, smoking habits (etc.)' would probably be specified in the hypothesis.
5. The hypothesis that 'there is an association between a specified disease and diet' is not sufficiently specific. The investigator may aim to compare the dietary histories of cases and controls, or compare incidence rates in vegetarians and others, or seek correlations between national disease rates and food consumption data. Neither is it stated in operational terms. In what aspect of diet is the investigator interested: in the average daily intake of calories, proteins, fats and other specific nutrients, or in the average amounts consumed of milk, meat, and other specific foodstuffs, or in the number of days a week that meat, fish, etc. are usually eaten, or in the average number of meals taken per day? It may be felt that such decisions can be postponed until later in the planning phase. There is no great harm in this, but it is arguable that since

these decisions may be very close to the nub of the research problem, they should be made at an early stage of planning. They are of a different order of importance from decisions on various methods of measurement, such as the choice of a technique for measuring the daily caloric intake (questioning, self-maintained dietary records, weighing of dishes and leftovers, etc.). Similar considerations arise when other vague terms are used, such as 'nutritional status', 'disability', 'emotional health', or 'stress'.

NOTES AND REFERENCES

1. 'One sometimes finds what one is not looking for' (Sir Alexander Fleming, the serendipitous discoverer of penicillin). Other discoveries based on unplanned 'chance' observations (immunization with attenuated pathogens, anaphylaxis, the connection between the pancreas and diabetes, etc.) are listed by Beveridge W I B 1957 in The Art of Scientific Investigation 3rd edn. Vintage Books, New York. This useful book, which stresses that 'the most important instrument in research must always be the mind of man', concentrates on the 'mental skills' of scientific investigation, such as the ability to recognize the importance of a chance or unexpected observation, to interpret the clue and develop a hypothesis, and to follow up the initial finding in a systematic way.
2. Isaac S, Michael W B 1977 Handbook in research and evaluation for education and the behavioural sciences. EdITS, San Diego, p 2.
3. Mager R F 1975 Preparing instructional objectives. Fearon, Belmont, California.
4. *Biological markers* are biochemical, molecular, genetic, immunological or other indicators (often quantitative) of past exposure, biological changes, disease processes, or predisposition to disease. Examples: lead content of blood, creatinine clearance, human leucocyte antigens, alpha-fetoprotein, antibody titres. Their uses in epidemiological research are discussed by Schulte P A 1987 Methodologic issues in the use of biologic markers in epidemiologic research. American Journal of Epidemiology 126: 1006.
5. *Health indicators*: a 'shopper's guide'—a 'list of things to think about' when choosing a measure of health status—is provided by Ware J E Jr, Brook R J, Davies A R et al 1981 Choosing measures of health status for individuals in general populations. American Journal of Public Health 71: 620. See Ware J E Jr 1984 Methodological considerations in the selection of health status assessment procedures. In: Wenger N K, Mattson M E, Furberg C D, Elinson J (eds) Assessment of quality of life in clinical trials of cardiovascular therapies. LeJacq Publishing (Waymarket-Doyma, New York), p 87. Murnaghan J H 1981 Health indicators and information systems for the year 2000. Annual Reviews of Public Health 2: 299 pays special attention to health indicators in developing countries. Purposes of health indicators are discussed by the above authors and by Jette A M 1980 Journal of Chronic Diseases 33: 567; Jette distinguishes between indicators of the status of a population and indicators of the status of individuals (some indicators serve both purposes).

   For descriptions of specific health indicators and their uses, see Holland W W, Ipsen J, Kostrzewski J (eds) 1979 Measurement of levels of health. WHO, Copenhagen; Jette (1980; see above) and the periodical Clearinghouse on Health Statistics.

   '*Health index*' may be a synonym for 'health indicator', or may refer to a numerical index based on two or more indicators, such as the Health Problem Index ('Q value') devised by the Division of Indian Health in the USA. This is based mainly on the mortality rate, the average age at death, and the numbers of outpatient visits and hospital days per head; see Haynes M A 1972 in Reinke W A (ed) Health planning: qualitative aspects and quantitative techniques. Johns Hopkins University, Baltimore, Md, p 158.
6. Kark S L, Gofin J, Abramson J H et al 1979 Prevalence of selected health characteristics of men: a community health survey in Jerusalem. Israel Journal of Medical Sciences 15: 732.
7. For methods of estimating the confidence limits of the prevalence of a disease in a population from the prevalence of a proxy attribute in the population or a sample, see Peritz E 1971 Estimating the ratio of two marginal probabilities in a contingency table. Biometrics 27: 223 (correction note: 27: 1104) and Rogan W J, Gladen B 1978 Estimating prevalence from the results of a screening test. American Journal of Epidemiology 107: 71.
8. Abramson J H, Gofin R, Peritz E 1982 Risk markers for mortality among elderly men: a community study in Jerusalem. Journal of Chronic Diseases 35: 565.
9. *Health hazard appraisal* (or *health risk appraisal*), which is becoming increasingly popular, is the use of a battery of information on health-related behaviour and personal characteristics in order to estimate an individual's chances of acquiring specific diseases, of dying, etc. It has been mainly used to enable individuals to identify hazards and to motivate them to lessen them. The technique offers promise as a tool for use in community medicine, both for identifying high-risk individuals and as a way of gauging a group or population's risk of preventable diseases and other outcomes. Many programmes over-reach existing scientific knowledge in order to accomplish the former aim. An important criticism is that the message generated for the client is based on the sometimes questionable assumption that changes made by the individual will necessarily change the risk—i.e. that risk markers are modifiable risk factors. Health hazard appraisal may be offered as an incentive to make participation in a health survey attractive. Schoenbach V J, Wagner E H, Karon J M 1983 The use of epidemiologic data for personal risk assessment in health hazard/health risk appraisal programs. Journal of Chronic Diseases 36: 625; Gordis L (ed) 1988 Epidemiology and health risk assessment. Oxford University Press, New York; Fielding J E 1987 The health of health risk appraisal. Health Services Research 22: 441.
10. See note 1, p 263.
11. See note 10, p 264.
12. Lemkau P V, Pasamanick B 1957 Problems in evaluation of mental health programs. American Journal of Orthopsychiatry 27: 55.
13. Margulec I (ed) 1966 Cerebral palsy in adolescence and adulthood: a rehabilitation study. Jerusalem Academic Press, Tel Aviv, p 8.

6. The study population

At an early stage in the planning of any investigation decisions must be made concerning the study population, i.e. the group of individual units (whether they are persons, families, medical records, certificates, nursery schools, specimens of milk, or dustbins) to be investigated. In the discussion that follows emphasis will be placed on human study populations.

The required decisions are:

1. *What is the study population*?—Or, if there is more than one (e.g. groups of cases or controls, or groups of people who differ in their exposure to a suspected health hazard), what are the study populations? The population or populations should be clearly and explicitly defined in terms of place, time, and any other relevant criteria.[1] Procedures to be used for finding and selecting cases, controls or other study subjects should be specified. (Methods of selecting controls will be discussed in Chs 7 and 30.)
2. *Will sampling be used*? If so, how will the selection from the study population be done? How big should the sample or samples be? How many controls are needed (see Ch. 8)?

If a sample is chosen, the group or population from which it is selected may be called the 'study population', the 'sampled population' or the 'parent population'. If the study population (all or some of whose members are to be investigated) is believed to be typical of a broader population to which it is possible to generalize the findings, the latter population may be termed the *reference* population.[2] As an example, the study population may comprise the elderly people in a given neighbourhood, all or a sample of whom may be studied; the investigators may decide they can apply the findings to elderly people in the whole city or nation.

SELECTING THE STUDY POPULATION

Often the investigator will have implicitly chosen his study population when he defined the topic of his investigation, through his interest in a specific community, a specific health programme, or the testing of a treatment for a specific category of patient. In other instances he may require purposefully to select a study population. Appropriateness and practicability should be taken into account.

The appropriateness of the study population refers mainly to its suitability for the attainment of the objectives of the study. If the hypothesis is that cancer is related to the consumption of carrots, is the population one where it can be expected that there will be sufficient variation in carrot intake to permit the hypothesis to be tested? On the other hand, there may be too much variation in a population, and the objectives may be such that they can be best met by restricting the study to a selected category, such as one sex or a single age group or families of a standard size and composition, in order to avoid the effects of characteristics that may confound the association which is to be studied. Maybe the study would best be performed in a very special kind of population—among vegetarians or monks—or in an occupational group subjected to seasonal emotional stress; the choice of a suitable study population is one of the factors making for originality in research. Paradoxically, some aetiological processes may best be investigated in a population where the disease under study is rare; it would be difficult to study the possibility that asymptomatic urinary tract infection may be an occasional cause of anaemia in a population with a high prevalence of anaemia due to hookworm disease or dietary iron deficiency.

A specific study population may also be chosen because it is believed to be typical of a broader reference population to which the investigator wishes to generalize the findings.

Practical questions also arise. Is the proposed study population one about which it will be possible to obtain the required information? Is it an 'accessible' population to which the investigator already has an *entrée*? Is it likely to co-operate in the study, or will it be a resistant one, possibly as a result of having been over-researched in the past? If patients with a specific disease are to be studied, will it be possible to identify enough cases to yield useful conclusions? If a long-term follow-up study is planned, is the population so mobile that it may be difficult to maintain contact with the subjects? A preliminary exploratory survey may sometimes be required in order to answer such questions.

SPECIFIC FEATURES OF THE STUDY POPULATION

The specific features of the study population may affect the validity of subsequent generalizations from the findings. For example:

1. *Volunteer populations.* Persons who volunteer to enter a study or submit to a procedure may differ in many respects from those who do not so volunteer, and therefore the findings in a volunteer population do not necessarily apply to the population at large. In some circumstances people who are anxious about their health may be those most likely to volunteer; in others, they may be the most reluctant. It is wrong to evaluate an immunization procedure by immunizing volunteers and then comparing them with persons who have not been immunized.
2. *Hospital or clinic populations.* Persons receiving medical care are obviously not representative of the general population or, necessarily, of all ill persons. People with rheumatoid arthritis who are treated in hospital may differ from those receiving ambulant care, and both groups may differ from patients with this disease who do not receive medical care for it. Expectant mothers who receive care from physicians may have different characteristics from those who do not—they may have higher incomes and include fewer teenagers,[3] or differ in other ways. Furthermore, the chance of entering a clinic population may vary for different diseases (or other characteristics) and for various combinations of characteristics, and this may produce spurious associations. For example, if people who have two specific diseases at the same time have an especially high chance of hospitalization, a study of hospital patients may reveal an association between the two diseases even if there is no such association in the population as a whole. If the two diseases carry different chances of hospitalization, a third characteristic (another disease, or a suspected aetiological factor) might turn out to be more frequently associated with one of the two diseases than with the other. Cigarette smoking, bunions, or some other factor might be found more frequently among hospital patients with bronchitis than among those with coronary heart disease, in the absence of any such association in the population as a whole. This problem of the interplay of admission rates, which is referred to as *Berkson's bias*[4] (admission rate bias) may arise in any population (not only hospital or clinic populations) in which individuals with different characteristics have different chances of inclusion. The use of hospital or clinic patients in case-control studies is discussed on page 70.

3. *Populations with good medical records.* It is often tempting to carry out studies in specific practices or clinics in which practitioners maintain good clinical records or are prepared to keep especially detailed records for the purposes of the study. This may be an essential condition for some studies, e.g. surveys of the work of general practitioners. But the doctors who are selected in this way may be singular in other respects also, and their practices may be atypical.
4. *People living at home.* A study population comprising people living at home necessarily excludes those who are in hospitals, old folks' homes, and other institutions; there may thus be a selective exclusion of persons with diseases and other conditions of interest to the investigator. Young adults who are unfit for army service may be over-represented, in a country where such service is compulsory.
5. *Patients notified as having a disease.* Even if notification is compulsory, it is unlikely that all cases are notified, and the notified cases may not be representative. Socially unacceptable diseases, such as venereal disease, may be more fully notified by public agencies than by private physicians. A study in the USA showed under-reporting (particularly by private physicians) of hepatitis B patients who were homosexual.[5]
6. *Autopsy populations.* Persons submitted to autopsy are obviously not necessarily representative of all decedents. Also, Berkson's bias may occur. It played a role in a well known epidemiological blunder, the discovery in 1929 of an apparent 'antagonism' between tuberculosis and cancer, which led to the institution of a 'programme for treating cancer patients with tuberculin'.
7. *Groups characterized by their behaviour or occupation* (smokers, joggers, migrants, bus drivers, etc). It is often worth considering the selective factors that may have led to membership in these groups or exclusion from them, especially if health status may have played a role. This has been called 'membership bias'.[7] Persistent cigarette smokers may be healthier than ex-smokers, not because smoking is salubrious, but because people stop smoking because of illness. The mental health status of immigrants may be a reflection of the characteristics that led to migration, rather than of the stresses or rewards of migration. Since ill health interferes with work, workers are ipso facto healthier, on average, than non-workers (this is termed the *healthy worker effect*). Since having children may keep women away from work, working women may be relatively infertile (the *infertile worker effect*).[8] Membership bias may crop up in unexpected places: a follow-up study in Finland showed that poor health at the age of 14 was predictive of a heavier coffee consumption at the age of 18, suggesting a 'sick drinker effect'.[9] If there are many cases where ill health has led to, for example, the adoption of a sedentary occupation, or retirement from work, or weaning from the breast, relationships that are subsequently detected between health and sedentary work, retirement or breast feeding may be misinterpreted.
8. *Populations in which the same individuals appear more than once.* If the same individuals appear more than once in a study population, the findings in these individuals may have an undue effect on the results.[10] This may arise in a study of the correlates of gastroenteritis, based on an investigation of all cases of this disease treated in hospital, including repeated hospitalizations of the same patients. A list of women who received antenatal care may include repeated pregnancies of the same women, and patients who consult their doctor frequently will be over-represented in a study based on records of medical visits. If the study is concerned with people rather than with episodes it may be decided to limit each person to a single appearance, e.g. by using the first episode or a randomly chosen one.

'HIDDEN' STUDY POPULATIONS

When an investigator sets out to compare populations, e.g. different villages or a group of cases and a group of controls, it is obvious that he is dealing with more than one study population. It is less obvious that the investigator is also dealing with two study populations in any epidemiological survey that makes use of rates.[11] These populations are firstly, the persons with a defined disease or other characteristic, who constitute the numerator for the calculation of the rate; and secondly, the total population at risk, who constitute the denominator. If the former group is completely contained within the latter and the same information is required about both groups, and this information can be collected in the same way for all persons in the population at risk, then no special problem arises. This is not the case, however, if different methods of obtaining information are required for the numerator and denominator populations, or if additional information is required about one of these populations. In these instances, although a single study population may have been specified, there are in effect two populations, to which separate consideration must be given in planning the study.

For example, in a study of the correlates of infant mortality, a single study population may be chosen (defined in terms, say, of geographical area and time). But information is actually required both about the babies who died (the numerator of the infant mortality rate) and about those who were born alive (the denominator). For a conventional infant mortality rate, which is based on births and deaths in the same year, these are two overlapping populations: some of the infants who died in 1990 were born in 1989. In practice it is often necessary to use different procedures to obtain information about the two populations, e.g. by the use of death and birth certificates respectively. Some data may be wanted for the numerator population only (e.g. age at death, cause of death), and the study plan should take this into account. If specific infant mortality rates are to be calculated, i.e. taking sex, birth rank and other characteristics into account, thought should be given to the practicability of obtaining parallel data about both populations. The biggest problem in such studies is often the unavailability of data about the denominator population.

A further instance of a 'hidden' study population may be given. It is often impossible to interview or examine all members of the study population or sample. Especially in a study requiring the co-operation of the persons to be investigated there may be many 'non-respondents'. When there is incomplete coverage of the study population or sample there is a possibility of bias. In a study of cardiovascular disease in California, for example, non-respondents were especially likely to be smokers, and were much less likely to have a family history of heart disease.[12] In Sweden, over half the non-participants in a health survey study said their reason was that they were ill, or in regular contact with a doctor; social insurance records revealed that non-participants in another Swedish study had over five times as many sickness benefit days, on average, as did participants.[13] It may thus be difficult to apply the findings to the study population, let alone to make generalizations to a wider population.

In order to test for bias, the demographic and other relevant characteristics of the individuals included and omitted (the respondents and non-respondents) should, if possible, be compared. From a practical point of view this means that during the planning phase the investigator should think of the non-respondents as a separate study population, since specific efforts may be required to obtain the requisite information about all or a representative sample of them. Similarly, members of the study population who are unwilling to participate in a trial may be seen as a 'hidden' study population.

SELECTING CASES FOR A CASE-CONTROL STUDY

There are at least three important considerations when deciding how to choose cases for a case-control study.

First, for a number of reasons it is best to use new ('incident') cases of the disease, rather than existing ('prevalent') cases varying in duration. The time lapse since exposure to the suspected causal factors is shorter, and it may be easier to obtain information about these factors. The time relationship between onset of the disease and exposure to these factors may be clearer than in long-established cases. Also, the use of new cases avoids *prevalence—incidence bias*:[7] if prevalent cases are used, patients who recover rapidly are likely to be under-represented, and those who die soon after onset (e.g. sudden deaths from coronary heart disease) will not be represented at all; so that if a difference in exposure to some factor is detected between cases and controls, it may be difficult to infer that the factor is a cause of the disease rather than a determinant of its subsequent course.

Secondly, it is generally hoped that associations that are found with the disease will apply not only to the specific study population investigated, but to a wider reference population, e.g. to all cases of the disease, or all severe cases. It is therefore important to consider whether the cases will be suitable representatives of the reference population the investigator has in mind. Cases drawn from clinical sources, rather than from a case-finding survey in a population, may not be representative of all cases, since there may be under-representation of those with no symptoms or with mild or atypical ones (over 25% of myocardial infarctions, for example, are not diagnosed clinically)[14] and of members of population groups with a low availability or use of medical services. Cases drawn from a hospital or consultative clinic may not be typical of all cases under clinical care; and cases drawn from a teaching hospital may not be representative of all hospital cases (*referral filter bias*[7]).

A third consideration is that the results of a case-control study using clinic or hospital cases may be affected by Berksonian bias (see p 59) if the postulated causal factor has an independent effect on the risk of entering the clinic or hospital population. There is no Berkson's bias if the case and control groups are both chosen from the community. If clinic or hospital cases are used, special precautions are needed when choosing controls in order to minimize this bias (see p 70).

Practical constraints (the availability of cases, the accessibility of disease registers and other records, etc.) usually enforce compromises.

But if the investigator is aware of the study's shortcomings he can take account of them when analysing the data and interpreting the findings.

The need for clear diagnostic criteria will be discussed in Chapter 11, and methods of sampling in Chapter 8.

It is often decided to specify *eligibility criteria*, determined mainly by the investigator's concept of the reference population—he may want to focus the study on elderly people or fertile women. He may also decide to restrict the study to a certain category of subject in order to avoid effects that might be confused with the effects of the factor under study; for example, the study may be restricted to non-smokers, so as to avoid effects connected with smoking. Confusion of effects ('confounding') may be significant if something that strongly influences the incidence of the disease, i.e. that helps to determine whether the subject will be a case or a control, is also strongly associated with the causal factor under study. Restriction of eligibility is one way—although not the only or necessarily the best one—of dealing with this problem (see page 258). Care must obviously be taken not to exclude cases because of characteristics or behaviour that may be consequences of the factor under study.

Subjects are sometimes excluded on the grounds that they could not have been exposed to the causal factor under study; for example, post-menopausal women and those who were sterilized many years previously might be excluded from a case-control study of the short-term effects of oral contraceptives. Such decisions will reduce the cost of the study (unless it is difficult to identify ineligible subjects). Other advantages have been questioned.[15]

All eligibility criteria will of course limit the generalizability of the findings—the findings of a case-control study of non-smokers may not be applicable to smokers. Needless to say, eligibility criteria applied to the cases must also (where relevant) be applied to the controls. Eligibility criteria should preferably be decided in advance, even if they can be applied only after the collection of data.

NOTES AND REFERENCES

1. A written record should be kept of the criteria for inclusion in the study population. These should be stated explicitly; e.g. if residents of a stated neighbourhood are to be studied, what is a 'resident'? (6 months' stay is often used as a criterion). If unforeseen problems of definition arise subsequently (e.g. students who live at home at weekends only) the new decisions should also be recorded, so that they can be applied uniformly.
2. The term 'target population', is best avoided in this context, since it is sometimes used for the sampled population and sometimes for the reference population. In the context of health care, it refers of course to the population at which a programme is directed.
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4. Real-life examples of *Berkson's bias*, from surveys in Ontario, include the detection of a strong association between diseases of the respiratory and locomotor systems in hospital data but not in the general population, and the finding that fatigue was positively associated with allergic and metabolic disease in the general population, but negatively in hospital data: Roberts R S, Spitzer W O, Delmore T, Sackett D L 1978 An empiric demonstration of Berkson's bias. Journal of Chronic Diseases 31: 119. In a clinic, the rate of neurological disorders in boys was found to be double that in girls; this unusual finding was attributed to the fact that the ratio of boys to girls was 4:1 in this clinic; Brown G W 1976 Berkson fallacy revisited: spurious conclusions from patient surveys. American Journal of Diseases of Children 130: 56. Algebraic explanations of Berkson's fallacy are given by Fleiss J L 1981 Statistical Methods for Rates and Proportions, 2nd end. John Wiley, New York, pp 8–13.
5. Alter M J, Mares A, Hadler S C et al 1987 The effect of underreporting on the apparent incidence and epidemiology of acute viral hepatitis. American Journal of Epidemiology 125: 133
6. Lilienfeld A M, Lilienfeld D E 1980 Foundations of epidemiology, 2nd edn. Oxford University Press, New York, pp 203–204; Mainland D 1963 Elementary Medical Statistics, 2nd edn. W B Saunders, Philadelphia, pp 121–122.
7. For lists and descriptions of possible biases, see Sackett D L 1979 Bias in analytic research. Journal of Chronic Diseases 32: 51; Schlesselman J J, Stolley P D 1982 Sources of bias. In: Schlesselman J J (ed) Case-control studies: design, conduct, analysis. Oxford University Press, New York, pp 124–143.
8. Joffe M 1985 Biases in research in reproduction and women's work. International Journal of Epidemiology 14: 118
9. Hemminki E, Rahkonen O, Rimpela M 1988 American Journal of Epidemiology 127: 1088.
10. Bias due to the over-representation of frequent attenders in a study that is based on records of medical visits can be controlled by a weighting procedure. This is described by Shepard D S, Neutra R 1977 American Journal of Public Health 67: 743, who show how estimates of the numbers and characteristics of hypertensive patients attending a medical clinic can be derived from a study of visits.
11. See Note 2 p 99, on rates.
12. Criqui M H, Barrett-Connor E, Austin M 1978 Differences between respondents and non-respondents in a population-based cardiovascular disease study. American Journal of Epidemiology 108: 367
13. Janzon L, Hanson B S, Isacsson S-O et al 1986 Factors influencing participation in health surveys: results from prospective population study 'Men born in 1914' in Malmo, Sweden. Journal of Epidemiology and Community Health 40: 174; Bergstrand R, Vedin A, Wilhelmsson C et al 1983 Bias due to non-participation and heterogeneous sub-groups in population surveys. Journal of Chronic Diseases 36: 725.
14. Over 25% of myocardial infarctions found at routine examinations in the Framingham study had not been recognized as such by the patient or attending doctor. Half were 'silent', and half caused atypical symptoms. The chances of subsequent heart failure, stroke, and death were the same for unrecognized and recognized infarctions. Kannel W B, Abbott R D 1984 Incidence and prognosis of unrecognized myocardial infarction: an update of the Framingham Study. New England Journal of Medicine 311: 1144.

8. Sampling

It is often decided to study only a part, or sample, of the study population (the 'sampled' or 'parent' population). Samples may be chosen of cases, people exposed to suspected causal factors, or potential controls. The decision to sample may be forced on the investigator by his lack of resources. The procedure may make for better use of available resources; because of the restricted number of individuals to be studied, it is possible to investigate each of them more fully than might otherwise have been possible, and to make greater efforts to ensure that information is in fact obtained from each individual. Frequently it is decided to have the best of both worlds, by obtaining easily acquired types of information about the total study population, but limiting certain parts of the study, which require more intensive investigations, to one or more samples.

Provided that certain conditions are met, there is no difficulty in applying the results yielded by a sample to the parent population from which it has been selected, with a degree of precision which meets the investigator's requirements. Statistical techniques are available which make it possible to state with what precision and confidence such inferences may be made. The conditions to be met are:

1. The sample must be *well chosen*, so as to be representative of the parent population.
2. The sample must be *sufficiently large*. If a number of representative samples drawn from the same parent population are investigated, it can be expected that, by chance, there will be differences between the findings in each sample; this problem of *sampling variation* is minimized if the sample is large.
3. There must be *adequate coverage* of the sample. Unless information is in fact obtained about all or almost all its members, the individuals studied may not be representative of the parent population; i.e. there may be *sample bias*.

Mere size is not enough. A sample that is badly chosen or inadequately covered remains a biased one, however big it may be. This was strikingly shown by the notorious poll conducted by the Literary Digest in 1936 which, although based on 2 000 000 ballots, dismally failed to predict Roosevelt's landslide victory in the presidential election. These ballots constituted 20% of the 10 000 000 that had been sent out to an unrepresentative sample comprising Literary Digest and telephone subscribers.

SAMPLING METHODS

A sample chosen in a haphazard fashion, or because it is 'handy', is unlikely to be a representative one. Such samples have been termed 'chunks' or 'accidental' or 'incidental' samples, or 'samples of convenience'. Their use has no place in community medicine research, except possibly in exploratory surveys where the investigator is doing no more than obtaining a 'feel' of the situation.

The recommended method is *probability sampling*, the distinctive feature of which is that each individual unit in the total population (each *sampling unit*) has a known probability of being selected. Generalizations can be made to the 'parent' population with a measurable precision and confidence (see p 270). We will discuss four types of probability sampling: random, systematic, cluster and stratified sampling. Probability sampling may be performed in more than one stage (two-stage and multi-stage sampling).

Use is sometimes made of *judgement samples*, i.e. quota and purposive samples. In *quota sampling* the general composition of the sample, e.g. in terms of age, sex and social class, is decided in advance; quotas, or required numbers, are determined for, say, men and women of different ages and social classes, and the only requirement is that the right number of people be somehow found to fill these quotas. The disadvantage of this method is that the persons chosen may not be representative of the total population in each category, and generalizations made from the findings may be incorrect. *Purposive samples* are those selected because the investigator believes them to be typical of the population he wishes to study. In a study of general practices, for example, he may select what he believes to be a representative cross-section of practices. Generalizations from the findings may or may not be valid.

It is important to set up the sampling rules in advance and to avoid any possibility that selection may be influenced by whim or convenience. The interviewers in a household survey, for example,

should be told in advance which homes to visit. If inclusion in the sample depends on information that is collected during the visit, the interviewer should be given precise instructions for making the choice.[1]

Random sampling

Random sampling (or 'simple random sampling') is a technique whereby each sampling unit has the same probability of being selected—the laws of chance alone decide which of the individual units in the parent (or 'target') population will be selected. To avoid confusion with the colloquial meaning of the word 'random', i.e. 'haphazard' or 'without a conscious bias', the term 'strict random sampling' is sometimes preferred.

The basic procedure is:

1. To prepare a *sampling frame*. This is usually a list showing all the units from which the sample is to be selected, arranged in any order. Its preparation may require considerable effort; it is seldom easy, for example, to obtain an up-to-date list of the elderly people living in a neighbourhood. In a country or city that maintains a population register, this may constitute a sampling frame; but such registers are often out-of-date, especially with regard to addresses; moreover, with the increase in concern for the individual's right to privacy, registers of this kind are becoming less accessible to investigators. The sampling frame for random-digit dialling (see p 85) is a list of telephone numbers. If the frame is an incomplete and biased representation of the study population, the sample too will inevitably be biased, however strictly the rules of random sampling are applied.
2. To decide on the size of the sample.
3. To select the required number of units at random, by drawing lots or using random numbers. The use of random numbers is explained on pages 87–89. When one matched control has to be chosen randomly from a small group of suitable candidates, it is often simplest to draw lots or (if there are up to six candidates) to throw a die.

The ratio 'number of units in sample/number of units in sampling frame' is referred to as the *sampling ratio* or *sampling fraction*. It is usually expressed either in the form '1 in n' (e.g. '1 in 3', '1 in 4', etc.) or as a percentage or proportion.

Random sampling does not ensure that the characteristics of the sample and the population will coincide exactly; chance differences will exist: but by the use of appropriate statistical methods[2] it is possible to calculate the probability that these divergences lie within given limits (see p 270).

Random sampling may be applied not only to the selection of subjects from a population, but to the selection of times or locations. In the latter instance, areas or the co-ordinates of points are used as the sampling units; the sampling frame may be a map rather than a list.

Systematic sampling

Instead of selecting randomly, a predetermined system may be used. The usual technique requires a list, not necessarily numbered, of all the sampling units. Having decided on the size of the required sample, the investigator calculates the sampling ratio, expressed as '1 in n', rounds n off to the nearest whole number, and uses this figure (k) as a *sampling interval*. He then selects every kth item in the list, starting with an item (from the first to the kth) selected at random. This technique is often easier than simple random sampling.

Such a sample can be considered as essentially equivalent to a random sample, provided that the list is not arranged according to some system or cyclical pattern. If a 1 in 30 systematic sample is selected from a list of persons arranged according to decreasing age, there may be an appreciable age difference between a sample where the first member selected was the first on the list, and one where the first person selected was the 30th. If the list is one of dwelling units, listed in such a way that ground-floor and upper-floor dwellings alternate, then a 1 in 2 systematic sample (or any systematic sample using an even number as the sampling interval) will contain either ground-floor dwellings only, or upper-floor dwellings only.

Other methods of systematic sampling may be used, not requiring prior listing of the sampling units. For example, it may be decided to select every third patient admitted to a hospital, or every patient whose personal identity number, social security number, hospital registration number, or birthdate (day of the month) ends with a predetermined and randomly selected digit or digits. These methods are usually chosen because of their convenience.

Systematic sampling is a convenient and objective way of selecting controls in a case–control study. The choice becomes automatic, e.g. the first patient, or the first eligible one, admitted after the study case; or the patient closest in age in the same hospital ward.

Cluster sampling

In cluster sampling, a simple random sample is selected not of individual subjects, but of groups or clusters of individuals. That is, the sampling units are clusters, and the sampling frame is a list of these clusters. The clusters may be villages, apartment buildings, classes of schoolchildren, housing units, households or families (note that these latter terms are not synonymous),[3] etc.

This is often a convenient method, especially when at the outset there is no sampling frame showing all the individual subjects; it is, of course, also more convenient to investigate people living in a relatively small number of households or villages, rather than the same number of persons, randomly selected, in more scattered places of residence.

The technique has the disadvantage, however, that if the clusters contain similar persons ('high intraclass correlation'), it is difficult to estimate the precision with which generalizations may be made to the parent population.[4] If attitudes to contraception are studied by questioning a simple random sample comprising 200 individuals, it is easy to state the precision with which the findings may be applied to the total population. On the other hand, if 40 families containing 200 individuals are selected, and if attitudes on contraception tend to 'run in families', then in effect only 40, not 200 entities have been studied. Moreover, if a quarter of these families each contain 10 or more individuals, these large families will contribute an undue proportion—at least half—of the individuals in the sample (and a relationship may be assumed between family size and views on contraception).

Other things being equal, a large number of small clusters is preferable to a small number of large clusters.

Stratified sampling

To use this method, the population (the sampling frame) is first divided into subgroups or *strata* according to one or more characteristics, e.g. sex and age groups, and random or systematic sampling is then performed independently in each stratum (*stratified random sampling, stratified systematic sampling*).

This procedure has the advantage that there is less sampling variation than with simple random or systematic sampling. It eliminates sampling variation with respect to the properties used in stratifying, and if the strata are more uniform than the total population with

respect to other attributes, it reduces sampling variation with respect to other properties also. The greater the differences between the strata and the less the differences within the strata, the greater is the gain due to stratification.

The same sampling ratio may be used in all strata. This is called *proportional allocation*, since the number of individuals chosen in each stratum is proportional to the size of the stratum. Alternatively, different sampling ratios may be used in different strata. This permits heavier sampling in subgroups with few members, so as to provide acceptable estimates, not only for the population as a whole, but also for each of its subgroups.

Estimates for the total population are prepared by combining the data for the various strata. If varying sampling fractions were used, an appropriate weighting procedure is required. If a uniform sampling fraction was used, the sample is *self-weighting* and can for some purposes be treated as if it were a simple random or systematic sample. The use of varying sampling ratios greatly adds to the complexity of the analysis and should not be decided upon lightly. There is of course no objection to the use of different sampling ratios if the strata are to be kept separate throughout the analysis—e.g. if Scotsmen, Irishmen and Jews are to be studied as separate groups; but then what we have is three study populations, and not a stratified sample.

Two-stage sampling

In two-stage sampling, the population is divided into a set of first-stage sampling units ('primary sampling units'), and a sample of these units is selected by simple random, stratified or systematic sampling. Individuals are then chosen from each of these primary units, using any method of sampling. The sample may be biased if very few first-stage units are selected.

The first-stage units may be census tracts, villages, classes of schoolchildren, households, or other aggregations. They may be time periods, e.g. if samples are chosen of patients who attend a clinic on randomly chosen days. This method has the same advantages as cluster sampling—less travel by interviewers, fewer school teachers to negotiate with, no need for a sampling frame showing all individuals in the population, etc.

The analysis is simplified if 'self-weighting' procedures are used. These ensure that each individual has an equal chance of entering the sample.[5] *Two-stage cluster sampling* (i.e. choosing a cluster within each cluster) is especially convenient, and may be sufficiently precise for some purposes.[5]

Multi-stage sampling

This method is used in large-scale surveys. A sample of first-stage sampling units is chosen, each of the selected units is divided into second-stage units, samples of second-stage units are selected, and so on. Different methods (simple random, stratified, systematic or cluster sampling) may be used at any stage.

Random-digit dialling

In a region where nearly everyone has a telephone at home, *random-digit dialling* (i.e. phoning numbers selected at random) is a convenient way of selecting a sample, either for telephone interviews or for subsequent home interviews or other investigations. Phone numbers are kept in the sample only if they turn out to be for residential addresses. If there is no reply the call is repeated a number of times, at different times and on different weekdays. A two-stage procedure may be used, whereby a sample of households is first selected by random-digit dialling and information is then obtained about the members of the household, the subsequent selection of subjects being determined by age, sex, or other eligibility criteria. The detailed procedure[6] is designed in a way that reduces the proportion of wasted calls; unlisted numbers are not excluded.

High success rates have been reported; in some studies in the USA, information on household composition was obtained for over 90% of the residential numbers phoned, and over 80% of the eligible subjects were subsequently interviewed.[6] Samples selected by random-digit dialling have been reported to be reasonably representative of the general population.

SUBSTITUTIONS

It usually happens that after a sample has been selected it is found that some of the selected subjects cannot be investigated. Persons may have died or moved away, may refuse, or may be unavailable for a variety of other reasons. It is tempting to replace such subjects with other randomly selected subjects. This is an acceptable (although usually unnecessary) procedure, provided that it is remembered that if the omissions produce a sample bias, substitutions will not remove

this bias. The outcome will merely be a large biased sample instead of a small biased sample. What is important, if there are more than a few omissions, is to examine the possible bias by determining the reasons for omission and, if possible, studying the demographic and other characteristics of the subjects omitted; the relevance of this bias to the study findings can then be appraised.

SAMPLE SIZE

If numbers are too small it may be impossible to make sufficiently precise and confident generalizations about the situation in the parent population, or to obtain statistical significance (see p 253) when associations are tested. It may thus be impossible to achieve the study's objectives. On the other hand, it is wasteful to study more subjects than these objectives require. Moreover, if numbers are large enough *any* difference, however small, will be statistically significant, and there may hence be a tendency to ascribe false importance to trivial differences. ('Samples which are too small can prove nothing; samples which are too large can prove anything.[7])

'How big should my sample be?' has been likened to the question 'How much money should I take when I go on vacation?'[8] (How long a vacation? Doing what? Where? With whom?) Calculations of sample size require both decisions and surmises. An investigator who wants to learn the incidence rate of diabetes, for example, must know how precise he wants his estimate to be and what confidence level he requires, i.e. (simplistically stated) what 'margin of error' will he accept, and what risk is he willing to take that the actual error is larger than this acceptable margin? To calculate the requisite sample size he must also have some idea of what the rate is. If he wishes to compare the incidence rates in two groups (in a survey or trial) he must start with an idea of the rate in one of the groups, and must know the magnitude of the difference he wants to be able to detect, what significance level he will use, and what power he wants the significance test to have for detecting the difference.[9]

Calculations can be avoided by using ready-made tables or computer programs.[10]

Consideration must also be given to practical constraints. A large sample may be difficult or impossible to find, or there may be an insufficiency of resources or time. A balance may have to be struck between the cost and the usefulness of the sample. The larger the sample, the less the sampling variation, i.e. the less the likelihood that the sample will be a misleading one. (The size of the sampled population is relatively unimportant.)[11] As a very rough guide, the usefulness of a sample is proportional not to its absolute size but to the square root of its size. To double the usefulness of a sample, its size must be increased fourfold; above a sample size of about 200, the absolute size of the sample must be augmented considerably to make an appreciable difference to its usefulness. This means that it may be necessary to balance increased cost (largely determined by the size of the sample) against increased usefulness (largely determined by the square root of its size). A 'sensitivity analysis'[12] may be helpful—a series of calculations of sample size, based on different assumptions and requirements.

Samples that are to be compared with one another, e.g. in case-control studies and clinical trials, are usually kept approximately equal in size, since (for a given total sample size) this provides the most precise results (i.e. a measure of association that has a narrow confidence interval). But equal groups are by no means essential, and there may be good reasons for having unequal ones.[13] The relative size of the groups must be taken into account when calculating sample size.

In some therapeutic and prophylactic trials in which the subjects enter the investigation serially, as they become available, no initial decision is made about the sample size. Instead, rules are set up in advance whereby at any stage it can be decided, on the basis of the findings to date, whether enough subjects have been studied to give a sufficiently definite answer, so that the trial can be stopped. This procedure is termed *sequential analysis*.[14]

A basic difficulty in calculations of sample size, whether they are done in advance or by the sequential method, is that the result depends on the attribute that is to be measured or compared. Samples of very different sizes are needed to study differences between two groups in their blood lipid levels, in their incidence of coronary heart disease, or in their mortality rates. It is seldom that a study is conducted to investigate only a single characteristic, and the real question often becomes not 'How many subjects do I need?' but 'With such-and-such a sample size (determined by practical considerations), about what variables and about what associations can I expect to get useful findings?—and in these circumstances, is the study worth doing?'

RANDOM NUMBERS

To use a list of random numbers in selecting a sample, a number must first be allocated to each sampling unit (e.g. from 1 to the total number of sampling units). Successive random numbers are then

read from the list, and the sampling units whose numbers coincide with these random numbers are chosen. This is continued until enough units have been selected.

Random numbers can be churned out by a computer; programs for doing this are easy to write.[15] Alternatively, use may be made of a printed table of digits arranged in a random order. A short specimen (provided as an illustration, and *not* for use) is shown here (Table 8.1), and a table for actual use is provided in the Appendix (p 327).

Table 8.1. Random numbers

Rows	Columns 1–4	5–8	9–12
1	96 22	74 70	80 46
2	82 14	73 36	41 54
3	21 47	59 93	48 40
4	89 31	62 79	45 73
5	63 29	90 61	86 39
6	71 68	93 94	08 72
7	05 06	96 63	58 24
8	06 32	57 11	81 59
9	91 15	38 54	73 30
10	54 60	28 35	32 94

The use of such tables is very simple, although sometimes tedious. Numbers are read off the table, beginning at any haphazardly chosen point and proceeding in any predetermined direction, until the required number of units has been selected. Numbers not appearing in the list of sampling units are ignored, and numbers that reappear after they have already been selected are generally also ignored.

As an example, if five units are to be chosen out of nine, numbered from 1 to 9, one could start say at the '8' in row 4 of Table 8.1, and read off numbers 8, 9, 3, 1 and 6 (moving horizontally). Or one could move vertically and select the units numbered 8, 6, 7, 9 and 5; the two zeros would be ignored, as there are no subjects numbered '0'. To choose a sample from 86 units, we would use pairs of digits. Moving horizontally from the same starting-point, we would select the units numbered 89 (ignored), 31, 62, etc. To choose a sample from between 100 and 999 sampling units, we would use sets of three digits (893, 162, 794, 573, 632, and so on). With between 1000 and 9999 sampling units, we would use sets of four digits (8931, 6279, etc.).

Sometimes many numbers have to be discarded and the process may become very tedious. For example, with 195 units to choose from, if we started from the same '8' in row 4 and moved horizontally, we would find only two helpful numbers among the first 16 we looked at: 162 in row 4 and 050 (or 50) in row 7. In such instances short-cut methods may be used.[16]

NOTES AND REFERENCES

1. Specimen instructions for interviewers: 'Ask if any children aged under 15 years live in the home. If 'yes', carry on with the interview if there is an 'A' in the sealed envelope'; this requires a prior allocation of the required proportion of As, in accordance with the sampling fraction; the envelopes should be well shuffled.
2. For a detailed exposition of the statistical aspects of sampling and the handling of sample data, see Cochran W G 1977 Sampling techniques, 3rd edn. John Wiley, New York. Formulae for calculating standard errors of means and proportions based on different sampling methods are listed by Kelsey J L, Thompson W D, Evans A S 1986 Methods in observational epidemiology. Oxford University Press, New York; pp 266–269.
3. One research institute used the following operational definitions: 'A *household unit* is a room or group of rooms occupied or vacant and intended for occupancy as separate living quarters. In practice, living quarters are considered separate and therefore a housing unit when the occupants live and eat apart from any other group in the building, and there is either direct access from the outside or through a common hall, or complete kitchen facilities for the exclusive use of the occupants, regardless of whether or not they are used'. (The definition then goes on to explain what is meant by 'living apart', 'eating apart', 'direct access', etc.) A *household* is everyone who resides in a housing unit at the time the interviewer speaks to a household member and learns who lives there, including those who have places of residence both there and elsewhere. The household also includes people absent at the time of contact, if a place of residence is held for them in the housing unit and 'no place of residence is held for them elsewhere'. 'A *family unit* consists of household members who are related to each other by blood, marriage, or adoption. A person unrelated to other occupants in the housing unit—or living alone—constitutes a family unit with only one member'. If there is more than one family unit in the household, the 'primary family unit' is the one that owns or rents the home. 'If families share ownership or rent equally, the one whose head is closest to age 45 is usually considered to be the primary family'. Survey Research Center, Institute for Social Research 1976 Interviewer's manual. University of Michigan, Ann Arbor, pp 39, 91, 94.
4. For statistical aspects of cluster samples, see Cochran W G 1983 in: Moses L E, Mosteller F, (eds) Planning and analysis of observational studies. Wiley, New York, pp 61–65.
5. To ensure that each individual has an equal chance of selection (the 'equal probability of selection method', or *epsem* sampling), primary units may be selected with a probability proportional to their size (*PPS*), and an equal number of individuals are then chosen from each primary unit. A technique that is convenient if there are not too many primary units in the sampling frame is described by Yeoman K A 1970 Statistics for the social scientist: 2. Applied statistics, Penguin Books, Harmondsworth, pp 131–132. If there are many primary units (e.g. households), it is easier to stratify them according to their size and use a sampling ratio that is proportional to their size. A simple method for

choosing a single member of each selected household is described by Cochran W G 1977 (see note 2), pp 364–365. An alternative to the 'proportional-to-size' selection of primary units is a selection by simple random or systematic sampling, and the use of a uniform sampling ratio in the second stage.

A *two-stage PPS cluster sampling* method has been used in many World Health Organization surveys in developing countries: randomly select 30 or more clusters, with probability proportionate to the size of the cluster, then randomly choose a household in each cluster, and then select one person from this household and each of the nearest households until a predetermined number has been chosen. Frerichs (1989) explains how a microcomputer spreadsheet program, operated by initially computer-illiterate health professionals, can be used to estimate the required sample size, select the first-stage clusters, and calculate confidence intervals. Frerichs R R 1989 Simple analytic procedures for rapid microcomputer-assisted cluster surveys in developing countries. Public Health Reports 104: 24.

6. *Random-digit dialling* is usually done by the procedure described by Waksberg J 1978 Sampling methods for random digit dialing. Journal of the American Statistical Association 73: 40. Its use is described by (inter alia) Hartge P, Brinton L A, Rosenthal J F, Cahill J I, Hoover R N, Waksberg J 1984 Random digit dialing in selecting a population-based control group. American Journal of Epidemiology 120: 825; Wingo P A, Ory H W, Layde P M et al 1988 The evaluation of the data collection process for a multicenter, population-based, case-control design. American Journal of Epidemiology 128: 206. The logistics of alternative methods are described by Harlow B L, Davis S 1988 Two one-step methods for household screening and interviewing using random digit dialing. American Journal of Epidemiology 127: 857.

   In a study in Washington requiring blood tests, potential subjects were chosen by random digit dialling. The response rate was 83% in this phase, 81% in the next phase (a telephone interview) and 67% in the third phase (blood-taking). The overall rate was thus (83 × 81 × 67)%, or only 45%, illustrating the effect of offering repeated opportunities for non-response. Brown L M, Tollerud D J, Pottern L M et al 1989 Biochemical epidemiology in community-based studies: practical lessons from a study of T-cell subsets. Journal of Clinical Epidemiology 42: 561.
7. Sackett D L 1979 Bias in analytic research. Journal of Chronic Diseases 32: 51.
8. Moses L E 1985 Statistical concepts fundamental to investigations. New England Journal of Medicine 14: 890.
9. *Calculations of sample size.* Refer to a statistics text, e.g. Fleiss J L 1981 Statistical methods for rates and proportions, 2nd edn. John Wiley, New York, pp 33–39 or Cochran (1977; see note 2) Chapter 4. Formulae for use with a wide variety of statistical tests are given by Lachin J M 1981 Introduction to sample size determination and power analysis for clinical trials. Controlled Clinical Trials 2: 93. For sample sizes when comparing several groups in a trial, see Fleiss J L 1986 The design and analysis of clinical experiments. Wiley, New York, pp 371–376. For matched-pair studies, see Fleiss J L Levin B 1988 Sample size determination in studies with matched pairs. 1988 Journal of Clinical Epidemiology 41: 727.
10. For tables showing the sample sizes required when comparing proportions (e.g. of therapeutic successes) in two equal groups, see Fleiss (1981; see note 9) Chapter 3 or Schlesselman J J 1982 Case-control studies: design, conduct, analysis. Oxford University Press, New York, Appendix A. For pocket-calculator programs for calculating sample sizes for estimating a proportion or mean or for detecting a difference between two proportions or means, see note 2, p 242. PC programs (see note 3, p 34) include Epistat and PC-Size.

11. The *finite population correction*, the factor introduced into the calculation to allow for the effect of the size of the parent population, is one minus the sampling fraction. If the sampling fraction is low this factor is close to unity, and the correction has a negligible influence and may be omitted. Cochrane (1977; see note 2), pp 24–25.
12. Laird N M, Weinstein M C, Stason W B 1979 Sample size estimation: a sensitivity analysis in the context of a clinical trial for treatment of mild hypertension. American Journal of Epidemiology 109: 408.
13. *Unequal groups* (see note 10, p 77): for the calculation of sample sizes, see Fleiss (1981; see note 9), pp 46–47.
14. See Armitage P 1975 Sequential medical trials 2nd edn. Blackwell, Oxford.
15. *Epistat* (see note 3, p 34) generates and prints *lists of random numbers.* So do the following simple programs (written in Basic and Turbo-Pascal respectively):

RANDNUM. BAS

```
10 INPUT "Largest random number required: ", X
20 INPUT "Number of random numbers required: ", N
30 RANDOMIZE TIMER
40 LPRINT N "RANDOM NUMBERS BETWEEN 1 AND" X
50 FOR I = 1 TO N
60 LPRINT, INT (RND*X) + 1
70 NEXT I
```

RANDNUM. PAS

```
program RANDNUM;
uses crt, printer; {Include for TurboPascal 4.0, not 3.0}
var X, N, I: integer;
begin
    write ('Largest random number required: ');
    readln (X);
    write ('Number of random numbers required: ');
    readln (N);
    randomize;
    writeln (lst, N, 'RANDOM NUMBERS BETWEEN 1 AND', X);
    for I: = 1 to N
    do writeln (lst,'                ', trunc((random*x) + 1))
    end.
```

16. Short cuts can be taken when *using tables of random numbers to choose a sample.* For example, if there are between 101 and 200 sampling units to choose from, read the successive three-digit numbers, and subtract the largest possible multiple of 200 from every number above 200 (also, read 000 as 200). Using the example in the text (p 88), the sampling units selected would then be 93 (893 minus 800), 162, 194 (794 minus 600), 173 (573 minus 400), 32, 190, 18, 39, etc. If there are between 201 and 300 sampling units, subtract a multiple of 300 from numbers above 300, discarding numbers above 900. If there are between 301 and 400 sampling units, subtract 400 from numbers above 400, discarding numbers above 800. And if there are between 401 and 500, subtract 500 from numbers above 500 (take 000 as 500).

2. Types of investigation

Before discussing the detailed planning of a study we will consider the various types of investigation and their nomenclature. The primary distinction is between surveys and experiments.

EXPERIMENTS

Since a survey is most easily defined negatively, as a 'non-experimental investigation', we will start by defining an experiment.

An *experiment* is an investigation in which the researcher, wishing to study the effects of exposure to or deprivation of a defined factor, himself decides which subjects (persons, animals, towns, etc.) will be exposed to, or deprived of, the factor. Experiments are 'studies of deliberate intervention' by the investigators.[1] If the investigator compares subjects exposed to the factor with subjects not exposed to it, he is conducting a *controlled experiment*; the more care he takes to ensure that the two groups are as similar as possible in other respects, the better controlled is his experiment. In a controlled experiment on the effect of vitamin supplements, for example, he will himself decide who will and who will not receive such supplements; in a survey, by contrast, he would compare persons who happened to be taking vitamin supplements with persons not taking such supplements.

A study is a true experiment only if decisions about exposure to the factor under consideration (e.g. to whom will vitamin supplements be offered?) are made by the experimenter. A researcher who wants to conduct an experiment does not always have full control over the situation, and may be unable to make such decisions. He may be able, however, to construct a study that resembles an experiment although in this respect it falls short of being a true one. For example, it may be possible to make observations before and after some intervention not under the investigator's control (medical treatment, exposure to a health education programme, etc.) and to make parallel

observations in an unexposed group. The study may then be called a *quasi-experiment*[2] (although some experts prefer to regard such studies as non-experimental). This term is also sometimes used if the allocation to experimental and control groups (even if under the experimenter's control) is not random (see *Randomization*, p 285).

Although they are sometimes given the unflattering appellation of 'pseudo-experiments', quasi-experiments are often well worth doing when a true experiment is not feasible (see pp 301 and 304); but their findings must be interpreted with caution—it is difficult to be sure that the outcome is in fact attributable to the intervention.

The term *natural experiment* is often applied to circumstances where, as a result of 'naturally' occurring changes or differences, it is easy to observe the effects of a specific factor. A famine may permit a study of the effects of starvation. Snow's classic comparison of cholera rates in homes with different water sources, some more contaminated than others, in London in the middle of the last century may be termed a 'natural experiment'.[3] 'Natural experiments' are surveys or, at most (if they examine the effects of man-made changes), quasi-experiments. They have also been termed 'experiments of opportunity'.

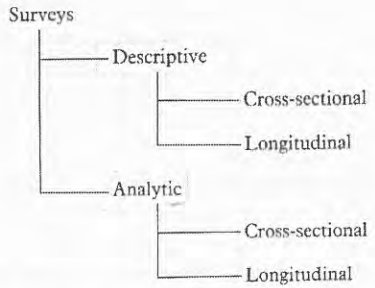
Manipulations of animals or human beings are not synonymous with experiments. An investigator who studies bacteriuria in pregnancy by needling the bladders of pregnant women through their abdominal walls in order to collect urine for examination is conducting a survey, not an experiment. An experiment is always a study of change.

SURVEYS

A *survey* is an investigation in which information is systematically collected, but in which the experimental method is not used. There is no active intervention by the investigators. To stress this feature, the term 'observational study'[4] is sometimes used. In this book the term 'survey' is used in a broad sense to cover non-experimental studies of any kind; the term is sometimes used more narrowly.[5] Surveys are not necessarily brief operations; they may involve long-term surveillance (see p 22) or repeated interviews or examinations.

Surveys may be descriptive or analytic. A *descriptive* survey sets out to describe a situation, e.g. the distribution of a disease in a population in relation to sex, age and other characteristics. An *analytic* (or *explanatory*) survey tries to explain the situation, i.e. to study the

Types of investigation



Experiments and quasi-experiments

determinative processes (Why does the disease occur in these persons? Why do certain persons fail to make use of health services? Can the decreased incidence of the disease be attributed to the introduction of preventive measures?). This is done by formulating and testing hypotheses. These may have various sources.[6] They may be based, inter alia, on the findings of previous descriptive surveys. The distinction between a descriptive and analytic survey is not always clear, and a single survey can combine both purposes. A broad descriptive survey may be so planned, for example, that it also provides information for the testing of a specific hypothesis. An analytic survey may be used to explain a local situation in a specific population in which the researcher is interested, or to obtain results of more general applicability, e.g. new knowledge about the aetiology of a disease.

Surveys, whether descriptive or analytic (or mixed), can be usefully categorized as cross-sectional or longitudinal, depending on the time period covered by the observations. A *cross-sectional* ('instantaneous', 'simultaneous', 'prevalence') survey provides information about the situation that exists at a single time, whereas a *longitudinal* ('time-span') survey provides data about events or changes during a period of time. A study in which children are measured in order to determine the distribution of their weights and heights, or to compare children of different ages, is cross-sectional; the children are examined once, at about the same time (not necessarily on the same day). A study in which the same children are examined repeatedly in order to appraise their growth is longitudinal. If the influence on child growth of parents' smoking habits is investigated in any of these studies, the study is an analytic one. The term 'cross-sectional' is also used in

other senses, e.g. for studies of total populations or representative samples ('cross-sections') of them.[7]

A longitudinal study in which a group of individuals (however selected) is followed up for some time may be called a *cohort* ('follow-up', 'panel') study; but the term 'cohort study' is often used more restrictively, to refer to a type of analytic study (see p 15); 'cohort study' should not be confused with 'cohort analysis'.[8] A study of the occurrence of new cases of a disease is an *incidence* study, and a follow-up study of persons born in a defined period is a *birth-cohort* study.

Surveys may use previously recorded data, or observations made after the start of the study. These kinds of data are best termed *retrolective* and *prolective* respectively (from the Latin root of the word 'collect')[9] rather than 'retrospective' and 'prospective', to avoid confusion with other meanings of the latter terms (see below).

EPIDEMIOLOGICAL STUDIES

Epidemiology is the science concerned with the occurrence, distribution and determinants of states of health and disease in human groups and populations. Epidemiological studies may deal with the distribution of diseases or health-relevant characteristics in groups (descriptive surveys) and with the factors influencing this distribution (analytic surveys, experiments and quasi-experiments).

Epidemiological studies have three main uses. First, they serve a diagnostic purpose. Just as the doctor caring for an individual requires a diagnosis of the state of health of his patient, so the doctor or other health worker caring for a community (or other defined group of people) requires a *community diagnosis*[10] or *group diagnosis*. Epidemiological studies provide the required information about the determinants of health in this specific community or group. Secondly, epidemiological studies can throw light on aetiology, the natural history of disease and growth and development. Such knowledge is of general interest, and has far wider applicability than in a specific local situation. And thirdly, epidemiological studies contribute to the evaluation of health care both in specific local situations (How well is this tuberculosis case-finding programme working?) and in general (Does this vaccine prevent disease?).

All three of these uses have a clear relevance to community medicine. Epidemiological studies have an obvious role in answering what Kark has called the cardinal questions that face practitioners of community medicine.[11]

What is the state of health of the community?
What are the factors responsible for this state of health?
What is being done about it by the health care system and by the community itself?
What more can be done, what is proposed, and what is the expected outcome?
What measures are needed to continue health surveillance of the community and to evaluate the effects of what is being done?

The role of epidemiological studies in community-oriented primary care, whose practitioners endeavour to integrate their care of individuals with the care of the community as a whole, will be described in Chapter 32.

Surveys of population health, it has been said, 'can be both the alpha and omega of health care by being the vehicle for both the discovery of need and the evaluation of the outcome of care and treatment'.[12]

Epidemiological and evaluative studies lend an organized structure to the practice of community medicine, and can be referred to as SHAPE activities (surveillance of health and programme evaluation).

Descriptive epidemiological surveys may be cross-sectional (How many blind people are there in the population?) or longitudinal.[13] Longitudinal surveys investigate *change*, e.g. studies of child growth and development or the 'natural history' of disease (What is the course of events after infection with AIDS virus?)

Analytic surveys may be group-based or individual-based. A *group-based* analytic survey is a comparison of groups or populations. It is a study of a group of groups, not a group of individuals. As an example, a group of countries could be compared with respect to their death rates from cirrhosis of the liver, on the one hand, and the average consumption of alcohol and various nutrients on the other.[14] Such studies are sometimes termed *ecological* or 'correlation' studies. We could also compare data for the same population at different times, e.g. by analysing the changing mortality rate from a disease in a single country in relation to changes in average fat intake and per capita tobacco consumption;[15] such studies are sometimes called *trend* studies. They are based on a comparison of successive descriptive cross-sectional studies. Inferences drawn from group-based studies are often misleading and are usually regarded as hints rather than definite conclusions. If we find that populations with a high consumption of beer tend to have a high death rate from cancer of the

Types of epidemiological study

- Descriptive surveys
  - Longitudinal (studies of change)
  - Cross-sectional
- Analytic surveys
  - Group-based (ecological studies, trend studies)
  - Individual-based
    - Longitudinal (time-span)
      - Prospective (cohort, forward-looking)
      - Retrospective (backward-looking) — (including case-control studies)
    - Cross-sectional (non-directional)
- Experiments and quasi-experiments (intervention studies, trials)
  - Group-based
  - Individual-based

rectum,[16] this does not necessarily mean that *individuals* who drink more beer are prone to develop this tumour; this should be tested in an individual-based survey, or maybe in a rather pleasant experiment. If a comparative study of 18 developed countries in Europe and North America has demonstrated a strong positive correlation between infant mortality and the number of doctors per 10 000 population,[17] this does not necessarily mean that infants should be kept away from doctors.

Group-based studies should, however, by no means be scorned. Doll & Peto have pointed out that although the striking correlations observed between colon cancer and meat consumption and between breast cancer and fat consumption, when countries are compared, may not mean that eating meat or fat is a major aetiological factor, they certainly show that the large international differences in the rates of these neoplasms are not chiefly genetic in origin, and suggest that these cancers are largely avoidable.[18] Trend studies often produce results of considerable interest, like the doubling of the rate of fractures of the proximal femur in Oxford between 1956 and 1983.[19]

Individual-based analytic surveys are of course (like all epidemiological studies) surveys of groups; but they utilize information about each individual in the group. In their simplest form, such surveys are performed to test a hypothesis that a specific causal factor is a determinant of a specific disease (or other outcome), by measuring each individual's exposure to the postulated causal factor and the presence of the disease in each individual.

Most individual-based analytic surveys can be categorized as prospective, retrospective or cross-sectional. This is a simple and useful classification. These studies can, however, be classified in other ways, and there is no generally agreed nomenclature. The terms 'prospective', 'retrospective' and 'cross-sectional' are sometimes used with meanings other than those explained below.[20] To avoid confusion, other connotations of these terms will be mentioned, and less ambiguous alternative names for these three kinds of study will be suggested.

A *prospective* study is a follow-up study in which people who are (respectively) exposed and not exposed to the postulated causal factor(s), or who have different degrees of exposure, are compared with respect to the subsequent development of the disease (or other outcome under study). The subjects may be chosen for follow-up because of their exposure or non-exposure to the causal factor, or they may be selected in some other way (say, because they live in a specific neighbourhood) and then characterized with respect to their exposure status. Inclusion in the study is not determined by the presence of the disease. This kind of survey resembles an experiment, except that exposure or non-exposure is not controlled by the investigator. The characteristic feature is that (like experiments) these surveys are 'forward-looking' in their *directionality*, i.e. when analysing the findings and reasoning about causal relationships, the investigator starts with the cause and goes forward to the outcome (Fig. 2.1). The term *cohort study* is often used as a synonym for 'prospective study'; the term *forward-looking study* may also be used. These names avoid confusion with the common use of the word 'prospective' to refer to the use of observations made after the start of the study (prolective data; see p 12).

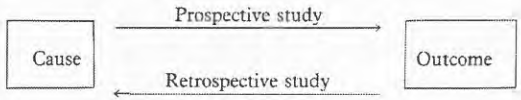


Fig. 2.1 Difference between prospective and retrospective studies.

In this scheme a *retrospective* study is also defined in terms of its directionality, with reference to the way the findings are analysed and inferences are drawn. It is a '*backward-looking*' *study* that starts with the outcome and goes back to the postulated cause: people with the disease are compared with those free of the disease, to determine whether they differ in their past exposure to the causative factor. A hypothesis that sudden frights during pregnancy are a cause of congenital anomalies could be examined retrospectively by comparing the histories of mothers of malformed and normal babies, or prospectively by comparing the occurrence of malformations among the offspring of mothers who did and did not have shocks during pregnancy. Samples of diseased and disease-free persons may be chosen for comparison, or the subjects of a retrospective study may be selected in some other way; they may, for example, be a random sample of a population, whose members are then investigated to determine whether the disease is present, so that people with and without the disease can be compared. Note that a retrospective study does not necessarily use previously recorded (retrolective) data.

Some epidemiologists base the definition of a retrospective study on the way that study subjects are selected, rather than on directionality, i.e. as a study where selection is based on the occurrence of putative outcomes, e.g. a comparison of groups of cases and controls.[20] It has been suggested that to avoid confusion, studies should be classified both according to their directionality and according to the criteria used in selecting subjects (by exposure, by outcome, or in some other way).[20]

Opponents of classifications based on directionality (who aver that these are 'founded on nonsense')[21] say that they reason from cause to effect even when they compare cases and controls—'the case-control design can be considered a more efficient form of the follow-up study, in which the cases are those that would be included in a follow-up study and the controls provide a fast and inexpensive means of inferring the person-time experience according to exposure in the population that gave rise to the cases';[22] 'the key distinction is that a case-control study involves gathering data on only a (disease-selective) subset of the source population'.[23]

The term *case-control study* is often used instead of 'retrospective study' to avoid the confusion engendered by the word 'retrospective' or the implication of backward-looking directionality. Most backward-looking studies are in fact based on comparisons of selected groups of cases and controls. However, not all comparisons of cases and controls are backward-looking. In some the time relationship between the variables is uncertain (as in a comparison of metabolic indicators in obese and non-obese subjects), so that the approach is non-directional rather than backward-looking; others use a forward-looking approach, as in a comparison of the birth weights of children born to samples of women who do and do not bleed during pregnancy; and others have nothing to do with the testing of an aetiological hypothesis (as in evaluative studies of screening or diagnostic tests). In this book 'case-control study' will refer to studies in which cases (of the outcome condition) are compared with controls in order to investigate a causal hypothesis; they may be backward-looking or non-directional, or may combine both these approaches (for different causal factors). Other terms used for what we have called retrospective studies include 'case-base' (or 'case-referent'), 'case-comparison', 'case history' and 'trohoc'[24] studies. The term *case-base* study gives emphasis to the comparison of cases with the population from which they are drawn.[25]

Prospective and retrospective studies are 'time-span' (longitudinal) studies, since directionality is possible only if the measurements of cause and outcome refer (or are believed to refer) to different points in time. In this classification a *cross-sectional* study is defined as one where the measurements of cause and outcome refer to the same or approximately the same point in time, and there is no inbuilt directionality. A common reason for the lack of directionality is that both the postulated causal factor and the postulated outcome have been present for some time before the study, and it is not certain which came first (the 'cart-or-horse' problem). A study of the relationship between obesity and physical inactivity (measured at the same time) is an example. Also, in some instances it may not be conceptually clear that one of the variables can be considered a cause of the other.

By this definition, cross-sectional studies may be case-control comparisons or based on samples of other kinds. It may be preferable to call them *non-directional*, to avoid confusion with other uses of the term 'cross-sectional', which is sometimes applied to studies in which information about cause and outcome is *collected* at the same time, or to studies of total populations or representative samples of them.

In some studies data that refer to a single point in time are treated as if they referred to different times. Reported disease in the subject's relatives, for example, may be taken as evidence of his prior exposure to genetic or other familial factors; or in a study of the association between lead poisoning and behavioural problems in school, the lead content of milk teeth may be used as an indicator of lead poisoning in

early childhood.[26] A backward-looking or forward-looking approach may then be used. In these instances, nomenclatural confusion may be avoided by calling them *quasi-retrospective* or *quasi-prospective* studies.[1]

The *timing* of the study (*when* it is conducted, in relation to the time of exposure to the suspected cause and the time of occurrence of the outcome) is of obvious importance, since the accuracy of information on prior events may be affected by the availability or quality of past records or by bias in recalling or reporting these events. But timing does not play a role in the classification we have used. A prospective (or cohort) study is not necessarily a study of outcomes that occur after the start of the investigation; it may deal with outcomes that occurred before the study was started. An example is a comparison of the mortality experience of obese and non-obese persons, based upon their weight when they originally took out life insurance policies, and their survival since then until the time of the study. A study of this sort may (among other terms)[27] be called a *historical prospective study*. As in ordinary ('concurrent') prospective studies, the information about exposure to the causal factor is usually, however, recorded before the appearance of the outcome. In a retrospective study, exposure to the suspected cause is generally measured only after the appearance of the outcome; but sometimes information about exposure is available from previous records. Information about the exposure and the outcome may be collected at the same time. A cross-sectional study may be based on retrolective or prolective data.

Prospective, retrospective and non-directional approaches may be combined in the same study, and numerous hybrid designs can be identified. One of these is the *nested case-control* or *ambidirectional* study, in which new cases of a disease are identified in a follow-up study of a population and are then compared with controls drawn from the same population. In some studies, distinctions based on directionality are artificial or blurred: in studies of population samples, for example, the results can often be analysed using either a forward- or backward-looking approach.[28]

Each kind of study has its advantages and disadvantages.[29] Backward-looking and non-directional studies are generally simpler to perform; they usually require less time and fewer subjects, and avoid the difficult task of following up the subjects. But the fact that information about exposure to the 'cause' is generally obtained when the disease is already present may produce various kinds of bias. There may, for example, be 'rumination bias' (cases may ruminate about causes for their illnesses, and this may influence their report of prior exposures) or 'exposure suspicion bias' (the investigator's knowledge that the illness is present may stimulate an especially intensive search for evidence of exposure).[30] Prospective studies are in many ways preferable. They generally leave less doubt about the time relationships between exposure and the disease, and can more easily provide information about the degree of risk associated with exposure, the natural history of the disease, and other effects of the exposure. They may, however, be impracticable if the disease is rare or if it develops long after exposure to the cause. For example, the hypothesis that severe diarrhoea is conducive to the development of cataract many years later is more easily tested retrospectively[31] than prospectively.

Epidemiological experiments that are designed to test cause–effect hypotheses may be termed *intervention studies*. They can be performed only if it is feasible and ethically justified to manipulate the postulated cause. 'The bearing of children, exposure to hazards, or personality type, are not normally subject to experiment'.[32] Like surveys, intervention studies may be group-based or individual-based. If the effect of fluoride on dental caries is investigated by fluoridating the water supplies of some towns and comparing the subsequent occurrence of dental caries in these towns with that in control towns, this is a group-based experiment; data are not available on the fluoride consumption of each individual. On the other hand, when the hypothesis that the administration of oxygen to premature infants caused retrolental fibroplasia (a blinding disease) was tested by administering oxygen continuously to some babies and not to others,[33] this was an individual-based experiment.

Experiments and quasi-experiments conducted to appraise the value of treatments, preventive procedures and health care programmes are generally termed *trials*.

EVALUATIVE STUDIES

Evaluative studies[34] are those that appraise the *value* of health care—they set out to measure how 'good' care is. (The criteria used will be discussed in Chapter 5.)

Evaluative studies are of two main types. These may be termed *reviews* and *trials*, and are distinguished by their different purposes.

A *programme review* is motivated by concern with the welfare of the specific patients, community or population to whom care is given, and it evaluates the care given to them. It may evaluate a

particular programme that operates in a defined setting, with well defined aims such as case-finding, immunization, the control of hypertension, fluoridation of water supplies, etc. (A programme may be defined as 'any enterprise organized to eliminate or reduce one or more problems').[35] It may also evaluate a specific health service (a national or regional service, a health centre, a group practice, a hospital, etc.), a part or aspect of a service, or even the work of an individual practitioner, and may be called a 'service review'.

Types of evaluative study

1. Programme reviews
2. Trials
   a. Of care given to groups and populations:
      Programme trials
   b. Of care given to individuals:
      Clinical trials
      Trials of screening and diagnostic tests

An essential feature of a programme review is that the findings should be helpful to whoever makes decisions about the specific programme or service. It follows that the evaluation can be conducted within the framework of the assumptions accepted by the decision maker or makers, e.g. the assumption that the performance of certain procedures will have beneficial effects. These assumptions, on which the programme is based, are not necessarily questioned or tested. The evaluation results can be useful without necessarily being found convincing by those who doubt the validity of the assumptions on which the programme is founded. Programme and service reviews are akin to a physician's periodic reviews of the treatment given to a specific patient, which enable him to decide whether to continue, modify or stop therapy. These assessments are an indispensable part of the clinical process, although the clinician can seldom obtain convincing evidence of the extent to which changes in the patient's condition can be attributed to the treatment.

A *trial*, by contrast, sets out to obtain generalizable knowledge, that can be applied in other settings, about the value of a *type* of health care. To meet its purpose a trial must yield conclusions that are well enough substantiated to be generally convincing. It is not enough merely to demonstrate a beneficial effect, but there must be evidence that the effect can be attributed to the care given. To this end, pains must be taken to eliminate or allow for the possible influence of other factors.

It is important to distinguish between programme reviews and programme trials, since the questions they ask and the methods they use are different. In a review, basic assumptions are not in question, and definitive tests of cause–effect hypotheses are not required; it is wasteful and may be self-defeating to use excessively rigorous study techniques. A trial, on the other hand, may be inconclusive if methods are insufficiently rigorous. There are other differences as well, which also have implications for the planning of the study. To be useful, a review must usually be rapid and (if possible) ongoing. Changes in circumstances, personnel and policy result in frequent changes in the procedures used in a service, and there may be little practical benefit in evaluating a programme as it used to be some years previously. If appraisal is rapid, it can give early warning of inadequacies and provide an up-to-date factual basis for decisions. Speed is less important in a trial. Further, a review is carried out in a service-oriented setting—this is the review's *raison d'être*. Evaluation may not be seen as an important element, and little time and resources may be available for special information-collecting procedures. A trial, on the other hand, is more likely to be conducted as a specific investigative procedure. Not infrequently the programme is set up specially, as a test or demonstration.

Programme reviews are generally descriptive surveys. Programme trials may be experiments or quasi-experiments.

An evaluation of a programme may be of a hybrid type, e.g. when a programme trial is conducted in the context of a service review. This may happen if there is a call for the appraisal of an innovative feature of the service, or if certain of the assumptions on which the service is based are questioned, or if there is a wish to generalize from the experience of the service. In such instances there will be a need for the demanding methods of study that are appropriate to a trial, as well as for the less rigorous ones needed for a review of other aspects of the service. Difficulties often arise when a programme trial is conducted in the setting of an established service, since evaluation and service may make competing demands.

A *clinical trial* appraises the worth of a form of care—preventive, curative, educational, etc.—given to individuals, rather than to a group or population; it may be an experiment or a quasi-experiment. Trials may also be conducted to evaluate screening and diagnostic tests (see pp 160–163).

While clinical and programme trials require separate consideration (see Chs 30 and 31), there is a degree of overlap between them, as some programme trials are based on a comparison of individuals who are exposed and not exposed to the programme under study.

Individual-based programme trials of this sort do not differ in their design from other clinical trials.

Some trials have double objectives: when testing a new form of treatment, the aim may be both to appraise its value for individuals and to evaluate the programme whereby it is provided to the public.

The use of case-control studies for the evaluation of preventive and therapeutic procedures is discussed on page 292.

The term '*inbuilt evaluation*' may be used if the evaluation is planned in advance and the requisite information is collected in a systematic way as an integral part of the provision of a service.

Medical audit is a technique used mainly in service reviews, whereby the quality of a service is evaluated by appraising the quality of the care given to individuals. It will be discussed in more detail in Chapter 20.

SURVEILLANCE

Surveillance denotes the maintenance of an ongoing watch over the status of a group or community. It yields information about new and changing needs, and provides a basis for appraising the effects of health care (see p 317). A watch may be kept on health status—in terms of mortality, morbidity, nutritional status, child growth and development, or other indices—and on environmental hazards, health practices, and other factors that may affect health.

Demographic surveillance[36] refers to ongoing measurement of the size of the population, its age and sex composition, and other demographic characteristics. Apart from other purposes, this is a prerequisite for the measurement of a community's health, since it provides information about the *denominator population*.

There is considerable confusion about the use of the terms 'surveillance' and 'monitoring', and they are often used interchangeably. *Monitoring* is probably best used to refer to the maintenance of an ongoing watch over the activities of a health service, e.g. the provision of answers to questions such as 'what are we doing at the present moment?'; 'what does it cost in resources to do what for whom?'[37]

Surveillance and monitoring may be based on ongoing data collection (often as a byproduct of the provision of a service) or a trend study, i.e. comparison of repeated cross-sectional surveys. The term 'inbuilt surveillance' may be applied if a health service has set up routine procedures for this purpose, such as the ascertainment and recording of births, deaths and movements, the notification of infectious diseases, and the use of records designed for the easy retrieval of diagnostic information, with periodic analysis of these data.

OTHER TERMS

The term *exploratory study* is often applied to a descriptive survey designed to increase the investigator's familiarity with the problem he wishes to study. The aim may be to formulate a problem for more precise investigation, to develop hypotheses, to clarify concepts, or to make the investigator more familiar with the phenomenon he wishes to investigate or with the setting in which he will study it. Such a study is sometimes called a *pilot study*; however, this term is better confined to another connotation, namely a dress rehearsal of an investigation performed in order to identify defects in the study design. A descriptive survey in which a very large number of characteristics are studied, i.e. in which the net is thrown wide, performed in the hope that the results will provide hypotheses for subsequent testing, is sometimes unflatteringly referred to as a *fishing expedition*.

A *methodological study* is one performed with the purpose of collecting information on the feasibility or accuracy of a research method (see Ch 15 and 16). In community medicine the aim of such a study is usually the evaluation of an investigative procedure for use in community diagnosis.

A *morbidity survey* is a study, usually descriptive, of the occurrence and distribution of a disease, or diseases, in a population. It may be a *prevalence study*, concerned with all cases of the disease present in the population at a given point in time or during the period of the survey, or an *incidence study*, concerned only with new cases (patients, or episodes of illness) occurring or diagnosed during a given period. A *two-stage morbidity study* is one in which screening tests (see p 38) are used to identify persons who may have the disease, and the presence of the disease is then determined by more exact tests.

The term *household survey* usually refers to a descriptive survey of illnesses and disability, performed by interviewing persons in their own homes, often by questioning a single informant about other members of his household.

KAP studies are studies of knowledge, attitudes and practices.

Health practice research (*health services research, operational research*) is concerned with organizational problems—with the planning, management, logistics and delivery of health care services. It deals with manpower, organization, the utilization of facilities, the quality of health care, cost, the relationship between need and demand, and

other topics. It makes use of systems analysis, computer simulation, and other sophisticated techniques of operations research.[38]

NOTES AND REFERENCES

1. Bailar et al (1984) define longitudinal studies as prospective or retrospective, depending on whether the selection of study subjects is based on the occurrence of putative causes or outcomes. They subclassify prospective and retrospective investigations as follows: studies of deliberate intervention by the investigators, observational studies (including studies of deliberate interventions not under the control of the investigators), and pseudolongitudinal (pseudoretrospective and pseudoprospective) ones. (Bailar J C III, Lewis T A, Lavori P W 1984 A classification for biomedical research reports. New England Journal of Medicine 311: 1482). The latter studies are called 'quasi-retrospective' and 'quasi-prospective' in this book.
2. *Quasi-experiments* are discussed by Campbell D T, Stanley J C 1966. Experimental and quasi-experimental designs for research. Rand McNally, Chicago. Campbell D T 1969 Factors relevant to the validity of experiments in social settings. In: Schulberg H C, Sheldon A, Baker F (eds) Program evaluation in the health fields. Behavioral Publications, New York. Cook T D, Campbell D T 1979 Quasi-experimentation: design and analysis issues for field settings; Rand McNally, Chicago, Illinois. Kleinbaum D G, Kupper L L, Morgenstern H 1982 Epidemiologic research: principles and quantitative methods. Lifetime Learning Publications, Belmont, California, p 44.
3. Snow J 1855 On the mode of communication of cholera. Churchill, London. Facsimile edition 1965: Hafner, New York.
4. The term 'observational study' does not imply that methods other than observation (questionnaires, documentary sources) are not used. Another term for non-experimental studies is 'naturalistic': Polgar S, Thomas S A 1988 Introduction to research in the health sciences. Churchill Livingstone, Melbourne, p 71.
5. The term 'survey' is sometimes used in a narrow sense to refer to specific types of non-experimental study, such as questionnaire-based ones (Blum M L, Foos P W 1986 Data gathering: experimental methods plus. Harper and Row, New York, p 255), descriptive studies of population characteristics (Polgar & Thomas 1988; see note 4), field surveys, household surveys (see p 23), cross-sectional studies (see p 11); Kleinbaum et al 1982; see note 2), or studies of public opinion.
6. How hypotheses about a possible cause are generated 'is little understood. They are products of their times, what is in the air, of what is known and being thought important, and of the prepared mind and individual imagination . . . *Where* epidemiological hypotheses come from is also interesting: they emerge—from everywhere . . . and from nowhere in particular'. Morris J N 1975 Uses of epidemiology, 3rd edn. Churchill Livingstone, Edinburgh, pp 233–249.
7. Fleiss J L 1981 Statistical methods for rates and proportions, 2nd edn. Wiley, New York, p 20.
8. Cohort analysis refers to the investigation of data concerning people born in various specific time periods (e.g. 1910–1919) with a view to learning about the morbidity, mortality, etc. of each birth cohort or its various subgroups, and to comparing people born in different periods. This may reveal a cohort effect—i.e. there may be differences in morbidity, mortality, etc. when people of the same age in different birth cohorts are compared, as a result of differences in the experience of different cohorts. In a cross-sectional survey 50-year-olds may be shorter and have a lower mean IQ than 30-year-olds, not because they are older, but because they belong to different cohorts with different prior experiences.

9. Feinstein A R 1981 Clinical biostatistics: LVII. A glossary of neologisms in quantitative clinical science. Clinical Pharmacology and Therapeutics 30: 564.
10. The principles and methods of *community diagnosis* are described by Morris (1975; see note 6; Chapter 2); Tapp J W 1974 Community diagnosis. In Kane R L (ed) The challenges of community medicine, Springer, New York, pp 13–26. For discussions and examples of community diagnosis in the context of community-oriented primary care, see Kark S L 1981 The practice of community-oriented primary health care. Appleton-Century-Crofts, New York; and the references cited in note 1, p 324. The use of epidemiological information as a basis for the planning and evaluation of health services is discussed in some detail by Dever G E 1980 Community health analysis. Aspen, Germantown, Maryland.
11. Kark 1981; see note 10.
12. Acheson R M, Hall D J 1976 In: Acheson R M, Hall D, Aird L (eds) Seminars in community medicine, vol. 2: health information, planning, and monitoring. Oxford University Press, London, pp 145–164.
13. For a detailed discussion of studies in which the same variable is examined repeatedly, see Cook N R, Ware J H 1983 Design and analysis methods for longitudinal research. Annual Reviews of Public Health 4: 1.
14. Qiao Z-K, Halliday M L, Coates R A, Rankij J G 1988 Relationship between liver cirrhosis death rate and nutritional factors in 38 countries. International Journal of Epidemiology 17: 414. The authors found that a higher average intake of protein, vitamins A and B2 and calcium (none of which was related to average alcohol consumption) was associated with a lower mortality from liver cirrhosis. They concluded that these relationships were not necessarily causal, but indicated a need for further studies.
15. After analysing trends in New Zealand, for example, Jackson & Beaglehole (1987) concluded that changes in fat and tobacco consumption provided a biologically plausible explanation for at least part of the decline in coronary mortality between 1968 and 1980. Jackson R, Beaglehole R 1987 Trends in dietary fat and cigarette smoking and the decline in coronary heart disease in New Zealand. International Journal of Epidemiology 16: 377.
16. Breslow N E, Enstrom J E 1974 Geographic correlations between cancer mortality rates and alcohol-tobacco consumption in the United States. Journal of the National Cancer Institute 53: 631.
17. Cochrane A L, St Leger A S, Moore F 1978 Health service 'input' and mortality 'output' in developed countries. Journal of Epidemiology and Community Health 32: 200.
18. Doll R, Peto R 1981 The causes of cancer. Oxford University Press, Oxford, pp 1204–1205.
19. Boyce W J, Vessey M P 1985 Rising incidence of fracture of the proximal femur. Lancet i: 150.
20. Kramer & Boivin 1987 review the confusion in the classification and nomenclature of epidemiological study designs. To 'unconfound' the situation they suggest a three-way classification by (1) the *directionality* in which exposure and outcome are investigated (cohort, case-control, or cross-sectional); (2) *sample selection* criteria (by exposure, outcome, or other criteria), and (3) *timing* of the study proper with respect to the calendar times of exposure and outcome, the categories being *historical* (exposure and outcome occurred before the study), *concurrent* (both exposure and outcome occur during the study) and *mixed* (exposure before the study, outcome during the study). Kramer J S, Boivin J F 1987 Toward an 'unconfounded' classification of epidemiologic research design. Journal of Chronic Diseases 40: 683.

    Debates on alternative classifications appear in the Journal of Clinical Epidemiology 1988 41: 705 and 1989 42: 819. For defences of the utility of

directionality as an axis of classification, see the following papers in that journal: Kramer M S, Boivin J-F 1988 The importance of directionality in epidemiologic research design: 41: 717; Kramer M S, Boivin J-F 1989 Directionality, timing and sample selection in epidemiologic research design: 42: 827; Abramson J H 1989 Classification of epidemiologic research: 42: 819; and Feinstein A R 1989 Directionality and scientific inference: 42: 829.

21. Miettinen O S 1988 Steps to deconfound the fundamentals of epidemiologic study design. Journal of Clinical Epidemiology 41: 709.
22. Rothman K J 1986 Modern epidemiology. Little, Brown, Boston, p 64. The 'person-time' concept is explained in note 3, p 99.
23. Greenland S, Morgenstern H 1988 Classification schemes for epidemiologic research designs. Journal of Clinical Epidemiology 41: 715.
24. *Trohoc*, a term proposed as an unambiguous replacement for 'retrospective' (Feinstein 1981; see note 9), is 'cohort' spelt backwards, and makes many epidemiologists shudder.
25. The 'case-base' or 'case-referent' approach is strongly championed by some epidemiologists: Miettinen O S 1985 Theoretical epidemiology: principles of occurrence research in medicine. Wiley, New York, chapter 4; Miettinen 1988 (see note 21); Axelson O 1985 The 'case-control' study: valid selection of subjects. Journal of Chronic Diseases 38: 553.

    Miettinen explains this approach as follows: 'Given a study population's experience over time, or a *study base*, it is necessary to ascertain the relevant facts about the occurrence of the illness in this experience. One approach to this is to employ a simple *census*, that is, to ascertain all of the relevant facts on all members of the study population... An alternative to this approach is one of combining census and sampling. First one uses a census of the base population ... to identify all cases. Then a second census is conducted on the cases to ascertain other facts (concerning the determinants, modifiers and confounders) on them. Finally, a sample of the base is used to obtain information of the latter type about it. This alternative to the census approach may be considered the *census-sample* or *case-base* approach. It may also be termed the *case-referent* approach, since the study base, which the sample represents, is the direct referent of the empirical pattern of occurrence in the study. On the other hand, the term "case-control" approach is a misnomer, as the base sample is no more a control series than a census of the base (referent) is'. Miettinen O S 1985 The 'case-control' study: valid selection of subjects. Journal of Chronic Diseases 38: 543.

    Other epidemiologists are less convinced, and suggest that the main issue is the appropriate selection of controls: Schlesselman J J 1985 Valid selection of subjects in case-control studies. Journal of Chronic Diseases 38: 549; Feinstein A R 1985 The case-control study: valid selection of subjects. Journal of Chronic Diseases 38: 551.
26. Needleman H L, Gunnoe C, Levison A et al 1979 Deficits in psychologic and classroom performance of children with elevated dentine lead levels. New England Journal of Medicine 300: 689.
27. A historical prospective study may be called a *non-concurrent prospective study*, a *retrospective cohort study*, a *prospective study in retrospect*, or a *retrospective design with forward directionality* (all this in the interest of greater clarity).
28. Kramer & Boivin 1987 (see note 20)
29. The uses of retrospective and prospective studies are discussed in all textbooks of epidemiology. Chapters describing the uses and limitations of cross-sectional studies (Abramson J H, p 89), cohort studies (Feinleib M, Detels R, p 101) and case-control studies (Greenberg R S, Ibrahim M A, p 123) will be found in the Oxford Textbook of Public Health 1985 vol 3: Investigative methods in public health (Holland W W, Detels R, Knox G, eds). Oxford University Press, Oxford. For an especially thorough treatment of the pros and cons of a large number of study designs, including hybrid designs, see Kleinbaum et al (1982)

(see note 2), Chapter 5. Case-control studies are discussed in detail in a symposium edited by Ibrahim M A 1979 Symposium on the case-control study. Journal of Chronic Diseases 32: 1 and by Schlesselman J J 1982 Case-control studies: design, conduct, analysis. Oxford University Press, New York and Breslow N 1982 Design and analysis of case-control studies. Annual Reviews of Public Health 3: 29.

30. Sackett D L 1979 Bias in analytic research. Journal of Chronic Diseases 32: 51.
31. An association between severe diarrhoea and cataract has been shown by case-control studies in India and England. Minassian D C, Mehra V, Jones B R 1984 Dehydrational crises from severe diarrhoea or heatstroke and risk of cataract. Lancet i: 751; van Heyningen R, Harding J J 1988 A case-control study of cataract in Oxfordshire: Some risk factors. British Journal of Ophthalmology 72: 804.
32. Susser M, Stein Z, Kline J 1978 Ethics in epidemiology. Annals of the American Academy of Political and Social Science 437: 128.
33. Kinsey V E, Hemphill F M 1955 American Journal of Ophthalmology 40: 166.
34. For a short introduction to evaluative studies, see Rundall T G 1986 Evaluation of health service programs. In: Last J M (ed) Maxcy–Rosenau public health and preventive medicine, 12th edn. Appleton-Century-Crofts, Norwalk, Connecticut, pp 1831–1847 or Spiegel A D, Hyman H H 1978 Basic health planning methods. Aspen Systems, Germantown, Maryland, Chapter 7.
35. Kane R L, Henson R, Deniston O L (1974) In: Kane R L (see note 10).
36. Accurate information on the size and composition of the population served is seldom easy to obtain. It is usually not possible to obtain suitable data from official censuses, and a community health service may have to develop its own data-gathering mechanism. If the population served is too large for accurate surveillance, a 'defined area' may be demarcated for this purpose (see p 311). If the service is provided to specific people (not to all comers or to all residents in a neighbourhood), a register of eligible persons will provide the requisite information.

    For information on microcomputer programs (*EasWesPo, DemProj, MCPDA, MortPak* and others) for demographic analyses, including the estimation of fertility rates, population projections and life tables from simple demographic survey data, write to Project Director, Software and Support for Population Data Processing, Department of Technical Cooperation for Development, Room DC2–1570, United Nations, New York 10017.
37. The meanings of the terms 'surveillance' and 'monitoring' are discussed by Acheson & Hall (1976; see note 12), p 126. 'Monitoring' often denotes not only watching, but using the observations as a basis for continual modification of goals, plans or activities; Knox E G (ed) 1979 Epidemiology in health care planning. Oxford University Press, Oxford, pp 18–19, 127–129. Its use in programme evaluation is briefly reviewed by Rundall (1986) In: Last J (see note 34), pp 1837–1839.
38. For a brief introduction to health services research, see Lewis C E Health services research: asking the painful questions. In: Kane (1974; see note 10), pp 69–86. Morris (1975; see note 6) defines *operational research* as 'the systematic study, by observation and experiment, of the working of health services as well as of health'. Operational and system studies are described by Cretin S 1985 Operational and system studies. In: Holland W W, Detels R, Knox G (eds) Oxford Textbook of Public Health, vol 3: Investigative methods in public health. Oxford: Oxford University Press, pp 222–236. The principles of decision analysis are reviewed by McNeil B J, Pauker S G 1984 Decision analysis for public health: principles and illustrations. Annual Reviews of Public Health 5: 135.

3. Stages of an investigation

The stages of an investigation may be listed in a logical sequence, in which each phase is dependent on the preceding phase.

1. Preliminary steps
   a. Clarifying the purpose
   b. Formulating the topic
2. Planning
3. Preparing for data collection
4. Collecting the data
5. Processing the data
6. Interpreting the results
7. Writing a report

After the investigator has clarified the purpose of the study and formulated its topic in general terms (see Ch. 1), he can prepare a detailed plan (Chs. 4–22). He can then prepare to collect data by testing the methods and making whatever practical arrangements are needed (Ch. 23). The data are then collected (Ch. 24) and processed (Ch. 25.). The researcher can then sit down to make sense of his findings and decide on their theoretical and practical implications (Chs 26–28). Finally he prepares a report to communicate the findings to others (Ch. 29).

In practice, this scheme is seldom followed rigidly, even by the most obsessional of researchers. There are two main reasons for this. First, it may be convenient for certain stages to overlap. For example, some of the preparations for the collection of data may be made before the study plan is complete, or it may be possible to collect and even analyse some types of information before other aspects have been fully planned. Secondly, and more important, the various phases may be influenced not only by the preceding phases, but also by subsequent ones. As one example, unforeseen snags may appear when

the methods are tested, or even after data collection has commenced, sending the investigator 'back to the drawing board'. As another example, in the above scheme the interpretation of findings follows their processing, which seems logical; but a basic element of the scientific method is that inferences are drawn from facts, and these inferences are then tested by obtaining further facts; this means that usually, except in the simplest of investigations, the researcher interprets the data that have been processed, decides what further analyses are needed, interprets the new facts, and so on; processing and interpretation have a two-way influence on each other, and usually proceed hand in hand.

REVIEWING THE LITERATURE

'Reviewing the literature' does not appear in the above scheme, not because it is unimportant, but because it is so important throughout the study that it cannot be seen as a separate stage. The published experiences and thoughts of others may not only indicate the presence and nature of the research problem, but may be of great help in all aspects of planning and in the interpretation of the findings. At the outset of his study the investigator should be or should become acquainted with the important relevant literature, and he should continue with directed reading throughout; he should know how to make effective use of library facilities,[1] and should file his references in an organized way, manually[2] or using a personal computer (PC or microcomputer).[3] (This is only one of the many ways in which a PC can streamline the conduct of a study.)[4] It is of limited use to wait until a report has to be written, and then read and cite (or merely cite) a long list of publications to impress the reader with one's erudition—a procedure that may defeat its own ends, since it is often quite apparent that the papers and books listed in the extensive bibliography have had no impact on the investigation.

Papers should be read with a healthy scepticism.[5] If the title and abstract suggest that the paper may be of interest, you should appraise the methods used in the study [which requires the kind of familiarity with research methods and their pitfalls that this book attempts to impart (advert)], assess the accuracy of the findings, judge whether the inferences are valid, and decide whether the study has relevance to your own needs and interests. Do not expect any study to be completely convincing, or reject a study because it is *not* completely convincing—avoid *'I am an epidemiologist' bias* (repudiation of any study containing any flaw in its design, analysis or interpretation) and other forms of what Owen (1982) has called 'reader bias'.[6]

THE PLANNING PHASE

1. Formulation of study objectives
2. Planning of methods
   a. Study population
      Selection and definition
      Sampling
      Size
   b. Variables
      Selection
      Definition
      Scales of measurement
   c. Methods of collecting data
   d. Methods of recording and processing

Needless to say, the value of any investigation depends on sound planning, which may necessitate a considerable amount of effort. The closer the attention to detail, the better the prospects of a fruitful study. The planning phase may take more of the investigator's time, or even of the total duration of the investigation, than any other phase of the study.

A dilemma frequently faced by investigators seeking research funds is that the success of the application may depend on the quality of the study plan, so that a considerable investment of time is required for planning, without any assurance that the study will actually be performed.

The first step in planning is to formulate the objectives of the investigation. The investigator already knows *why* he is undertaking the study, and has formulated the topic in general terms (see Ch. 1). He must now decide what his detailed study objectives are, i.e. precisely what knowledge he wishes the study to yield. (Note that the term 'objective' is sometimes used to indicate what we have called the 'purpose' of the study on page 2; we are specifically excluding this connotation.) His decision on what he wishes to learn from the study determines the further planning of the investigation, and the methods of the study can be judged by their appropriateness to these study objectives. The formulation of objectives will be discussed in Chapters 4 and 5.

The second step is to plan the methods. Consideration must be given to:

1. *The study population* (see Chs 6–8): Whom is it proposed to study? Will a sample or samples be used? How will sampling be done? What will be the sample size?
2. *The variables to be studied* (Chs 9–13). What characteristics will be measured? How will the variables be defined? What scales of measurement will be used?
3. *Methods of data collection* (Chs 14–20): Will data be collected by direct observation, from documentary sources, or by interviews or self-administered questionnaires? What are the detailed procedures and questions to be used?
4. *Methods of recording and processing* (Chs 21–22): How will the data be recorded? What data-processing techniques will be used? What is the analysis plan?

Chapters 3–22 have relevance to the planning of both non-experimental and experimental studies. Specific aspects of the planning of trials will be discussed in Chapters 30 and 31.

The various elements of planning are interdependent, and should be regarded as different aspects on which attention must be focused, rather than as discrete entities. A decision on the characteristics to be measured, for example, may depend not only on the study objectives, but on the nature of the study population and on the practicability of various methods of data collection; or a detailed consideration of the methods required to satisfy the study objectives may lead to a reformulation of the objectives.

Some investigators see their main planning task as the design of a 'form'—a schedule on which findings will be recorded, or a questionnaire—and make this their first (and sometimes only) planning activity. This approach cannot be recommended.

It is usually helpful to commit the study plan to writing, whether briefly or in detail, since human memory is fallible. The study objectives and an outline of the methods will in any case require to be described in the report of the study. If an application is made for research funds the objectives and methods may have to be stated in a detailed study protocol.

It may not be frivolous to suggest that, as the plan of the study begins to take form and a clearer picture emerges of the effort and cost involved, the investigator should ask himself whether the investigation is still seen as worthwhile—is its performance warranted by

the importance of the problem which was its starting-point? It is better to scrap a study at the outset than to decide afterwards that it was not worth doing.

MUST A STUDY BE PERFECT?

In the pages which follow, a great deal of attention will be paid to various aspects of sound planning—the careful choice of definitions, the use of standardized and accurate methods of collecting information, etc. The better the techniques of investigation, the greater are the prospects of producing useful findings, and the more certain the researcher can be that his findings will be reproducible. However, there are very few perfect studies. Almost invariably, practical difficulties, oversights and accidents produce methodological imperfections. What is important is that the investigator should be aware of these imperfections, examine their impact, and take them into account in interpreting his findings; if this is done, the study will still be a sound and possibly a useful one. While striving for perfection, the investigator should from the outset realize that his reach will almost certainly be shorter than his grasp, and be prepared to make compromises with reality. In fact, an undue insistence on impeccable techniques at all costs may well ruin a study. There is much truth in the statement that 'in science as in love a concentration on technique is quite likely to lead to impotence'.[7]

NOTES AND REFERENCES

1. Pertinent publications may be sought in cumulative indexes, such as Index Medicus (its Bibliography of Medical Reviews is especially helpful), or journals of abstracts (e.g. Excerpta Medica), or by a computerized (e.g. MEDLINE) search. If a key source is known, use the Science Citation Index to identify recent papers that cite it; with luck, some of these will have extensive relevant bibliographies. A convenient way of keeping up-to-date is by scanning the weekly issues of Current Contents, which reproduce the contents pages of hundreds of journals. For a simple guide to the use of Index Medicus and MEDLINE, see Sackett D L, Haynes R B, Tugwell P 1985 Clinical epidemiology: a basic science for clinical medicine. See Little, Brown Boston, pp 271–283. Haynes R B, McKibbon K A, Fitzgerald D, Guyatt G H, Walker C J, Sackett DL 1986 How to keep up with the medical literature. Annals of Internal Medicine 105: 149, 309, 574, 636, 810 & 978.

   Hewitt & Chalmers 1985 explain how to use MEDLINE in the following articles: Hewitt P, Chalmers TC 1985 Using MEDLINE to peruse the literature. Controlled Clinical Trials 6: 75. Perusing the literature: methods of accessing MEDLINE and related databases. Clinical Trials 6: 168. Using MEDLINE for perusing the literature: software and search interface of interest to the medical professional. Controlled Clinical Trials 6: 198. Use of a personal computer to make access to MEDLINE is described by Haynes et al 1986; see above p 810 and Hewitt & Chalmers 1985; see above p 198.

2. A card index of references is a great help (one reference per card). Full bibliographical details should be included (names of all authors, first and last page numbers, etc.) so that the article will not have to be hunted again when a bibliography is prepared for the report. If photocopies, reprints or tear-out copies of articles are collected they should be filed and indexed in an orderly way. The planning of a filing system is described in detail by Haynes et al (1986; see note 1), p 978.
3. As a rule, only public-domain and user-supported software for IBM PC and compatible computers will be mentioned by name in this book (commercial programs can afford their own advertising). These programs may be freely copied, and are available free or at low cost from computer clubs, bulletin board systems, software libraries, and other sources (consult a computer magazine). In some cases the full version is available only after payment of a registration fee. Remarks on named programs may well be out-of-date by the time you read them.

   To make a file of references, use any database program that has good sorting and searching capabilities (usually based on author's name, words in the title, or key words) and a large field for your notes. *PC-File Plus* and *PC-File db* are examples. Instant Recall (a speedy pop-up program) indexes every single word in free-format entries, and text is easily transferred to or from ASCII files; the database of the free-distribution version cannot exceed 80 Kbytes (a fuller version is sold commercially under another name). *Papers (Scientific Paper Database)* can store long notes as well as bibliographic details; it has good search facilities; text can be imported from ASCII files. *MedLit* is designed as a medical literature data-base; entries can be typed in, or imported from MEDLINE; but there is no place for notes, and the free version can take only 150 references. *RefList* maintains a master list of references (without notes) for a single purpose, viz. helping writers to prepare bibliographies and text citations; it can modify the format of references. Commercial programs are listed by Haynes et al (1986; see note 1), p 978; also, see Hewitt & Chalmers (1985; see note 1), p 198.
4. The uses of microcomputers in research are reviewed by Madron T W, Tate C N, Brookshire R G 1985 (Using microcomputers in research. Sage Publications, Newbury Park, California (and by Schrodt P A 1987) Microcomputer methods for social scientists, 2nd edn. Sage Publications, Newbury Park, California). Schrodt provides down-to-earth advice for PC tyros. (Examples: 'Computers and liquids . . . do not mix . . . Even tears have been known to short-circuit a keyboard . . . There is one and only one source of reliable information about software: word of mouth . . . The secret to getting the full potential out of a program has been enshrined in the acronym RYFM, which, for public consumption, may be translated as 'Read your factfilled manual'.)

   There is increasing experience with the use of microcomputers in surveys in developing countries; this may require special computer–literacy courses and the use of equipment that contends with electric power problems (voltage regulators, battery-powered computers). The main problem is the lack of a local hardware and software support system. See Frerichs R R, Miller R A 1985 Introduction of a microcomputer for health research in a developing country—the Bangladesh experience. Public Health Reports 100: 638; Gould J B, Frerichs R R 1986 Training faculty in Bangladesh to use a microcomputer for public health: followup report. Public Health Reports 101: 616; Frerichs R R, Tar K T 1989 Computer-assisted rapid surveys in developing countries. Public Health Reports 104: 14.

   However helpful a computer may be, it cannot work magic. A description of one computer program claims that it 'is designed to allow anyone, no matter how knowledgeable or ignorant of statistical and survey methods, to conduct a useful and correctly designed survey. It has everything you need' (PC Magazine 1989, 8: 254). If only that were true!
5. For guides to the critical reading of clinical journals see Sackett et al (1985; see note 1), pp 285–321 or a series of papers in Canadian Medical Association Journal 1981 124: 555, 703, 869, 985, 1156; 1984 130: 377. If you like using checklists, they are provided by Polgar S, Thomas S A 1988 Introduction to research in the health sciences. Churchill Livingstone, Melbourne, p 279 and (for case-control studies) by Lichtenstein M J, Mulrow C D, Elwood P C 1987. Guidelines for reading case-control studies. Journal of Chronic Diseases 40: 893. Checklists should be used with circumspection, to avoid confusing 'the *possibility* that a bias might exist with the actual occurrence of the bias in the study at hand': Vandenbroucke J P 1987 A checklist for observational research. Journal of Chronic Diseases 40: 1067.
6. Other forms of 'reader bias' listed by Owen . . . (1982) include *rivalry bias* (pooh-poohing a study published by a rival), *personal habit bias* (over-rating or under-rating a study to justify the reader's habits, e.g. a jogger favouring a study showing the health benefits of running), *prestigious journal bias* (over-rating results published in a prestigious journal), *esteemed professor bias* ['more readily accepting the conclusion of the reader's professor, who spoke only the truth (and looked like Moses)'], *pro-technology bias* (over-rating or under-rating a study owing to the reader's enchantment with medical technology) and *anti-technology bias*; Owen R 1982 Reader bias. Journal of the American Medical Association 247: 2533.
7. Berger P L 1969 Invitation to sociology: a humanistic perspective. Penguin Books, Harmondsworth, p 24.

4. Formulating the objectives

Having decided *what* to study, and knowing *why* he wants to study it, the investigator can now formulate his study objectives. That is, he can state what knowledge he wants the study to yield—*what questions* is he setting out to answer? Serendipity apart—and accidental discoveries are less uncommon than some researchers may care to admit[1]—he will not learn anything he has not set out to learn.

The explicit formulation of study objectives is an essential step in the planning of a study. It may be an exaggeration to say that 'a question well-stated is a question half-answered',[2] but a question that is poorly stated or unstated is unlikely to be answered at all. The specification of objectives determines the whole subsequent planning of the study. 'If you don't know where you're going, it is difficult to select a suitable means for getting there.'[3] In fact, 'if you're not sure where you're going, you're liable to end up someplace else'.[3]

The objectives of a descriptive survey of a specific group or population—a survey carried out with a diagnostic purpose—are usually easy to formulate. The investigator needs only to state the characteristics he wants to measure. These may be diseases, deaths, or other 'disagreeable Ds' (disabilities, discomforts, dissatisfactions, deviations from statistical or social norms); they may be positive aspects of health (e.g. physical fitness, life expectancy); or they may be somatic or psychological characteristics (body weight, biological markers,[4] behaviour patterns, etc.) that are not necessarily negative or positive, but are seen as elements of health status or expressions of health. There are numerous health indicators and health indices, serving different ends and appropriate in different circumstances.[5] The investigator may also want to study other characteristics of the group (demographic, biological, behavioural, social or cultural), or environmental features. He may also be interested in the health services provided to the population, or in their use.

These objectives are easily stated, e.g. 'to determine the infant

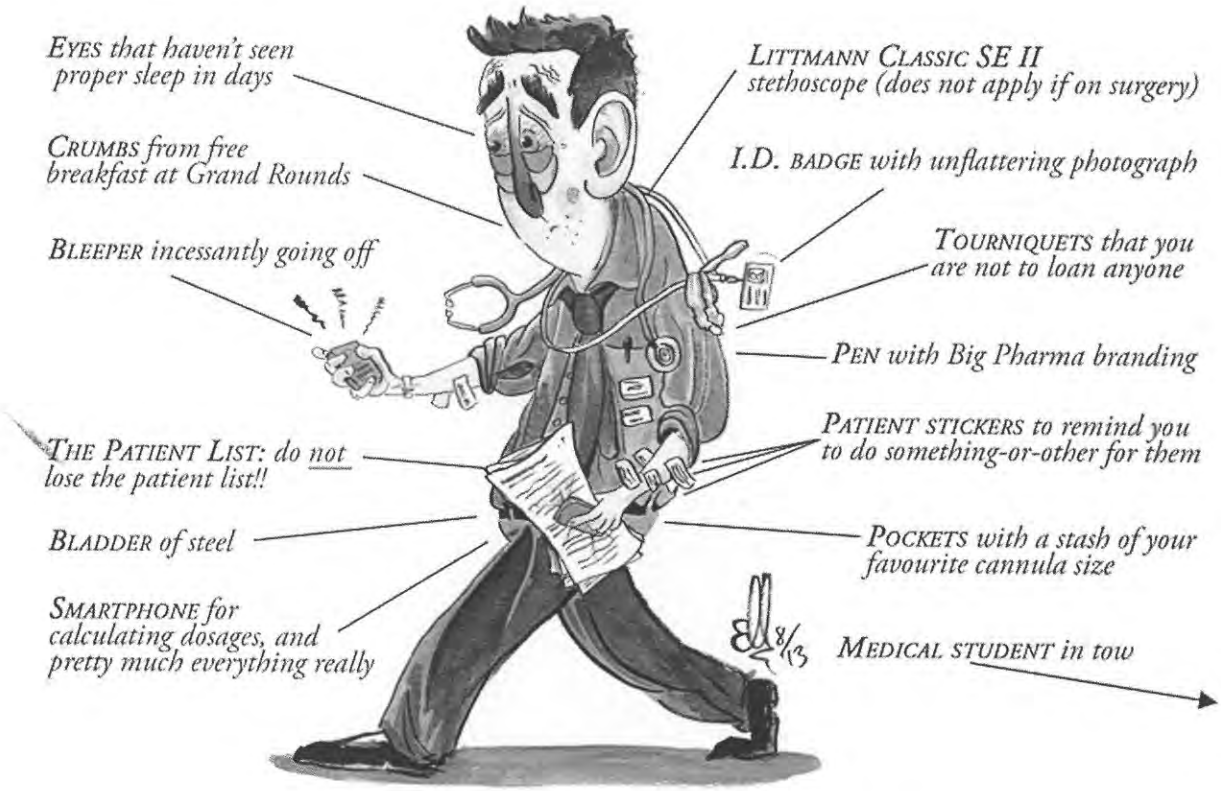
mortality rate in population Y during period Z', 'to measure the incidence rate of rabies', 'the prevalence rate of scabies', 'the case fatality rate of tabes', 'to determine the distribution of serum cholesterol values', etc.

Objectives may be stated in general terms, e.g. 'to measure the prevalence of disability (in population Y at time Z)', or may be phrased more specifically, e.g. in terms of mobility, capacity to work, ability to perform activities of daily living, or other selected functions. The more specifically the objectives are stated, the more helpful they will be in the further planning of the study. A formulation that is too general, e.g. 'to study the health status of . . .' will not be helpful at all. If general objectives are stated, more specific ones should be listed as well. Careful thinking about specific objectives may help to ensure that the study meets its purposes.

Even in a simple descriptive survey there is usually interest in obtaining separate information for different groups—for specific age groups, for the two sexes, for ethnic groups or parts of a city, etc. The objective might be stated as 'to measure X in population Y by age, sex (etc.)'. In a survey of the 'community diagnosis' type, findings may provide pointers to the different health needs of different parts of the population. If alcoholics are concentrated in one neighbourhood, that neighbourhood may need a special programme.

Not uncommonly, a survey centres not on the characteristic (say, disease D) in which interest actually lies, but on something that is known to be associated with this characteristic. The main circumstances in which the study may focus on an associated characteristic or characteristics (C) are as follows:

1. If it is easy to obtain information about C and difficult to obtain information about D, C may be used as a *proxy measure* of D. As an example, an investigator may be interested in the occurrence of prostatic hypertrophy in a community; if rectal examinations to establish the diagnosis are not feasible, he may investigate the prevalence of a specific symptom pattern (frequency, nocturia, hesitancy, weak stream, terminal dribbling) believed to be associated with the disease.[6] It may be possible to estimate the prevalence rate of D from the prevalence rate of C.[7] If C is a poor proxy measure many individuals will be misclassified, and problems of interpretation may arise (see p 159).
2. The presence of C may be of use as a *screening test*—that is, to discriminate between people who are likely and those who are unlikely to have D. Once people who have C (say a high casual blood pressure measurement) have been identified, they can be invited to be examined more fully in order to determine whether D (hypertensive disease) is present. To warrant such use of the association, C must be easier to study than D; C and D must be present at the same time; and certain other conditions (see pp 161–162) must be met. The study objective might be stated as 'to identify people with positive screening tests for D'.
3. If C precedes D in time, it may be of use as a *risk marker*—that is, to distinguish between people who are likely and those who are unlikely to develop D in the future. The presence of C identifies vulnerable individuals or groups (*at risk* or *high risk* groups) who are especially likely to develop the disorder, and who hence have a special need for preventive care. C *points to* the increased risk, it does not necessarily *cause* it. It may be a cause, or it may be a precursor or early manifestation of the disorder, or it may itself be an effect or correlate of the factor that increases the risk. In a study of elderly men, for example, the risk markers for dying within the next 5 years were found to include impaired memory and inability to work.[8] These are unlikely to *cause* mortality—any special care given to these high-risk men would be directed at other factors. On the other hand, a risk marker may itself be a cause of the increased risk—the same study showed that a high diastolic blood pressure was another indicator of mortality risk, and presumably a reason for the high risk. A study might aim to 'determine the prevalence of a (specified) risk marker' or 'to identify people who are at special risk of a (specified) disorder'. *Health hazard appraisal*[9] is a particular instance of the use of risk markers.
4. C may also be of interest because it is a *cause* of D—that is, its presence or degree influences the risk of developing D. If C is amenable to change, and if a change in C will reduce the risk of D, there may be a case for intervention directed at C. In such instances C is possibly best termed a *modifiable risk factor* (the adjective 'modifiable' refers both to the factor and to the risk). The unqualified term '*risk factor*' is generally used, but unfortunately this has more than one meaning; it is also often used to denote *any* cause of a disorder (modifiable or not), and sometimes to denote a risk marker. A causal factor may or may not be of use as a risk marker, and it may or may not be modifiable. The general objective of a study of modifiable risk factors might be formulated as 'to determine the prevalence of' or 'to identify people who have' specified factors.



Anatomy of a JUNIOR DOCTOR

Sociology

AS APPLIED TO

MEDICINE

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1 Society and Changing Patterns of Disease

Ray M. Fitzpatrick

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MODERN MEDICINE AND HEALTH 15

One of the most important recent developments in ideas about health care and illness has been the widespread recognition that social and economic conditions have a major effect on patterns of disease and death rates. A wide range of sources – historical, medical and sociological – have provided the evidence for such influences. This chapter considers how lines of influence from society and the economy can be traced to patterns of disease.

The starting point of this analysis is the dramatic variation to be found in death rates both in the past and at present. For example, the death rate per annum has virtually halved in England and Wales over the last 150 years: in 1851 it was 22.7 per 1000 population and by 1990 it had fallen to 11.9. Another way to express the difference over this period is in terms of the average number of years an individual could expect to live at birth, i.e. life expectancy. In 1840 a man and woman could, on average, expect to live to 40 and 43 years, respectively, whereas by 1990 life expectancy had risen to 72 and 77 years, respectively. Such differences in overall mortality rates, however, disguise a more complex picture if we look at particular age groups. The higher death rates of the mid-nineteenth century were much more severe in particular age groups, especially in infancy and childhood. Thus, future life expectancy for those who have reached the age of 45 years has improved slightly over the last 100 years, but not nearly as dramatically as has the life expectancy of a child at birth.

The higher death rates and lower life expectancies are not of course simply an historical phenomenon. At present, many third world countries have crude death rates much higher than those of England; for example, Ethiopia 23.6 per 1000 and Sierra Leone 23.4 per 1000. Third

world countries with higher death rates resemble nineteenth-century England and Wales in that infant and child mortality are one of the main reasons for lower life expectancy.

Variation in Disease Patterns in Human Society

The diseases encountered by humans have not remained the same over time. The history of humans might be viewed as a progressive victory over disease, but this is an over-simplification. Although some diseases are less important than in the past, others have become more important. Complex social and biological processes have altered the balance between humans and disease. A number of authorities (Powles 1973; McKeown 1979) now agree on three characteristic disease patterns in historical sequence.

Preagricultural disease patterns

Before about 10 000 BC, indeed for most of the evolution of humans as a distinct species, humans lived as hunter–gatherers, that is without any form of settled agriculture for subsistence. Although conclusions based on such early evidence are somewhat speculative, anthropologists and epidemiologists have argued that the infectious diseases which were later to become major causes of illness and death were relatively uncommon at this stage of social evolution. Furthermore, diseases which are sometimes described as diseases of civilization, such as heart disease and cancer, were less common than at the present time (Powles 1973). It is likely that mortality in adults arose from environmental and safety hazards, for example hunting accidents and exposure.

Diseases in agricultural society

Knowledge of the diseases which plagued agricultural societies is more certain. These were predominantly the infectious diseases, which for purposes of discussion can be divided into the following:

1. air-borne diseases, such as tuberculosis;
2. water-borne diseases, such as cholera;
3. food-borne diseases, such as dysentry;
4. vector-borne (i.e. carried by rats or mosquitoes) diseases, such as plague and malaria.

In England and Wales, and in Europe generally, the plague was a particularly important cause of death and at its most virulent, in the Black Death of 1348, it killed one-quarter of the English population. It last occurred on any large scale in England and Wales in 1665 and disappeared from Europe shortly after. The plague was spread by the fleas carried by black rats. Its disappearance was due to the replacement of the black rat by the brown rat which was much less prone to infest human habitations.

Malaria was never as great a health problem in England and Wales as it has been in the tropics where conditions are ideal for the natural life cycle of both vector and parasite. By the mid-nineteenth century, when reliable vital statistics were available in England and Wales and the country's economy was changing from agricultural to industrial, the major causes of death were tuberculosis, bronchitis, pneumonia, influenza and cholera.

The modern industrial era of disease

By the mid-twentieth century, infectious diseases had become relatively unimportant causes of death in England and Wales and in the western world in general, although some infectious diseases such as influenza remained common causes of death, particularly in the elderly. The infectious diseases have been replaced as major causes of death by the so-called degenerative diseases, cancer and cardiovascular disease.

Because of these changes in patterns of death the major medical problems of today are such chronic illnesses as atherosclerosis, diabetes and osteoarthritis. These are all problems involving multiple risk factors, rather than a single cause. Their onset is quite early in life; they tend to be progressive; and they appear in all modern societies. Fries (1983) argues that there appear to be quite definite limits to the extension of the human lifespan, so that life expectancy at age 100 years has barely changed in the last 80 years. However, if one looks at such indices as age at first heart attack or age-specific lung cancer rates in the USA, there have been quite definite improvements in recent years. Fries concludes that health policy should make the compression of morbidity a major objective. Combining medical and social approaches to reducing the risk factors for chronic illnesses such as atherosclerosis would result in a life in which serious illness and decline in functioning were increasingly confined to later ages and the years of vigorous life extended.

This dramatic increase in importance of the chronic degenerative diseases is characteristic of almost all countries that have undergone industrialization, although the exceptions and the variations in rates from one country to another provide important and intriguing problems for the medical and social scientist. Japan, for example, has a much lower incidence of heart disease than comparable industrialized societies. On the other hand, the level of stomach cancer is considerably higher in Japan compared with, for example, the USA.

Explaining changes in disease prevalence

It would be all too easy to regard changes in disease patterns as the inevitable consequences of medical and technical progress without further explanation. Close examination of the major influences on disease patterns, however, uncovers a complex picture which is increasingly recognized as important for the understanding of disease in the contemporary world. The study of how disease patterns have changed indicates the pervasive influence of social and economic factors on disease prevalence.

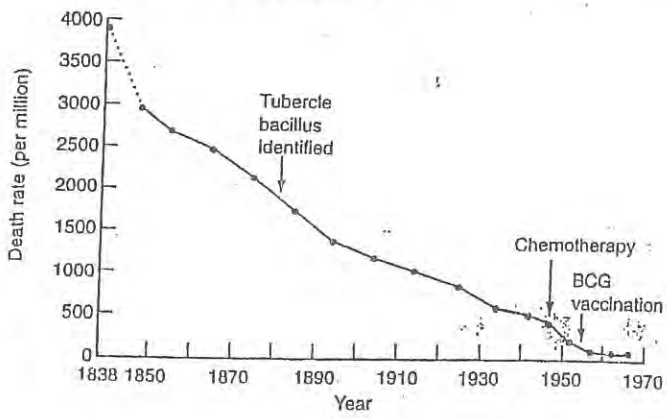
Three main factors seem important in the changes in disease patterns that followed the transition from nomadic hunting and gathering to agricultural life. First, the development of cereals such as wheat allowed agricultural societies to feed more mouths and hence support higher population densities. Evidence from epidemiological studies, however, shows that many infectious organisms thrive when human populations grow above certain densities. Second, agricultural work necessitated permanent settlement, whereas hunter–gatherers periodically moved settlement in search of fresh food sources. However, in the absence of sanitation and awareness of its importance, permanent settlement often led to the contamination of water supplies by waste products, which increased the risks of infection from a number of organisms. Third, the

development of cereals as the major source of food, whilst supporting greater numbers of people, paradoxically narrowed the range and quality of diet, a factor which crucially reduced resistance to infection.

More careful examination is needed to explain the remarkable changes in death rates and the decline in significance of mortality from infectious disease that occurred with the transition from agricultural to industrial economies. The nineteenth and twentieth centuries' victory over death and diseases still represents the most dramatic improvement in health in the history of human kind. Death rates for the various infectious diseases did not decline simultaneously. Tuberculosis, the most common cause of death in the nineteenth century, began to decline in the first half of that century, as indicated in Fig. 1.1.

There are a limited number of possible explanations for such a marked decline in mortality from an infectious organism. Box 1.1 shows the competing explanations that have been offered, not only for the decline of tuberculosis but for the wide range of infectious diseases for which mortality rates dramatically declined in the course of the nineteenth century in Britain and other parts of western Europe. It is possible that a change occurred in the virulence of the organism itself or that the genetic immunity of the population improved. Both these possibilities are generally discounted. There is no theoretical reason why the organisms responsible for tuberculosis and a number of other infectious diseases should fortuitously change in their virulence at approximately the same period. It is very unlikely that genetic immunity could improve in such a short time since the selection processes implied would require dramatic increases in mortality rates across a range of diseases. For these reasons, the first and third explanations in Box 1.1 are normally rejected as unlikely. The most convincing explanation for the decline in mortality from tuberculosis and, later in the century, from air-borne diseases such as pneumonia, is that of greater acquired resistance. An increased resistance to infection resulted from improvement in nutritional intake as agricultural techniques improved and transportation of produce became

Fig. 1.1 Pulmonary tuberculosis: annual death rates for England and Wales, 1838–1970. (Reproduced with permission from McKeown, 1979.)



BOX 1.1

Possible Explanations for the Decline of Mortality from Infectious Disease in Britain in the Nineteenth Century

- Decline in virulence of organisms: organisms responsible for diseases, e.g. tuberculosis, bronchitis, became less lethal due to changes in biological properties.
- Reduction in exposure of humans to infectious organisms: for example, through changes in domestic housing and urban planning or through reduced contamination of food and water supplies.
- Genetically induced increase in resistance of humans to infection: human genes associated with resistance to infection may be favoured by Darwinian selection processes and thus individual and population resistance increased over time.
- Acquired resistance of humans to infection: general fitness brought about by improved nutrition resulted in greater resistance in terms of probability of (a) being infected and/or (b) recovering from infection.
- Specific medical interventions: rates of recovery from infectious diseases were improved by developments in medical treatment and therefore mortality rates were reduced.

faster and more efficient. Much of the nineteenth century also saw unprecedented increases in real wages and standard of living in Britain. It is also possible to argue for the significance of nutrition with contemporary evidence. In many third world countries today, diseases such as measles or tuberculosis have a much higher fatality, especially among the very young in populations whose resistance is reduced by malnutrition. McKeown cites the conclusion of the World Health Organization report that one-half to three-quarters of all statistically recorded deaths of infants and young children are attributed to a combination of malnutrition and infection (McKeown 1979).

However, the role of the second possible explanation in Box 1.1 – reduced exposure to infectious organisms – is also of importance. The incidence of illness and mortality from water-borne diseases such as cholera declined somewhat later in the nineteenth century, largely as the result of concerted efforts by the public health movement to prevent the contamination of drinking water supplies by sewage; gastroenteric infectious diseases came under control by the beginning of the twentieth century, resulting in a dramatic impact on infant mortality. The sterilization and more hygienic transportation of milk in particular, and improved food hygiene in general, constitute another form of environmental change that produced the decline in infectious disease mortality.

Thus, most of the decline in death rates achieved in this country and in the western world generally by the Second World War can be attributed to environmental factors such as improvements in food and hygiene, which were the products of economic development. Other social changes, such as the decline in the birth rate, reduced the demand for food and housing

resources. Improved housing and better personal hygiene also played their role in reducing mortality rates.

Historians still dispute the precise nature of the changes that brought about the decline in mortality rates just described. The nature of that debate can, with some simplification, be termed one between the 'public health' form of explanation and the 'invisible hand' version of events (Box 1.2). The debate is of more than purely historical interest because it mirrors and has implications for current debates. Even now, some would argue that improvements in the economy and wealth are the most effective ways of producing improvements in the health of modern populations ('the invisible hand' (Guha, 1994)). Others would argue that more direct and political intervention is required by a modern public health movement to address the ills described later in this chapter (Szreter, 1988). Box 1.2 shows how difficult it is to disentangle claims even with historical hindsight!

BOX 1.2

THE DEBATE BETWEEN 'PUBLIC HEALTH' AND 'THE INVISIBLE HAND' TO EXPLAIN IMPROVED LIFE EXPECTANCY IN NINETEENTH CENTURY BRITAIN

The 'public health' explanation emphasizes deliberate government interventions

- The public health movement improved water supplies, housing standards, regulation of food sold to public
- Increased income of working classes sometimes coincided with deteriorating death rates because of migration into more unhygienic industrial towns

The 'invisible hand' explanation emphasizes benefits of rising incomes

- Some areas of London enjoyed improved death rates in the nineteenth century before reforms to water supplies
- Studies of claims to insurance societies show that while working class sickness rates due to infectious disease were stable, deaths from the same causes declined
- In some nineteenth century towns such as Mansfield, deaths from infectious disease remained high despite excellent water supplies
- The greatest benefit of improved diet is upon capacity of infants and children to survive infectious disease

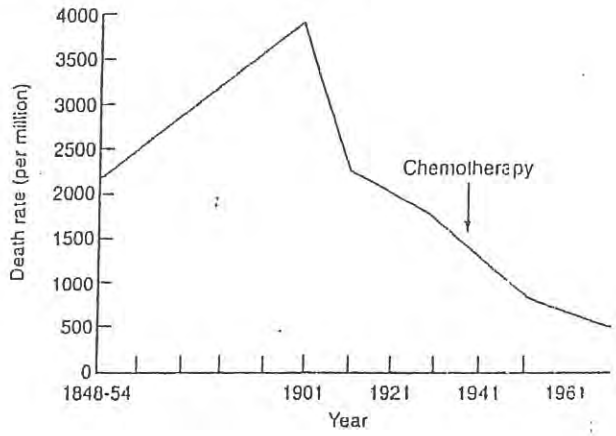
THE HISTORICAL ROLE OF MEDICINE

To this point nothing has been said about the role that medical intervention (the last possible explanation listed in Box 1.1) has played in the relationship between man and disease. At first glance, this might seem an important omission, given that medical knowledge was accumulating throughout the period and that hospitals had grown in number since the latter part of the eighteenth century. The evidence that McKeown and others have gathered, however, suggests that very little of the decline in mortality rates can be attributed to improvements in medical care. They list a range of evidence against the role of specific medical interventions having a substantial effect on mortality.

- Hospitals and surgical procedures were actually harmful. When Florence Nightingale began to reform the hygienic conditions in hospitals, it was widely thought that hospitals constituted a risk to health; in other words, one stood a high risk of cross-infection, contracting a disease from other patients, since wards were unsegregated as well as unhygienic. Similarly, in spite of the advances in surgery made possible by the development of anaesthetics, there is little evidence that surgical procedures made any impact on life expectancy in the nineteenth century (McKeown and Brown 1969).
- Drugs were largely ineffective. Before the twentieth century a large armoury of medicines appears to have been available to the Victorian doctor. However, only a few, such as digitalis, mercury and cinchona, used in the treatment of heart disease, syphilis and malaria, respectively, would be recognized by modern standards as having specific efficacy and, in any case, dosages were unlikely to have been appropriate.

The first drugs which can be shown to have influenced mortality rates did not appear until the end of the 1930s. The antibiotics used in the treatment of a wide range of bacterial infections were developed in the 1930s and 1940s. Prophylactic immunization against such diseases as whooping cough and polio date from the 1950s. In the case of these medical breakthroughs, however, it is easy to overstate the contribution that they made to mortality rates. The decline in mortality for most infectious diseases took place before the introduction of antibiotics. For tuberculosis the period of decline can be seen in Fig. 1.1, and the mortality rates for bronchitis, pneumonia and influenza are shown in Fig. 1.2. Moreover, it is difficult to distinguish between

Fig. 1.2 Bronchitis, pneumonia and influenza: death rates for England and Wales, 1848–1971. (Reproduced with permission from McKeown, 1979.)



the improvements in disease mortality that can be attributed to the introduction of treatment or immunization and those due to the continuing influence of improving social and economic conditions. Most likely, the immunization programmes for diphtheria and polio brought about the greatest improvement which can be attributed to specific medical intervention.

Disease Rates and Social Factors in Modern Society

The association between diseases and social and economic circumstances is not a purely historical phenomenon. In many parts of the third world life expectancy at birth is much lower than in Europe or North America. Many aspects of the environment in the third world provide much more favourable conditions for the spread of infectious diseases than those that prevailed in historical Europe. For example, tropical ecology is particularly favourable for such vectors of disease as the mosquito (malaria) and tsetse fly (sleeping sickness). Nevertheless it is the extremely low standard of living above all else that produces high mortality rates in countries such as Bangladesh and Ethiopia.

In countries like Britain, the social and environmental factors that are responsible for many kinds of commonly occurring disease are somewhat different and may require different explanation. The association between standard of living and the risk of disease, however, is still apparent in the social-class differences in illness and mortality rates discussed in Chapter 8. It is evident that environmental factors, whether in the home or at work, continue to play an important role in influencing the risks of illness and mortality.

The report of the Research Working Group on Inequalities in Health (DHSS 1981) makes clear in many of its recommendations which aspects of the social and economic environment it considers responsible for inequalities in health in Britain. Its proposed strategy largely targets poverty and low income.

- Benefits such as the maternity grant and child benefits need to be increased in order to reduce child poverty.
- Major programmes are needed in housing improvement, the prevention of accidents to children and the provision of school meals.
- More action is needed to prevent accidents in the work place, largely in manual occupations.

These recommendations are a clear reminder that, for large sections of society, health is harmed by material deprivation in terms of income, diet and housing, rather than because of the 'diseases of affluence'.

Although environmental conditions associated with poverty increase the risk of disease, many kinds of disease are now associated with behaviour which may have little or nothing to do with poverty. Increasingly, the mass media are focusing attention on the role that over-eating or inappropriate diet, smoking and excessive alcohol consumption have in a wide variety of disorders such as heart disease, diabetes, lung cancer and cirrhosis of the liver.

The association between smoking and lung cancer has been established beyond all reasonable doubt. It is important to recognize, however, that contemporary health risks associated with [illegible] a function of current social conditions as were the infectious health

grasp, since it is all too easy to view behaviour such as smoking simply as reflecting an individual's decisions and preferences. To focus on an individual smoker would not only lead to erroneous and oversimplified explanations of the causes of his or her behaviour, but more importantly it might lead to misguided or naive attempts to change that behaviour (Box 1.3).

The example of smoking illustrates that disease is as much a reflection of the economy today as it has been in the past. Diet is another example. It has been estimated (Lock and Smith 1976) that 56% of women and 52% of men in Britain over the age of 40 years are at least 15% overweight. The mortality risks of men who are 10% overweight are one-fifth higher than average, especially in mortality associated with diabetes and vascular disease. Clearly, over-eating may be a major health risk. Burkitt (1973) and others have argued that inappropriate diet is also a problem. He argues that diverticular disease, cancer of the bowel, diabetes and indeed various venous diseases such as varicose veins and deep vein thrombosis may all be linked to lack of fibre. Populations which have diets with high fibre content seem relatively free of many such diseases. In Britain the daily fibre intake from bread has been reduced to about one-tenth of its level in 1850, whereas we have almost doubled our consumption of sugar and other refined carbohydrates. Again the statistics of change do not reveal the causal links. Changes in diet have reflected

Box 1.3

Smoking: A Product of the Economy as Much as of Individual Behaviour?

Who smokes is socially patterned

- 17% of men and 15% of women in social class I are smokers (see Chapter 8 for the definition of the five social classes).
- 49% of men and 36% of women in social class V are smokers.
- Attitudes and behaviour are influenced by:
  Advertising and marketing strategies
  Governmental health warnings
  Taxation
- Effective health policies require evidence of social factors, e.g. there is no point in increasing spending on health education to alter the behaviour of groups who do not respond to such influences.

Economic significance of cigarettes

- An analysis of smoking should include political, economic and health issues.
- An increase in taxation would make cigarettes cost-prohibitive to some, but this would result in a decline in revenue.
- A reduction in smoking would lead to a decrease in National Health Service costs but an increase in pensions as greater numbers would live to old age.
- A reduction in the tobacco industry would reduce the amount of sickness absence but lead to unemployment in areas dependent on the industry.

changes in the food-producing industries which are now concentrated in a small number of multinational companies more concerned with producing standardized and well-accepted, easily transported commodities: nutritional values have taken second place to the expansion of profits.

Another essentially modern form of health hazard may be identified in the 6000 deaths and 80 000 serious injuries that occur annually as a result of road traffic accidents. Doll (1983) makes the point that the rate per million of deaths on the roads is actually lower now than it was in the 1930s and is in this sense a testament to the beneficial effects of legislation with regard to prevention. Nevertheless, some 2000 hospital beds are occupied each day by the victims of road traffic accidents (Butler and Vaile 1984) which represents a considerable demand on health-care resources. Risks of accidents are 18 times higher to motorcyclists than to car drivers, and much more still could be achieved to prevent accidents to this group by, for example, legislation on training and testing riding ability.

It may seem that an analysis of the relationship of social and economic factors to health is unhelpful because it points to features of our economic system that are central, firmly established and difficult to change. If this is the case, then another parallel is suggested with the [illegible]enth-century problems of environmental disease. The changes in sanitation, urban planning and building that were required to transform the pattern of infectious diseases in Victorian times were similarly regarded as unrealistic and resisted for long periods by politicians and business interests; but the reforms were slowly adopted and growing awareness of the relationship between commercially promoted behaviours such as smoking and unhealthy eating in our own time should help to speed the process of securing reforms.

A multidisciplinary committee has produced a major report to assess the effectiveness of existing public health policies and to stimulate new national strategies (Smith and Jacobson 1988). Six areas of current life-styles that influence health were identified, for which research evidence of harmful effects is strong and support for the feasibility of action is clear cut:

- tobacco
- diet
- physical activity
- alcohol
- sexuality
- road safety.

Similarly, five areas of preventive services were identified where evidence is very strong that public health interventions could now produce dramatic improvements:

- maternity services
- dental health
- immunization
- early cancer detection (breast and cervix)
- high-blood-pressure detection.

The approach in each of these 11 priority areas is to identify precise quantitative targets and make specific recommendations to public bodies and institutions. Thus one of a number of specific

nutritional targets is to increase the total dietary fibre intake from 20 g per person per day to 30 g. The list of agencies to whom nutritional targets and specific actions are recommended includes the food industry, local authorities, health authorities and government. Their view is that agencies need specific targets to stimulate action and to provide a ready means of monitoring results.

The Economy and Health Policy in Modern Society

Some of the most recent research on the relationship between the economy and health suggests that, even in modern societies, economic factors play the predominant role in determining patterns of illness, and that the role of health services is negligible by comparison. Four different views of how the economy generally, and patterns of employment and income in particular, may affect health are evaluated here (Box 1.4).

BOX 1.4

Alternative Models of the Economy and Health

- Unemployment is major cause of ill-health
- Rapid economic growth is a major cause of ill-health
- Particular forms of employment are causes of ill-health
  'job-strain' model
  'effort–reward imbalance' model
- Income distribution is a major cause of ill-health

Unemployment and health

Brenner (1977) has argued that most of the variation in annual overall mortality rates for the USA can be statistically explained in terms of changes in the annual level of employment, provided that a time lag of 5 years is allowed for unemployment to have its effect on health. This impact is produced in two ways: first, unemployment reduces family income and, therefore, material standard of living; second, the individual loses a sense of meaning and purpose found at work and experiences increased fears about the future and tension at home. This results in greater vulnerability to ill health. From USA data, Brenner concluded that a 1% increase in unemployment, if sustained for 5 years, was statistically responsible for nearly 37 000 extra deaths. Similar results have been found from analyses of data collected in England and Wales and Sweden (Brenner 1979).

Rapid economic growth and health

This work has been challenged by Eyer (1977), who argues that the influence on health of experience such as unemployment generally occurs within a much shorter time than the 5-year lag that Brenner allows. If this is the case, the association between unemployment and mortality is consid[illegible] redu[illegible] stead, [illegible]rgues [illegible]ath r[illegible]rease [illegible]ime c[illegible]ess b[illegible]

when employment rates are high. The association between employment and mortality he explains in terms of four connected social factors that attend business cycles.

1. Economic booms increase workers' migration, which weakens social networks that normally protect individuals against disease.
2. 'Stress' through overwork in times of business peaks increases ill health.
3. The unhealthy consumption of alcohol and tobacco increases.
4. Conversely, during low periods of the economy, social networks are strong and act to protect individuals.

Forms of employment and health

Increasingly it is argued that it is the nature of work processes that need to be examined for possible health effects. One very influential theory is associated with the work of Karasek and Theorell (1990). According to the 'job-strain' model, individuals who have very demanding jobs but who see themselves as having very little control over their work, experience not only higher levels of stress than others but also elevated cardiovascular disease. A number of studies have been carried out in Sweden and the United States to support this approach. A related model – the effort–reward imbalance model – argues rather similarly that those whose work is demanding and stressful but who perceive themselves as insufficiently rewarded for their efforts are also more prone to distress as well as cardiovascular disease (Siegrist et al. 1990). Rewards are not primarily monetary but prospects of status enhancement or promotion. Both models, when tested on work forces, have been found to demonstrate the highest levels of risk in semi- and unskilled manual workers.

Income distribution and health

One final model of the effects of the economy on health argues that it is the relative degree of inequality in incomes within a country that influences health (Wilkinson 1994). The evidence to support this model comes from international comparisons of countries where it is claimed that countries with the smallest spread and least inequality of incomes from top to bottom (Japan, Sweden) have higher life expectancies than those with large income differentials such as the USA and the UK. The emphasis of the model is, therefore, not on how absolute income influences health but how people attach meaning to disadvantage in ways that actually harm them.

Of the four models outlined, only the role of unemployment has been researched to any great extent. The other three need further investigation. Bunn (1979) examined national statistics for the incidence of ischaemic heart disease in Australia. He found that economic recessions and their associated problems of high unemployment were associated not only with subsequently higher levels of heart disease mortality, but also with increased rates of drug prescribing. The latter he interpreted as a potential indicator of the stress of the recession, which resulted in increased general practice prescribing. One of the most convincing pieces of statistical evidence to support this research is the Office of Population Censuses and Surveys (OPCS) Longitudinal Study (OPCS 1984). This found that men who were unemployed in 1971, and their wives, experienced a 20% higher mortality rate than those men employed in the following 10 years (Moser et al. 1987).

Other studies, instead of looking at correlations in national statistics, have examined at close hand the experiences of unemployed families. Fagin (1981) examined in detail a small sample of families in which the male breadwinner had been without work for at least 16 weeks. In many families the breadwinners developed clinical depression, loss of self-esteem, insomnia and suicidal thoughts, much of which necessitated psychotropic drug treatment by their general practitioners. Physical symptoms included asthmatic attack, backache and skin lesions. The health of younger children in some families also seemed to be affected.

Modern Medicine and Health

The issues raised by these contrasting approaches are far from resolution. All four models at least agree in placing the main responsibility for health and illness on economic policy rather than on the health services. This controversial position is partly shared by more radical writers who are more concerned with analysing directly the contribution of modern medicine to health. Perhaps the best known is Illich (1977), who argues that medicine has played a very small role in improving health and that its contribution has actually been negative, insofar as it has:

1. raised public expectations of 'wonder cures' which in reality are ineffective;
2. extended too far the kinds of problem that are thought to be medical;
3. been responsible for large amounts of iatrogenic (medically induced) illness;
4. decreased the ability of individuals to cope with their own illness by fostering a debilitating dependency on the expert (see Chapter 12).

Illich's own solution is first to break down the monopoly of medicine in health care, so that there is a 'free market' in which anyone can practise healing, and second to reverse the social trend towards dependency by restoring the value of personal responsibility.

This approach, which is attractive to many advocates of 'alternative medicine' and self-help groups, is rejected as mistaken and utopian by writers such as Navarro (1975) because it wrongly blames the medical profession and a 'gullible' public for aspects of ill health which are best understood as products of a capitalist economy. It is this which directly creates much illness, maintains an unequal distribution of illness and encourages a very inappropriate health-care system for treating illness once it has occurred. Hence Navarro advocates radical political changes in society as the only solution to the kinds of problems that have been identified in this chapter.

Other writers such as McKeown and Powles place more emphasis on the need to reform health care rather than concerning themselves with wider issues of social change. First, they argue that, since much disease is environmentally caused, preventive medicine in teaching, research and practice should concentrate on the prevention of disease rather than treatment after it has occurred. Not only has prevention had a significant impact in the past, it appears to be a simple, more humane and sound means of reducing disease for the present.

Second, these analysts also maintain that health-care resources and energy have become too concentrated on high technology and hospital-based acute medicine at the expense of preventive and community resources. In the light of the evidence reviewed above, it seems that there is an unwarranted faith in technological medicine. With the possible exception of antibiotics and

immunization, few improvements in health can be attributed to breakthroughs in laboratory medicine. Cochrane (1972) argues that all too few medical procedures have been submitted to rigorous evaluation of their effectiveness (see Chapter 18).

Third, it is argued that another shift in the emphasis of medicine is needed, that from cure to care. Since medicine can claim few cures to be effective, it must confront the task of caring for the sick with greater zeal and effectiveness. Caring necessitates concern with the quality of life of the ill and reduction in any handicap or disadvantage consequent to disease. However, financial and other resources, reflecting medical values, are at present spent more in efforts in acute medicine than in the psychiatric or geriatric units. Medical education perpetuates such values because it is conducted predominantly in acute hospitals where consultants maintain traditional values in their teaching.

Clearly these arguments are controversial and have not gone unchallenged. Lever (1977) has argued that inferences about current health planning based on historical patterns are hazardous. To prove that environmental factors were the most important determinants of mortality in the past does not necessarily prove that environmental measures will produce such beneficial effects in the present. Given limited funds for health services, a major shift towards environmental and preventive health care would be a major gamble. Whatever the merits of such points, it has to be acknowledged that at present insufficient resources have been committed to such preventive services as health education and occupational medicine, compared with expenditure on hospital technology, to allow any serious examination of their potential role.

It might also be argued that analysts like McKeown are too pessimistic in their interpretation of the impact of medical treatments, which have been shown to have led to markedly improved survival rates for many forms of childhood cancers and Hodgkin's disease and cancer of the testis amongst adult cancers (Doll 1990). Moreover, the debate has tended to focus on death rates, thereby ignoring substantial benefits that may have been derived from medical treatments in improving individuals' quality of life, for example by mitigating symptoms of pain, discomfort or disability (see Chapter 18).

At present much work remains to be done regarding the influence that social and economic factors exert on health. At the same time controversial debates continue unresolved about the priorities in efforts and expenditure that are most appropriate to modern patterns of illness.

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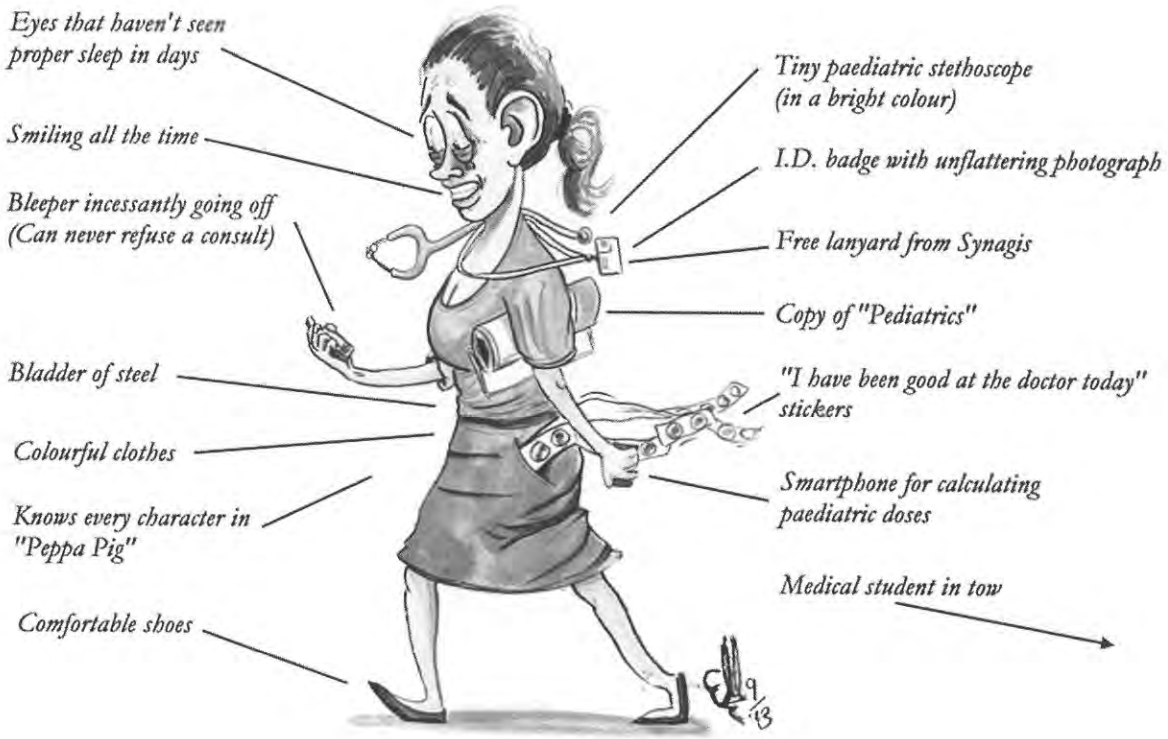
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Anatomy of a Paediatrician

Revised

DECLARATION OF LISBON

ON THE RIGHTS OF PATIENTS[1]

The World Medical Association approved a new, and much expanded version of its 1981 declaration on the rights of the patient at its meeting in

Bali, Indonesia, in September 1995.

Preamble

The relationship between physicians, their patients and broader society has undergone significant changes in recent times. While a physician should always act according to his/her conscience, and always in the best interest of the patient, equal effort must be made to guarantee patient autonomy and justice. The following Declaration represents some of the principal rights of the patient which the medical profession endorses and promotes. Physicians and other persons or bodies involved in the provision of health care have a joint responsibility to recognize and uphold these rights. Whenever legislation, government action or any other administration or institution denies patients these rights, physicians should pursue appropriate means to assure or to restore them.

In the context of biomedical research involving human subjects-including non-therapeutic biomedical research- the subject is entitled to the same rights and consideration as any patient in a normal therapeutic situation.

PRINCIPLES

1. Right to medical care of good quality

a. Every person is entitled without discrimination to appropriate medical care.

b. Every patient has the right to be cared for by a physician whom he / she knows to be free to make clinical and ethical judgments without any outside interference.

c. The patient shall always be treated in accordance with his/her best interests. The treatment applied shall be in accordance with generally approved medical principles.

d. Quality assurance should always be part of health care. Physicians in particular, should accept responsibility for being guardians of the quality of medical services.

e. In circumstances where a choice must be made between potential patients for a particular treatment, which is in limited supply, all such patients are entitled to a

[1] Revised Declaration of Lisbon on the Rights of the Patient. Bull.Med.Eth. January 1996:114:8-10.

fair selection procedure for the treatment. That choice must be based on medical criteria and made without discrimination.

f. The patient has a right continuity of health care. The physician has an obligation to cooperate in the coordination of medically indicated care with other health care providers treating the patient. The physician may not discontinue treatment of a patient as long as further treatment is medically indicated, without giving the patient reasonable assistance and sufficient opportunity to make alternative arrangements for care.

2. **Right to freedom of choice**

a. The patient has the right to choose freely and change his/her physician and hospital or health service institution, regardless of whether they are based in the private or public sector.

b. The patient has the right to ask for the opinion of another physician at any stage.

3. **Right to self-determination**

a. The patient has the right to self-determination, to make free decisions regarding himself /herself. The physician will inform the patient of the consequences of his/her decisions.

b. A mentally competent adult patient has the right to give or withhold consent to any diagnostic procedure or therapy. The patient has the right to information necessary to make his/her decisions. The patient should understand clearly what is the purpose of any test or treatment, what the

c. Results would imply, and what would be the implications of withholding consent.

d. The patient has the right to refuse to participate in research or the teaching of medicine.

4. **The unconscious patient**

a. If the patient is unconscious or otherwise unable express his/her will, informed consent must be obtained whenever possible, from a legally entitled representative where legally relevant.

b. If a legally entitled representative is not available, but a medical intervention is urgently needed, consent of the patient may be presumed unless it is obvious and beyond any doubt on the basis of the patient's previous firm expression or conviction that he/she would refuse consent to the intervention in that situation.

c. However, physicians should always try to save the life of a patient unconscious due to a suicide attempt.

5. The legally incompetent patient

a. If a patient is a minor or otherwise legally incompetent the consent of a legally incompetent the consent of a legally entitled representative, where legally relevant, is required. Nevertheless the patient must be involved in the decision making to the fullest extent allowed by his/her capacity.

b. If the legally incompetent patient can make rational decisions, his/her decisions must be respected, and he/she has the right to forbid the disclosure of information to his/her legally entitled representative.

c. If the patient's legally entitled representative, or a person authorized by the patient, forbids treatment which is, in the opinion of the physician, in the patient's best interest, the physician should challenge this decision in the relevant legal or other institution. In case of emergency, the physician will act in the patient's best interest.

6. Procedures against the patient's will

a. Diagnostic procedures or treatment against the patient's will can be carried out only in exceptional cases, if specifically permitted by law and confirming to the principles of medical ethics.

7. Right to information

a. The patient has the right to receive information about himself/herself recorded in any of his/her medical records, and to be fully informed his/her health status including the medical facts about his/her condition. However, confidential information in the patient's records about a third party should not be given to the patient without the consent of that third party.

b. Exceptionally, information may be withheld from the patient when there is good reason to believe that this information would create a serious hazard to his/her life or health.

c. Information must be given in a way appropriate to the local culture and in such a way that the patient can understand.

d. The patient has the right not to be informed on his/her explicit request, unless required for the protection of another person's life.

e. The patient has the right to choose who, if anyone, should be informed on his/her behalf.

8. Right to confidentiality

a. All identifiable information about a patient's health status, medical condition, diagnosis, prognosis and treatment and all other information of a personal kind, must be kept confidential, even after death. Exceptionally, descendants may have a right of access to information that would inform them of their health risks.

b. Confidential information can be disclosed if the patient gives explicit consent or if expressly provided for in the law. Information can be disclosed to other health care providers on a strictly "need to know" basis unless the patient has given explicit consent.

c. All identifiable patient data must be protected. The protection of the data must be appropriate to the manner of its storage. Human substances from which identifiable data can be derived must likewise be protected.

9. Right to health education

Every person has the right to health education that will assist him/her in making informed choices about personal health and about the available health services. The education include information about healthy lifestyles and about methods of prevention and early detection of illnesses. The personal responsibility of everybody for his/her own health should be stressed. Physicians have an obligation to participate actively in educational efforts.

10. Right to dignity

a. The patients dignity and right to privacy shall be respected at all times in medical care and teaching, as shall his/her culture and values.

b. The patient is entitled to relief of his/ her suffering according to the current state of knowledge.

c. The patient is entitled to humane terminal care and to be provided with all available assistance in making dying as dignified and comfortable as possible.

11. Right to religious assistance

The patient has the to receive or to decline spiritual and moral comfort including the help of a minister of his/her chosen religion.

TURKISH MEDICAL ETHICS REGULATION [1]

(TIBBİ DEONTOLOJİ TÜZÜĞÜ) (T.C. Resmi Gazete 19.Febr. 1960 No.10436)

Article 1: Ethical rules and regulations of physicians and dentists are shown in this regulation. Member physicians and dentists of local chapters of the Turkish Medical association are under the jurisdiction of article 7 of No.6023 Act.

SECTION: 1

Article 2: The first duty of a physician and dentist is to care and respect human life, health and personality, no matter what the sex, race, nationality, religion or denomination, moral values, character or personality, social status, educational level political beliefs.

Article 3: The physician should take care of emergency cases no matter what his official duty and specialty in desperate situations.

Article 4: A physician or dentist cannot reveal the confidentiality of a patients unless he is forced by law.

Article 5: A patients is free to choose his physician or de[illegible] although certain health facilities may have their own rules.

Article 6: While he is performing his profession, a physician or dentist must act according to their conscience and opinion. They are free to determine their own method in treatment.

Article 7: Physicians and dentists must unethical conduct even in areas other than medical practice to protect the integrity and honor of medicine.

Article 8: The medical and dental profession should not be a commercial issue. In his publications, a physician and dentist must protect the professional dignity. He cannot advertise himself in his publications.

A physician and dentists cannot allow patients to express their gratitude in the news media.

Article 9: Physicians and dentists cannot advertise news media and in their prescriptions other than their names, address, specialty as defined by regulations, their academic title, days and hours of their work.

The size, number and shape of their signs, inside or should be regulated by local medical societies. Not more than 2 colors can be used in signs; they cannot be illuminated by light.

Article 10: A research physician cannot apply diagnostic and therapeutic methods which he invented to his patients unless he is confident of good effects and there is no serious side effects

[1] From Lectures on Medical Ethics, Yahya Kıyak, Marmara Üniversitesi Tıp Fakültesi, İstanbul 1987.

after several in-vitro and in-vivo trials. He should notify the proper authorities about precautions, making it sure that is on trial period. No misleading statements should be used.

Article 11: No surgical procedure can be done for research purpose, nor any physical, chemical or biological experiment and diagnosis.

If a traditional mode of treatment is believed to useless a new method may be applied after enough and acceptable animal experiments. In orders to apply this new method, it is necessary to know that the new method is beneficial and at least not worse than the old one. If there is no other way to help the patient, a new untried method may be used, if used if there is no possible harm, in order to save the patient.

Article 12: Physicians and dentists

A- Cannot perform any procedures on patients to obtain unjust benefit.
B- Cannot ask or offer a benefit in their referring cases to each other. (Fee splitting).
C- Cannot offer any compensation to pharmacists or ancillary medical personnel or anybody for the referral of patients.
D- Cannot recommend any drug, medical gadget or tools to patients for unlawful personal benefit, and cannot refer or admit patients for same reasons.
E- Cannot accept a third person's medi[illegible]n to determine fees for diagnosis and treatment.

SECTION: II
The Relations with Patients:

Article 13: A physician or dentist makes his diagnosis and treatment in accordance with scientific principles. He cannot be criticized ethically when the illness is not perfectly cured if he did his best.

Deceptive diagnosis and treatment against medical principles and rules are prohibited.

A physician cannot do any diagnostic or therapeutic procedure which decreases the physical and mental strength of patient in order to please him.

Article 14: A physician and dentist must give necessary care to their patients. Even he cannot save the patient's life, at least the physician could try to decrease or stop the patient's pain and misery.

A physician and dentist should give hope to their patients. If believes that bad news about the prognosis of the disease does not worsen his patient's condition, he should tell the truth openly on diagnosis in order to take proper precautions. However, it is recommended that the physician should not tell the patient about a potentially fatal outcome.

A hopeless prognosis may be hinted at with great precaution. Such a prognosis may be revealed to a patient's family if the patient did not ask not be revealed.

Article 15: A physician also tries prevention when he is called for examination in a patient's home or other places. The physician informs the patient and the people around him about their responsibility of their environment.

A physician tries to show the patient his or her responsibilities for hygienic and preventive rules, even at the expense of losing his patient.

Article 16: A physician or dentist writes his report on his patient according to his own observations and to conscience and scientific belief.

No report or any other document may be given for a personal purpose or to please his patient.

Article 17: A physician and dentist cannot interfere with their patient's personal and family affairs. However, every possible help and support should be given life threatening cases.

Article 18: A physician and dentist may refuse to take care of a patient for personal or professional reasons expect in emergency cases, in official duties and humane reasons.

Article 19: A physician and dentist may quit his treatment for personal or professional reasons. However, he should give enough time to his patients to find another doctor carry on the treatment. If there is a possibility of a life threatening situation, they cannot leave the patient before finding another colleague.

A physician and dentist have to give his notes and observations to a patient if he finds it necessary or the patient wants them.

Article 20: A physician and dentist need not give any medication to a patient if he believes it is useless. However, some medications may be given for consolation if there is no possibility of treatment.

Expensive placebos should not be given to patients in financial difficulty if there is no absolute necessity.

A physician and dentist should not recommend any treatment method which is beyond the patient's financial ability and not really necessary.

Article 21: A surgeon, family physician or dentist are free to choose their assistants in surgical and other procedures. The fee of assistants is paid by the patient expect in piece-rate prices.

A family physician or dentist cannot ask for compensation for attending the surgery if patient did not request his presence.

All rights are reserved for the health organizations which are financed by general, subsidiary or private funds, municipalities or other establishments under their jurisdictions.

Article 22: Abortion is allowed only in cases where it is necessary to save the mother's life. If the mother's life is in serious danger and she needs surgical or other procedures to terminate the pregnancy, these procedures cannot be done without certificate of two expert physicians or in their absence just two doctors, who must rely on objective evidence. The original copy of the certificate is kept by the physician who performs the abortion, and the other copy is sent to local medical association by certified mail. This will later be certified by the performing doctor but will not contain the name of the mother.

The date and place of the abortion should be added to the certified copy.

In serious and emergency cases where other physicians certificate cannot be obtained, the physician acts independently but informs the local medical association with a certified letter.

Written consent of the patient and her guardian (if available) must be obtained.

When the abortion is performed in the establishments mentioned in article 21, it is under regulation of those institutions.

Article 23: The physician must try to save the mother and ...id in difficult labors. The physician carries out scientific and technical requirements without consideration of family and other reasons.

Article 24: A family physician and dentist accept the patient's request for consultation.

If a family physician and dentist feels the necessity of consultation, they inform the patient about this. If the patients does not accept this recommendation, they may terminate treatment.

Hospital regulations define how and when consultations are done in the institutions mentioned in article 21.

Article 25: Discussions and deliberations on consultations are done in a fashion that the patient and his family cannot hear or understand.

Professional dignity should be carefully taken into consideration during discussion and deliberations in consultations.

The consultant should tell his opinion frankly without a second thought such as protecting or praising his colleague or for other emotional reasons.

Article 26: The results of the consultation are written down and signed in a report.

The results of the consultation are revealed by the senior consultant. This should be clear and should not disturb the feelings of the patient and the people around him.

Article 27: If a consultant thinks the present treatment is not right, he writes his opinion only; he cannot interfere with therapy.

Article 28: In case there is a discrepancy between the consultant and the family physician and if the latter insists on his opinion and the patient prefers the consultant's opinion, the family physician may leave the patient.

Article 29: A consultant cannot treat the patient unless the patient insists upon it. A consultant should not attend the patient for the same illness before the permission of the patient's family physician.

Article 30: Each consultant charges a patient separately. Fees should not be taken and split among consultants.

A family physician has the same rights as the consultant in collecting fees.

Article 31: The physician and dentist should not accept the fees less than the defined minimum charges in regions where minimum charges are fixed.

Article 32: It is recommended that physicians an dentists should not charge to their colleagues or their dependents. However, they may ask for indispensable expenses.

Article 33: A fixed fee may asked for surgical intervention, delivery, physical therapy, radiotherapy, dental treatment and for treatments which require follow up care.

A fixed fee may be asked in a treatment center or establishment. A fixed fee is not permissible for other treatments except the above mentioned cases.

All rights are for in the places mentioned in Article 21.

Article 34: If treatment is terminated for any before it is completed in the cases in which contract price is permissible, the family physician charges only for the time he spent until that moment; if he was paid in advance, he must pay back the proportional part of the money he receive.

Article 35: In emergency cases, the physician and the dentist may ask for their later.

Article 36: Physicians and dentist working in the places mentioned in Article 21 of this regulation cannot ask the patients seen in those establishments to come into their private offices and cannot charge them separately.

SECTION: III. Colleagues Relations with each other and Ancillary Personal.

Article 37: Physician and dentist should maintain their good professional relationship with each other and help each other. They should try to solve their professional disagreements among themselves first. If they are not successful, then they should report to the local chapter of their association

Article 38: A physician or dentist should not criticize his colleagues nor should he belittle them. A physician or dentist protects his colliques's dignity to others.

Article 39: Physicians and dentists should not take away (entice) their colleque's patients.

Article 40: Physicians and dentists should not violate the independence of paramedical people, should treat them kindly and should not put them in trouble with their patients.

SECTION: IV. Miscellaneous Rules

Article 41: Every year in early January, the local chapters of medical association must prepare lists of their members with their names and addresses.

Article 42: Physicians and dentists have to notify to local chapters within one week after they open office or laboratory and also one week after they close or relocate. This should be in writing.

Article 43: A physician or dentist cannot make another colleague work for him in his office. However, they could leave their office to another colleague temporarily when this time is more than one month.

Article 44: The board of Directors of local chapters are responsible for disciplining physicians and dentists in their court of honor when they disobey regulations in accordance with Article 30 of Turkish Medical Association Law No. 6023 In addition to disciplinary action, physicians and dentists may be punished by law.

Article 45: These regulations which are prepared in accordance with subsection (g) of article 59 of the Law No.6023 are effective two months after their publication in Resmi Gazete.

Article 46: The decrees of these regulations are execute by the Ministers of Justice and Health and Social Welfare.

LEVINE, C.: Cases in Bioethics
St. Martin's Press Inc.
New York 1989

Glossary

Advance Directive An advance directive is a declaration by a person that stipulates the forms of medical treatment to be provided by caregivers and/or designates someone to act as a proxy should the person at some future date lose decision-making capacity. In written form, an advance directive is often referred to as a "living will."

Autonomy Derived from Greek words meaning "self-rule." In bioethics, autonomy typically refers to the patient's right of self-determination concerning medical care. Autonomy may be used in various senses including freedom of action, effective deliberation, and authenticity. It supports such moral and legal principles as respect for persons and informed consent.

Beneficence The principle of beneficence involves duties to prevent harm, remove harm, and promote the good of another person. In bioethics, beneficence refers to the obligation of health care professionals to seek the well-being or benefit of the patient.

Best Interests A decision-making standard used in the absence of an advance directive or when a substituted judgement is not possible, best interests involves more objective, societally shared criteria about what reasonable persons would probably choose in a particular situation.

Competence Competence refers to a patient's capacity to make decisions about the provision of medical care for him or herself. It is an element of informed consent, and involves comprehending information, choosing in accordance with one's values, and communicating a decision. The decisions of competent patients are usually respected, while a determination of incompetence may warrant paternalistic and coercive measures, such as involuntary commitment.

Conscience Moral agents often appeal to conscience in making ethical judgements about particular cases. The content of conscience is informed by basic moral values. In medical ethics, health care professionals may refuse to perform certain procedures, for example, abortions, sterilizations, or withdrawal of life-sustaining treatment, based on fidelity to conscience, a phenomenon known as "conscientious objection."

Deontology Derived for the Greek *deon* or "duty," deontological moral theories (along with utilitarianism) form the philosophical basis for contemporary bioethics. A deontological position holds that the moral worth of acts is not limited to assessing the character of the agent of the consequences or the performance of the

even be decisive for moral deliberation. The principles of autonomy, respect for persons, and distributive justice are typically grounded in a deontological theory.

DNR Orders Do-Not-Resuscitate orders are directions not to initiate cardiopulmonary resuscitation (CPR) in the event of cardiac or respiratory arrest. DNR orders raise ethical questions about when life-sustaining treatment should be withheld and who should make that decision.

Ethics Ethics is systematic reflection on the norms, principles, or values that do or should guide human conduct or action; and as such can be distinguished from morality, which is the practice or conduct itself. Bioethics is a form of *applied normative* ethics that involves the application of general ethical principles and rules to specific moral problems that arise in medical practice, the provision of health care, and scientific research.

Euthanasia Eytmologically, euthanasia means easy or gentle death. Contemporary usage is often ambiguous, and modifiers are used to make the intended sense clearer. "Active" euthanasia refers to the direct killing of a patient, and is typically contrasted with "passive" euthanasia, which involves the withdrawal of medical technologies in order to allow the underlying disease process to take its natural course. "Voluntary" euthanasia (either active or passive) means that the action is undertaken at the behest of the patient, and should be distinguished from "nonvoluntary" euthanasia where the patient has not made or is not capable of making such a request, and "involuntary" euthanasia, where the action is performed against the patient's wishes.

Extraordinary/Ordinary Means of Treatment Historically, extraordinary and ordinary means of treatment have been distinguished according to whether (a) a proposed medical intervention has a reasonable chance of succeeding, and (b) the benefits of the intervention outweigh the burdens. The distinction is based on a moral or professional obligation to provide ordinary treatments, but no obligation to provide extraordinary treatment. The "extraordinary/ordinary" distinction has been criticized recently for focusing attention on treatments for diseases rather than patient interests, leading to decisions about the provision of treatment based on what is routine or customary in medical practice. The terminology of "optional/obligatory" has been proposed as a preferable, patient-centered, standard for such judgments.

Informed Consent Except in emergency situations, physicians are morally and legally required to obtain the patient's informed consent to invasive medical procedures. The elements of informed consent include professional disclosure and patient comprehension of information, and patient voluntariness and competence to consent.

Justice As a general moral concept, justice requires that persons be given what they are due. Theories of justice have specified different criteria upon which such a determination can be made, for example, societal benefits might be distributed to persons based on equality, need, effort, merit, or contribution to society. In bioethics, distributive justice is especially important in decisions about the fair allocation of health care resources.

Nonmaleficence The principle of nonmaleficence prohibits the infliction of harm, injury, or death upon others, and supports more specific moral rules such as the prohibition of killing. Nonmaleficence is related to the maxim *primum non nocere* ("above all, or first, do no harm"), which is widely used to describe the duties more stringent than the duty to benefit others and it also imposes moral limits on autonomy.

Paternalism Paternalism assumes a parent (father)-child relationship in which an authority figure acts to benefit the subordinate party even against his or her desires or choices. Medical paternalism normally involves the refusal of a health care professional to accept the wishes, judgments, or acts of a patient on the grounds that the health care professional knows best. Paternalism is widely viewed as morally suspect because of its assumptions of moral inequality in the professional-patient relationship and because it violates patient autonomy. However, paternalism is usually considered warranted if the patient's capacity for autonomous choice and competent decision making is restricted or impaired.

Personhood Philosophers and theologians frequently propose criteria—for example, sentience, consciousness, or purposive action—that specify when a living entity is or becomes a person. The concept of personhood is critical in many bioethical debates. Divergent views of personhood are assumed in arguments over the moral status of the human fetus and animals, and over the determination of death.

Professional Ethics Ethical standards are important in defining the boundaries of a profession such as medicine or nursing. Most professions have developed codes of ethics that identify the responsibilities of the professional in special relations with patients or clients. These standards are viewed as obligatory upon members of the profession, and may not be applicable to nonmembers or to relationships outside the professional setting.

Proxy Consent When a patient has been determined to be incompetent and incapable of giving informed consent to the provision of medical teatment, a proxy may be appointed to make decisions for the patient. The proxy, frequently a family member or relative, may be appointed by the court or designated by the patient through an advance directive.

Quality of Life Quality of life is often contrasted with quantity or sanctity of life and indicates that there are moral limits to the use of life–prolonging medical interventions. It is portrayed as a patient-centered moral criterion, emphasizing the worth of the patient's own life to him or herself.

Respect for persons The moral principle respect for persons is based on the maxim that a person should never be treated simply as a means, but always as an end. At a minimum, it requires providing reasons or moral justification for actions that infringe upon the liberty and life plans of others. Respect for persons supports moral rules, such as privacy, confidentiality, and truthtelling.

Rights Rights are justified claims upon others for action or forebearance. "Negative" rights are rights to noninterference by others, such as the "right to life," to undergo an abortion based on the right of privacy, or to refuse medical intervention. "Positive" rights are claims on others for assistance, such as federal or state funding for access to abortion, or the right to health care.

Risk-Benefit Analysis Risk-benefit analysis weighs the probability and magnitude of potential harm against the probability and amount of potential benefit. Various measures of harm and risk are used. This form of analysis is widely used to set standards of safety and health for the workplace and to assess medical technologies.

Sanctity of Life The principle of sanctity of life assumes that the moral and religious value of life transcends judgments about its quality. In bioethics, the sanctity of life principle is associated with conservative, life-prolonging positions in debates

Slippery Slope Argument A "slippery slope" or "wedge" argument raises questions about the precedents that may be set and the consequences that may follow if a particular practice is accepted. In its *sociological* version, the slippery slope argument suggests that if X is accepted, then Y will follow as a matter of due course. The legal acceptance of active, voluntary euthanasia, for example, is often predicted to erode society's respect for the value of life so that moral barriers against nonvoluntary or involuntary euthanasia would be undermined. In its *logical* version, the slippery slope argument suggests that the acceptance of X already contains an implicit justification of Y, even if in practice Y never occurs. For example, arguments that support the use of infants with anencephaly as organ donors might seem also to validate harvesting organs from patients in a persistent vegetative state.

Substituted Judgment In a case of substituted judgment, a proxy decision maker makes a decision about medical treatment for an incompetent patient based upon his or her understanding of what the patient would have decided if competent. The "substituted judgment standard" has been important in influential legal decisions and is typically contrasted with the "best interests standard."

Supererogation Supererogatory acts are those considered "above and beyond the call of duty." Such acts, like a rescue that imposes substantial risk to the rescuer, are not considered morally obligatory and failure to perform them would not be regarded as morally wrong. The moral agents who do perform them are often praised for their heroism. Judgments about supererogatory action are often role dependent: because of commitments to standards of professional ethics, the ethical expectations of lifeguards or physicians to save life are often higher than those imposed upon normal citizens.

Triage Drawn from a French term for "sorting," triage is important in emergency medicine and in procedures for determining which patients should receive scarce medical resources. Patients may be classified according to whether they will probably (1) survive without immediate medical treatment, (2) die even with immediate treatment, or (3) survive only with immediate treatment.

Utilitarianism Utilitarianism is a philosophical theory that assesses the moral worth of acts according to their extrinsic features, particularly their outcomes and consequences. In a utilitarian position, the morally justifiable act is that which produces the greatest amount of value over disvalue. Utilitarianism supports a range of ethical principles, including nonmaleficence and beneficence, and methods of moral assessment, such as risk-benefit analysis.

20

Selective Termination of Pregnancy

Ms. Q. is a thirty-year-old woman who is pregnant for the first time, having spent several years in a local infertility program. She had been treated previously with clomiphene citrate, a fertility drug that increases the incidence of multiple births among those who subsequently become pregnant from 1 percent to 8 percent. Dr. G., the physician who prescribed the drug, had indicated to the patient that its use involved "some risk of multiple gestation."

At nine weeks gestation, ultrasound reveals the presence of triplets. After discussion with her husband, Ms. Q. asks Dr. G. to terminate two of the fetuses. She says she really wants to have a child and "be a good mother," but doesn't feel capable of caring for more than one child at a time. Even though all three fetuses appear healthy, her preference is to abort all rather than have triplets.

A technique similar to amniocentesis (in which the uterine cavity is entered) has been used to terminate selectively a defective fetus, when a serious fetal anomaly, such as Down's syndrome, occurs in a multiple gestation. This technique could be used to terminate two of the triplets, but it entails an incremental risk of miscarriage. Legally, Dr. G. could: (1) terminate the pregnancy through a standard method of abortion; (2) selectively terminate the gestation of two of the triplets; (3) refuse to terminate the pregnancy, with transfer of care to a physician who is willing to do so. Should Dr. G. acquiesce in Ms. Q.'s request? Is this request morally valid?

18

When a Mentally Ill Woman Refuses Abortion

Ann Brown is a twenty-seven-year-old woman with a diagnosis of chronic paranoid schizophrenia. She has a history of prolonged institutionalization, with intermittent attempts at independent living. Presently living in a mental hospital, Ann Brown is now twelve weeks pregnant. She has firmly indicated her desire to continue the pregnancy and to keep the child. Abortion, she declares, "is against my principles." The father is unknown.

While Ann's psychiatrist does not consider her capable of responsible parenthood, he does think that she is capable, at times at least, of meaningful moral decisions. Her schizophrenia and medication taken early in pregnancy slightly increase the possibility of fetal defect.

Ann Brown's mother wants her to have an abortion, and has secured legal custody of her daughter in order to effect that result. She feels that the experience of pregnancy and the trauma of labor and delivery will worsen Ann's mental state. Moreover, she herself is unable to care for the child and fears that Ann will suffer further if she is forced to give up the child to strangers.

The hospital attorney has indicated that she will oppose Ann's mother's request for an abortion. She will argue that it cannot be performed without consent.

There is little likelihood that Ann Brown would be allowed to care for her child. However, because of the ambiguity surrounding parental consent, the child would probably be placed in foster care rather than with adoptive parents.

Should the abortion be performed? Who should decide?

17

The Unwanted Child: Caring for the Fetus Born Alive after an Abortion

Last spring [1976] the California State Legislature passed a bill specifying that a viable fetus which is live-born following an abortion or attempted abortion is a ward of the state. Furthermore, the bill required that physicians performing abortions must take "all reasonable steps, except extraordinary means, in accordance with good medical practice, to preserve the life and health of the live-born person." However, the bill also specified that it was not to be construed as granting priority to the live-born person over its mother with respect to the provision of livesaving medical treatment.

The bill defined a "viable fetus" as one which is biologically viable, based on the consideration of a minimal number of independently sustained, basic, integrative functions. The viable fetus is able to (1) increase in tissue mass, (2) increase the number, complexity, and coordination of basic physiological functions, and (3) develop into a self-sustaining whole organism independent of any connection with the mother. A "fetus" would be considered a live-born person if, outside the womb, it manifests a sustained heartbeat, umbilical pulsation, spontaneous respiration, and movement of voluntary muscles.

In addition to any criminal or civil liability which may be imposed by law, any violation of the law would constitute unprofessional conduct under the State Medical Practice Act.

In August the bill was amended and sent to Governor Edmund G. Brown Jr. in this form: "The rights to medical treatment of an infant prematurely born alive in the course of an abortion shall be the same as the rights of an infant of similar medical status prematurely born spontaneously." Three of the commentators whose views are presented here (Walters, Nathan, Nathanson) also presented written testimony on the bill.

The bill was signed by the governor in its amended form, as part of the California Health and Safety Code, in September.

[The law is still in effect.]

COMMENTARY

5.6 Rejection of a Consultant's Advice

C.P., an eighty-two-year-old man, was brought to the hospital after a monthlong bout with nausea, vomiting, and alternating periods of constipation and diarrhea. Although he had experienced abdominal pain and weight loss for about a year, X-ray studies of his gastrointestinal tract ten months and two months before admission had not revealed any disease. His wife and son reported that he had also suffered periods of mental confusion in recent weeks. His medical history included irregular heartbeat (cardiac arrhythmia) and mild Parkinson's disease, a slowly progressive disorder of the central nervous system which causes tremors, rigidity of muscles, and slowness of movement. But until recent weeks he had remained self-sufficient, chopping wood for his fireplace and caring for his fruit and vegetable garden.

A diagnostic workup revealed serious chemical abnormalities. His hemoglobin level was below normal, indicating a reduction in the blood's oxygen-carrying capacity (anemia). He had excessive calcium in his bloodstream, as well as excessive amounts of urea nitrogen, uric acid, and creatinine, waste materials normally removed from the blood by the kidneys. His urine output was greatly reduced (less than 600 ml per day), and excessive amounts of protein were found in his urine.

The symptoms and laboratory results suggested the possibility of multiple myeloma, complicated by acute kidney failure. Multiple myeloma is a cancer involving unregulated multiplication in the bone marrow of plasma cells, a type of blood cell that produces antibodies. Because the tumor cells release large amounts of protein that interfere with urine formation, the disease often results in renal failure. Further tests of bone marrow, blood, and urine confirmed both aspects of the diagnosis. A complete X-ray series also revealed several cancerous lesions in the patient's skull and ribs, sites in which patches of tumor frequently develop.

Multiple myeloma is invariably fatal, although some patients live for years. Prediction of length of survival is very difficult. A hematology consultant thought C.P. might survive up to eighteen months if his disease responded to chemotherapy. He recommended chemotherapy with melphalan and prednisone, and the treatment was initiated.

However, the daily increases in the urea nitrogen and creatinine in the patient's blood suggested that he could only survive a few more days without aggressive treatment for the kidney disease. The attending physician requested a consultation by a nephrologist (kidney specialist), who confirmed the seriousness of the kidney failure. He did not believe that they could wait for the cancer chemotherapy to relieve it. (A positive response to chemotherapy may gradually resolve the kidney failure by reducing the number of cancer cells secreting the proteins that impair kidney function.) Rather, he suggested that the patient undergo regular hemodialysis. If this treatment did not restore satisfactory renal function, then plasmapheresis might be tried.

Hemodialysis is a process in which waste products resulting from inadequate kidney function are removed from the blood. Blood is delivered continuously from the patient's arm into the dialysis machine and returned after cleansing. The dialysis procedure lasts four to six hours, and most patients require treatment three times per week. Plasmapheresis is a procedure in which the blood is also delivered from the patient's arm into a machine. However, the machine removes the plasma from the blood (it is the plasma that contains the harmful proteins) and replaces it with fresh plasma. Although the procedure has only been used experimentally in a few cases of multiple myeloma, preliminary results suggest that it may remove ten times the amount of harmful protein eliminated by hemodialysis. In the experiments, the procedure has been performed about once per week.

However, the attending physician was opposed to acting on the consultant's recommendations. He believed that the acute renal failure should be managed conservatively with dietary restrictions and intravenous medications. He had several reasons for this view. First, given the extent of the cancer, the degree of kidney failure, and the general condition and age of his patient, he believed that the patient would not survive more than a few months, even with abatement of his renal failure. Second, death caused by renal failure would probably involve less pain and suffering than death from cancer. Thus, he ordered conservative management for the kidney failure and continuation of the chemotherapy and entered a do-not-resuscitate note in the patient's chart.

The consulting nephrologist was appalled. He thought the patient had a right to decide whether he preferred more aggressive therapy. Although the consultant suggested to the attending physician that the patient should make the decision, the recommendation met with resistance. The attending physician expressed concern that dialysis might compromise the patient's quality of life. Emotional distress can result from dependence on the machine and changes in body function. Because dialysis patients receive medications to keep their blood from clotting, brain hemorrhages can occur, and dramatic shifts in body chemistry caused by dialysis can produce seizures. Moreover, even if successful, it might only keep the patient alive long enough to undergo severe pain that develops as skeletal lesions caused by the multiple myeloma spread. Finally, the attending physician regarded lightly the hope that plasmapheresis might help. The evidence from the medical literature regarding its usefulness was only anecdotal; besides, it had only been used with much younger myeloma patients.

The consultant replied that the dialysis might not compromise the patient's well-being. Whether serious physical or emotional side effects would occur was a matter of conjecture. The impact on quality of life could not be determined without the patient's own assessment of his degree of suffering and remaining capacity for meaningful life. It seemed reasonable to at least try dialysis. The patient could later decline further aggressive care if his life became intolerable. Moreover, conservative management of his kidney failure hardly seemed to promote his well-being; he was likely to die shortly without more aggressive treatment.

However, these remarks did not alter the attending physician's view. At this point the nephrologist considered whether he should talk directly with the patient. He knew that this would violate the hospital's rules of etiquette, which required that recommendations be made only to the attending physician. However, professional etiquette seemed less important than his obligations to the patient. Besides, the patient, not the attending physician, was paying for the consultant's involvement in the case.

However, the appropriateness of speaking directly with the patient about more aggressive care was not clear-cut. C.P. might become very confused, especially if the attending physician then gave the patient a strongly negative appraisal of this option. C.P. had no more than a fourth-grade education, making an explanation of the medical situation difficult. The likelihood that he would be able to sort matters out was further constrained by his increasingly frequent periods of mental confusion, resulting from kidney failure and the excess calcium in his blood.

The intervention might also intensify the patient's suffering. The conflicting opinions were bound to create substantial anxiety and erode C.P.'s faith in his attending physician. If his kidneys were already irreversibly damaged, the intervention might only make his final days more difficult. There was also the obvious danger that the patient's interests would get submerged in a struggle between the physicians about the handling of the case.

The established system for making consultant's recommendations assigned to the attending physician the obligation of evaluating conflicting information and presenting a treatment plan to the patient. There were good reasons for this approach. Not only does it spare the patient from having to sort out technical points of dispute, but it also allows the attending physician, who is presumed to know the patient better than others, to tailor the information and advice to the needs and interests of the patient. It was hard to make an exception to such a generally sound approach.

Finally, the consultant knew that his colleagues carefully observed the rules of etiquette regulating consulting relationships. As a staff member accepting consultations from attending physicians, he believed that he was making a tacit promise to observe these rules. Speaking to the patient would require breaking this promise.

31

Active Euthanasia with Parental Consent

Hunter C. Leake III

Andrea was a nine-year-old girl who had been diagnosed as having cystic fibrosis at the age of thirteen months. Since then she had been hospitalized twelve times, eight times during the last year.

When admitted for the last time she was already receiving an experimental antibiotic, which was being administered in an attempt to control a resistant pneumonia superimposed on severely damaged lungs, a result of her underlying disease. She was at that time a severely ill, emaciated child with moderately labored breathing. She seemed to have no interest in her environment and refused to communicate with anyone but her mother.

Because of the severity of the child's illness and because the parents had accurately perceived that the experimental antibiotic was a "last ditch" attempt to control her pulmonary infection, the physician discussed with the parents their perception of "extreme medical measure" and the significance of a "no code" order. The parents indicated that in the event of a cardiac or respiratory arrest, they did not want their child to be resuscitated and the appropriate "no code" order was written. The child was not involved in these conversations or subsequent decision making, nor had the mother previously been able to answer her daughter's questions about death and dying.

As the child's condition continued to decline, the parents asked how much longer she would live and how she would die. At one point the father said: "Watching your own child die is worse than dying yourself." This comment led to a discussion of active euthanasia utilizing intravenous potassium chloride or a similar drug. The physicians pointed out that no matter how hopeless a situation or the amount of suffering that the patient and family were enduring, the law prohibits the active taking of a patient's life. They refused to consider this option.

The following day Andrea's heart began to fail. Her condition became progressively worse, and she died approximately forty-eight hours later. During these last two days her parents were appalled by her grotesque appearance, with "eyes bulged out like a frog," and were in great despair because of her steadily deteriorating condition. They felt helpless and impotent to alleviate their daughter's distress. Medical treatment was continued to the end, and no measures were taken to hasten Andrea's death.

Approximately two months after her death, the mother was asked if she would still have given permission for active euthanasia if she had been offered that option. She replied, "Yes."

Should active euthanasia be permitted to spare the patient and family from suffering when death is inevitable?

believe that his choice of "death with dignity" should be respected.

30

"No Feeding Tubes for Me!"

Pauline Randall, a sixty-five-year-old married woman with three adult children, has been suffering from amyotrophic lateral sclerosis (ALS) for several years. Her neurological condition has deteriorated so that she can no longer control any voluntary muscles. Confined to bed in a nursing home in a small midwestern American city and breathing with the aid of a respirator, she communicates through the electronic monitor that responds to eyelid blinks. She can "write" words and brief sentences in this way.

Mrs. Randall understands that her condition cannot be treated and that it will inevitably lead to her death. But she has been an active participant in her health care and has been determined to continue functioning as long as possible.

Her physician, Dr. Samuels, believes that she is not receiving adequate nutrition and that the time has come to insert a nasogastric feeding tube. When he proposes this procedure to her, she blinks quickly, "No more!" He asks, "Do you understand that you will die slowly of starvation if we do not insert this feeding tube?" "Yes," she blinks, "No more."

When Mrs. Randall's family, which has been close and supportive throughout her illness, learns of her opposition, they have divided opinions. Her husband believes that her wishes should be respected, but two of their three children are convinced that her life should be prolonged. The nursing staff believes that she should not be made to suffer any longer.

There is no question that Mrs. Randall is legally competent, that is, that she understands the procedure being proposed and the consequences of refusal. Should her refusal of the feeding tube be honored, even though it will lead to her death?

1.4 Rehabilitation of a Dependent Patient

L.R., a seventy-year-old woman, was admitted to the rehabilitation center to gain improved facility in walking and self-care. In recent years, she had suffered from numerous medical problems. Fifteen years ago she was diagnosed as having adult-onset diabetes, which had been well controlled with a rigid diet. Six years ago she had a serious heart attack and underwent coronary bypass surgery. Within the last year, she had suffered from blocked arteries in her left leg and underwent a graft procedure in which a vein was inserted to circumvent the blocked artery. After the surgery, she had substantial edema in her lower left leg, which compressed the peroneal nerve. Although the pressure was surgically relieved, the damage to the nerve was permanent. As a result, her left foot did not lift properly when she attempted to walk, and she needed a leg brace and a walker to get around.

She recently had several episodes in which she became too weak to return to her bed after going into the bathroom. During these incidents, L.R. had no pain, dizziness, loss of consciousness, or heart palpitations. Rather, her inability to walk farther seemed to involve decreased strength and balance. After a general diagnostic evaluation for new disease proved negative, she was admitted for physical therapy to improve her strength and balance while walking.

Her daughter reported that L.R. had rapidly declined during the past eighteen months. She had become progressively less active and ambulatory. She spent most of her time in bed, only walking back and forth to the bathroom. L.R.'s husband, who was seventy-six years old and in good health, bathed her and assisted her in dressing. In addition, he did all the shopping, housework, and cooking. He said that those responsibilities were very tiring, and he wished that his wife could assist with the cooking and cleaning. L.R.'s daughter, who lived out of town, claimed that her mother was able to get around and help with household chores but expected her husband to do all the work. She also said that her father seemed all too willing to submit to her mother's persistent demands.

L.R. was assessed by the occupational and physical therapists. The occupational therapist determined that she was still sufficiently dexterous and ambulatory to work in the kitchen and perform other simple household tasks. The physical therapist found that her leg strength had declined through lack of use and that the previous nerve damage caused her left foot to drop and drag when she lifted it while walking. But it was clear after a few therapy sessions, as her strength improved, that she was able to get around quite effectively using her walker when she gave deliberate attention to the placement of her left foot. The

most salient feature of both assessments concerned L.R.'s attitude. She was unwilling to take any initiative in performing the occupational tasks or walking exercises. She repeatedly said that she was unable to perform tasks that she would later complete satisfactorily. It usually required two or three requests from the therapists before she would begin each activity. L.R. also constantly complained about being too tired and sore to continue the sessions.

The attending physician found no physical basis for L.R.'s self-perceived inability to undertake various activities or for her discomfort. In addition, there were no clinical signs of reactive depression, such as melancholy, loss of appetite, or sleep disturbance. The patient simply seemed satisfied to be entirely dependent on her husband in dealing with her personal needs.

Tensions were rising in the family. The daughter had investigated several nursing homes and made tentative arrangements for her mother's entry following discharge from the hospital. She insisted that her father had reached the limit of his ability to care for her mother. In discussions with the staff, he had not expressed any definitive opinion about the nursing home option and seemed willing to let his daughter make the final decision. But L.R. had said on three separate occasions that she was looking forward to returning home.

The situation placed the attending physician in a difficult dilemma. On one hand, L.R. preferred to be dependent on others for the satisfaction of her basic needs. In the hospital, she had tenaciously held to this regressive style of coping and had refused to discuss the matter with staff members. The physician believed she had made a conscious decision to handle her physical problems in this way and would have to live with the consequences. In addition, interference with her habitual dependence would undoubtedly cause anxiety and annoyance for the patient. It might also undermine their therapeutic rapport, inclining the patient to avoid contact with the attending physician when future medical problems arose. If the physician accepted this reasoning, it would now be time to discharge the patient. He should explain to the family and the patient what she was capable of doing but should leave it up to them to determine what would be done following discharge.

On the other hand, there are good reasons for a more active stance. The patient's well-being would probably not be served by entry into a nursing home as long as she remained physically capable of living independently. If she were placed in a nursing home, the physician feared that her decline into permanent physical incapacitation would be much more rapid. Moreover, she clearly would rather remain at home with her husband. If the physician did not intervene, she probably would be pressured to accept the nursing home option. Unfortunately, she refused to recognize that her desire to remain dependent on her husband conflicted with her desire to remain at home. In light of these considerations, it may be appropriate to keep her in the hospital and aggressively address her attitudinal problems. This would involve pointed discussions with her about her need to assume responsibility for self-care and housework if she wishes to avoid exhausting her husband and being sent to a nursing home. A similar aggressive stance could be taken by the therapists in their sessions with her. At the same

time, attempts could be made to alter the behavior of the family. Discussions with L.R.'s husband might emphasize the importance of refusing to do things she is able to do for herself. In conversations with the daughter and the husband, the physician might also strongly insist that it would be inappropriate to place L.R. in a nursing home.

But the physician knew that this approach would create considerable friction. The patient may angrily resist any attempt to change her dependence. After all, her needs were being met and her responsibilities minimized, and she could easily manipulate her husband to provide assistance. Given her behavior in previous therapy sessions, it would require a good deal of pressure to goad the patient into more appropriate behavior. Similar difficulties could be expected in attempting to neutralize the daughter's role in the discharge plans.

1.5 Alternative Approaches to Informed Consent

W.L. was a twenty-two-year-old man who worked as a farm laborer. He was married with one child.

The patient first noticed a swelling on his left hip about fifteen months earlier. It was tender but caused no serious impediment in his daily work. It remained relatively stable in size for ten months. At that time, W.L. began to experience pain in his left leg and some restriction in its use. Soon thereafter he noticed a lump in his abdomen. He consulted a general practitioner in a nearby town and was referred to a cancer center 275 miles from his home.

Diagnostic evaluation established that W.L. suffered from a bone cancer (osteosarcoma) arising in the ridge of the left hip (the iliac crest). The cancer was extended along the pelvic bone and across the middle of the abdomen. Workup for tumor elsewhere in the body (metastases) was negative. Extension of the tumor across the middle of the abdomen and its position around key anatomic structures precluded surgical treatment, such as a hemipelvectomy (removal of half of the pelvis and the adjoining leg). The patient was placed on a chemotherapy regimen of vincristine, cyclophosphamide, and adriamycin, which was a front-line experimental protocol. But within two months there was documented progression of the tumor. With the failure of this regimen, it was no longer realistic to hope that he could be cured. However, alternative chemotherapies might achieve temporary remissions of the disease. The patient was switched to a regimen involving escalating doses of methotrexate, which had shown positive preliminary results in treating osteosarcoma.

At this time, the management of pain was becoming a significant problem. The patient was requiring very high doses of morphine and dilaudid to relieve his pain. These were not sufficient to provide adequate pain control yet often caused him to slip into a clouded state of consciousness. The problem was complicated by the fact that W.L. had not developed lung metastases characteristic of osteosarcoma, even though his disease had been present for at least a year before therapy. This fact, conjoined with clinical observation that the tumor was growing slowly, suggested that he might remain alive for as long as a year. Given this prospect, there was deep concern about the adequacy of the narcotics in providing pain relief. Being in relatively constant and often severe pain, W.L. began to press the staff for more adequate management of his pain.

There were essentially three alternatives for improving control of the severe pain in the patient's hip, abdomen, and left leg. One was to amputate his left leg by performing a hemipelvectomy. This would remove the leg in which intense pain was occurring and reduce the amount of tumor in the abdomen. Substantial pain relief (following postsurgical recovery) could be expected, although pain might recur with further spread of the disease. Some rehabilitation would also be necessary, such as learning to use crutches.

Two other options were outlined by a consulting neurosurgeon. One was to control pain through nerve-block procedures. This would require a series of procedures in which specific nerve roots are exposed to chemicals that impair their ability to conduct pain impulses. The results of each procedure would be used to determine what additional nerve roots might be blocked to achieve additional pain relief. Completion of this process might require several weeks. Although nerve-block procedures carry less than a 10 percent risk of urinary bladder and bowel incontinence, there may be motor weakness in the affected limb. The neurosurgeon thought it unlikely that W.L.'s pain could be completely controlled in this way, but it was reasonable to expect a very substantial reduction in the need for analgesics.

The other neurosurgical approach involved performance of a cordotomy. In this procedure, nerve tracts responsible for pain conduction are surgically severed. The neurosurgeon believed that the procedure would need to be performed at the level of the twelfth thoracic (T12) vertebra. He was virtually certain that it would produce complete pain relief. The patient would also be able to leave the hospital within a few days after the operation. However, there are side effects. Although sensation of touch, vibration, and position are preserved in the denervated area, sensation of temperature is eliminated. More importantly, the neurosurgeon estimated an 80 percent chance that a cordotomy at T12 would cause urinary bladder incontinence and sexual impotence.

An important problem facing W.L.'s physician concerned how he should manage the informed-consent process. On one hand, he recognized that there were significant trade-offs among the treatment options. How the patient might assess these options would depend on his reaction to the specific benefits and problems associated with each treatment. For example, if complete pain relief were his overriding and exclusive concern, the cordotomy would be the obvious choice. By contrast, if he were hesitant to risk the loss of bladder function and impotence and willing to accept an extended hospitalization away from his family, he might choose to have the nerve blocks.

The importance of the patient's preferences in evaluating the options supported an open-ended approach to the consent process. On this model, the physician would lay out, as completely as possible, each procedure and its

associated risks and benefits. He would help the patient compare the three alternatives. But he would remain neutral, leaving it up to W.L. to make a final choice.

On the other hand, several factors inclined the physician to be more directive. First, W.L. had shown a clear proclivity toward surgical removal of his tumor. Although the uselessness of surgical resection for curing his disease had been explained before initiation of chemotherapy, he continued to ask frequently about surgery. This persistent interest in surgery appeared to have a couple of components. The patient seemed to view it as a decisive, one-shot approach to the removal of the tumor and the relief of his pain, which did not carry the chronic suffering (nausea, vomiting, etc.) associated with chemotherapy. W.L. also seemed to have difficulty understanding how chemotherapy works. Although he had a commonsense understanding of cutting a tumor out, the idea of "melting" it away with drugs was confusing, and he had little confidence in this mode of treatment. In some preliminary discussions about management of his pain, he seemed to lean toward the hemipelvectomy for these inappropriate reasons, despite its mutilative impact and temporary results for pain control.

A second concern was that W.L.'s preference seemed to vary with the intensity of his pain. On a couple of occasions when his pain was especially severe and had persisted for several hours, W.L. said that a cordotomy would probably be the best step to take. However, on several occasions when he had achieved moderate relief of his pain, he expressed much deeper concern about being rendered impotent and incontinent by the cordotomy. At these times he was also much less inclined to undergo the hemipelvectomy. As a result, he would lean toward a series of nerve blocks. Thus, there was a legitimate worry that the patient's choice might reflect how tolerable his pain was on a given day, rather than being determined by a careful weighing of the risks and benefits of each option.

Third, the physician was very concerned about the patient's needs in the coming months before his death and about W.L.'s ability to genuinely appreciate these needs at the present time. The physician believed that his most serious need would be for relief of his pain. It could be expected to worsen with time. Only the cordotomy would ensure complete pain control without moderate-to-heavy use of analgesics. If performed, it would reduce the physical drain of pain-related suffering and allow him more quality time to share with his family.

The patient's other major need was to be reunited with his family. They had little money, and his wife could not afford to visit him. After nearly three months away from home, he was very lonely. The remaining period before death was quite limited, so spending time back home was quite important. Moreover, the physician felt that the patient's degree of suffering might decline if he could be with his wife, child, and extended family. Again, either alternative to the cordotomy would require an additional hospitalization of several weeks. With the cordotomy, he could return home within a few days.

The physician appreciated the importance of respecting the patient's choice and knew that this treatment decision involved numerous value considerations.

But he was also very concerned about these various impairments of the patient's capacity to make a decision based on his own values and interests. Whereas the former considerations inclined him to leave the decision entirely to the patient, the latter factors prompted him to be very directive and persuasive in recommending the cordotomy. Because W.L. was typically very quiet, cooperative, and deeply respectful of the authority of the nurses and physicians, his doctor felt confident he could be persuaded to undergo the cordotomy.

Medikal Etik

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GEBELİĞİN SONLANDIRILMASINDA KARŞILAŞILAN ETİK SORUNLAR

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TANIM

Fetüsün uterusun dışında yaşama yeteneğini (*viable*) kazanmadan gebeliğin sonlandırılması kürtaj veya düşük olarak tanımlanır. Herhangi bir müdahale olmadan sonlanan gebelikler kendiliğinden düşük (*spontaneous abortion*), müdahale ile gebeliğin sonlandırılması ise isteyerek düşük (*induced abortion*) olarak tanımlanmaktadır .

TARİHÇE

Gebeliğin sonlandırılması, avcı toplayıcı topluluklardan, kırsal kesimde yaşayanlara, gelişmekte olan ülkelerden, günümüzün modern olarak tanımlanan toplumlarına kadar hemen her toplumda tarihin her döneminde görülen bir olgudur[2].

Mezopotamya'da, Hamurabi Kanunlarında kadına şiddet uygulanması sonucu çocuğunun düşmesine neden olanlara para cezası uygulandığını biliyoruz[3]. Mezopotamya Uygarlıklarının daha sonraki yüzyıllarında, Orta Asur dönemine (M.Ö. 1450-1250) ait olan kanunlarda da çocuk düşürtülmesine cezalar getirilmektedir[4]. Hamurabi kanunlarında öngörülen ceza para cezası olurken, Orta Asur Kanunlarında çocuk düşürtmenin ölüm cezası ile cezalandırıldığını görüyoruz.

Eski Mısır'da gebeliğin sonlandırılması cezalandırılmakla birlikte bazı durumlarda hoşgörülebiliyordu[5]. Çin'de çocukların babaları tarafından öldürülmesi (infantisid) çok

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[1] Bkz. Ulusal Aile Planlaması Hizmet Rehberi. Cilt I., T.C. Sağlık Bakanlığı Ana Çocuk Sağlığı ve Aile Planlaması Genel Müdürlüğü. Ankara 1994., s. 10-2. ayrıca bkz. Rypins' Medical Licensure Examinations. Topical Summaries and Questions. Ed. by E.D.Frohlich. J.B.Lippincott Company. London.,14th ed. s.804.

[2] Bkz. R.N.Shain, A Cross-Cultural History of Abortion. Clinics in Obstetrics and Gynecology 1986:13(1):1-17.

[3] Hamurabi Kanunları 207-209, 211, 213. Bkz. M.Tosun – K.Yalvaç, Sumer, Babil, Assur Kanunları ve Ammi-Şaduqa Fermanı. TTK Yayınları VII. Dizi – Sayı 67. Türk Tarih Kurumu Basımevi. Ankara 1975 s.206.

[4] Orta Asur Kanunları no. 21,49,51-53 Bkz. M.Tosun – K.Yalvaç, Sumer, Babil, Assur Kanunları ve Ammi-Şaduqa Fermanı. TTK Yayınları VII. Dizi – Sayı 67. Türk Tarih Kurumu Basımevi. Ankara 1975. s.248 ve 255.

[5] Bkz. E.Strouhal, Life of the Ancient Egyptians. University of Oklahoma Press. Norman 1992. s.15.

yaygındı. Bu nedenle Han Hanedanı döneminde (M.Ö.206-M.S.220) çocukların öldürülmesine ve gebe kadınlara şiddet uygulanmasına cezalar getirilmeye başlandı. Tang Hanedanı döneminde ise gebe kadına şiddet uygulamak ve bu nedenle kadının ölümüne neden olmanın cezası idamdı[6].

Eski Yunan'da gebeliğin sonlandırılmasına bakdığımızda Hipokrat Andındaki "....kadınlara çocuk düşürmek için vasıtalar temin etmeyeceğim. ..."[7] sözlerinden Hipokrat okulunun gebeliğin sonlandırılmasına karşı olduğu düşünülebilir[8]. Bununla birlikte Hipokrat külliyatında gebeliğin sonlandırılmasına yönelik bilgilere de rastlanmaktadır[9]. Eski Yunan'da, Hipokrat'ın Andını temel alan bazı hekimler gebeliğin sonlandırılmasına karşı çıktılar[10]. Eski Yunan'daki düşünürler ise gebeliğin sonlandırılmasını savundular. Platon'a göre fetüslerin öldürülmesi ideal devletin uygulamalarından biri idi. Aristo ise nüfusun belli sınırlar içinde kalmasını ve böylece iyi yönetilen bir toplum yaratmanın en iyi yolunun gebeliğin sonlandırılması olduğunu düşünüyordu[11]. Ancak embryo erkekse döllenmeden kırk gün sonra, kız ise doksan gün sonra hareket etmeye başladığına inanan Aristo[12], bu dönemden sonra gebeliğin sonlandırılmasına karşı çıkıyordu. Platoncular ve stoacılar Aristo'nun bu görüşüne katılmadılar. İnsanın hareket etmesini "doğum anı" olarak kabul edip tüm gebelik boyunca uygulanan kürtajı savundular[13].

Eski Yunan'daki bu görüşler arasında Pisagorascılar ise tamamen farklı bir düşünceye sahiptiler. Onlara göre embryo döllenme anından itibaren hareket etme yeteneğine sahipti. İnsan tohumu sıcak buharları içeren beynin bir kılıfı idi. Ruh ve duyunun da bu sıcak buharlardan kaynaklandığına inanıyorlardı. Bu nedenle Pisagorascılara göre gebeliğin sonlandırılması canlının yokedilmesi anlamını taşıyordu[14].

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[6] Bkz. S.M.Rigdon, Abortion Law and Practice in China : An Overview with Comparison to the United States. Soc.Sci.Med. 1996:42(4):543-560.

[7] Bkz. E. M. Atabek, Tıbbi Deontoloji Konuları. Yenilik Basımevi. İstanbul 1983. s.19. Ayrıca Bkz, Hippocratic Writings. Edited with an Introduction by G. E. R. Lloyd, Translated by J. Chadwick – W. N. Mann – I. M. Lonie – E. T. Withington., Penguin Books. 1983., s. 67., Hipokrat andının Eski Yunanca aslından türkçe çevirisi için bkz. K. Dinçmen, Hipokrates'in Yemini. Adli Tıp Dergisi 1995:11:107-109.

[8] Bkz. M.Şehiraltı (Ilgıcı), Aile Planlaması Uygulamalarında Tıp Etiği ile İlgili Sorunların İncelenmesi. (Basılmamış Doktora Tezi) I.Ü.Sağlık Bilimleri Enstitüsü Deontoloji Anabilim Dalı. Danışman A.Altıntaş. İstanbul 1993. s.4

[9] Bkz. Intercourse, conception and pregnancy. Cos, 4th cent. (Hippocrates, On the Generating Seed and the Nature of the Child 4-7, 13, 30.4 = VII. 474-80, 488-92, 536-8 Littre. Tr. I. M. Lonie. G)

http://www.uky.edu/ArtsSciences/Classics/wlgr-medicine341.html

[10] Bkz. Ancient Medicine. Selected Papers of Ludwig Edelstein. Edited by O.Temkin – C.L.Temkin. Translated from german by C.L.Temkin. John Hopkins Press. Baltimore 1967. s.14.

[11] Bkz. Ancient Medicine. Selected Papers of Ludwig Edelstein. Edited by O.Temkin – C.L.Temkin. Translated from german by C.L.Temkin. John Hopkins Press. Baltimore 1967. s.18. ayrıca Bkz. R.N.Shain, A Cross-Cultural History of Abortion. Clinics in Obstetrics and Gynecology 1986:13(1):1-17.

[12] Bkz. J.Areen, "Limiting Procreation". R.M.Veatch (ed), Medical Ethics, Second Edition. Jones and Bartlett Publ. Massachusetts. 1997. s. 122.

[13] Bkz. Ancient Medicine. Selected Papers of Ludwig Edelstein. Edited by O.Temkin – C.L.Temkin. Translated from german by C.L.Temkin. John Hopkins Press. Baltimore 1967. s.18.

[14] Bkz. Ancient Medicine. Selected Papers of Ludwig Edelstein. Edited by O.Temkin – C.L.Temkin. Translated from german by C.L.Temkin. John Hopkins Press. Baltimore 1967. s.18-19.

Eski Yunan'da olduğu gibi Roma'da da fetus kadının bir parçası olarak kabul edilirdi[15]. Roma'da yeni doğan çocuk ancak babası onu kabullenirse yaşayabilir ve topluma katılabilirdi. Aksi takdirde çocuk sokağa terkedilir veya öldürülürdü[16]. Bu nedenle yenidoğanların veya kölelerin dünyaya getirdiği çocukların öldürülmesi ve "gebeliğin sonlandırılması" Roma'da yaşamın bir parçası idi. Doğum sırasında ölen annelerin çocukları da genellikle öldürülürdü . Stoacı düşünürlerden Seneca-"anormal olarak doğanları imha ettiklerini, doğal olmayan oluşumları olan ve zayıf doğan çocukları suda boğduklarını" açıkca yazmıştı[17]. Eski Yunan ve Roma'da hénüz doğmamış olan çocukları koruyan bir yasa olmamakla birlikte bazı kentlerde gebeliğin sonlandırılması yasaklanmıştı. Bunun nedeni babanın soyunu sürdürecek olan çocuğu annenin öldürmesini önlemekti[18].

Efes'li Soranus ebelik ve kadın hastalıkları ile ilgili olan kitabında rastgele yapılan düşüklere karşı çıkmış ve bu uygulamanın ancak annenin sağlığının tehlikede olması durumunda yapılması gerektiğini savunmuştur[19]. Soranus gebeliğin sonlandırılması için nelerin yapılması gerektiğini de ayrıntılı olarak aktarmıştır[20].

Justinian döneminde kürtaja sınırlama getirilmiş ancak bu sınırlamadaki amaç doğacak olan çocuğun haklarını korumak yerine babanın haklarının korunması olmuştu[21].

Ortaçağda kilise ve din adamları gebeliğin sonlandırılmasına karşı olsa da tıp ile ilgili yazma eserlerde bu konuda bilgilere rastlanmaktadır[22]. 11. yüzyıla ait bir yazma eserde verilen cerrahi aletlerin listesi Bizans'da kürtaj uygulamalarının olabileceğini düşündürmek-

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[15] Bkz. M.Mori, Abortion and Health Care Ethics I : A Critical Analysis of the Main Arguments. Principles of Health Care Ethics ed. by R.Gillon, John Wiley & Sons Chichester 1994., s.533.

[16] Bkz. P. Veyne (Ed), A History of Private Life Vol. I., From Pagan Rome to Byzantium. General Editors P. Aries – G. Duby., Translated by A. Goldhammer., The Belknap Press of Harvard Un.Press., London 1987., s. 9-11.

[17] Bkz. J. Noonan, Contraception: A History of Its Treatment by CatholicTheologians and Canonists. Cambridge, MA., Harvard Univeristy Press, 1970'den aktaran Bkz. J. Areen, "Limiting Procreation". R. M. Veatch (ed), Medical Ethics, Second Edition. Jones and Bartlett Publ. Massachusetts. 1997. s. 122.

[18] Bkz. Ancient Medicine. Selected Papers of Ludwig Edelstein. Edited by O. Temkin – C. L. Temkin. Translated from german by C. L. Temkin. John Hopkins Press. Baltimore 1967. s.15-16.

[19] Bkz. M.Şehiraltı (Ilgıcı), Aile Planlaması Uygulamalarında Tıp Etiği ile İlgili Sorunların İncelenmesi. (Basılmamış Doktora Tezi) İ.Ü.Sağlık Bilimleri Enstitüsü Deontoloji Anabilim Dalı. Danışman A.Altıntaş, İstanbul 1993. s.5. ayrıca Bkz. Ancient Medicine. Selected Papers of Ludwig Edelstein. Edited by O. Temkin – C. L. Temkin. Translated from german by C.L.Temkin. John Hopkins Press. Baltimore 1967. s.14.

[20] Bkz. Mensturation, conception, contraception and abortion. Rome, 1st cent.A.D. (Soranus, Gynecology 1.24,26,34,39,40,60,61,64. Tr.O.Temkin.G.) http://www.uky.edu/ArtsSciences/Classics/wlgr-medicine355.html Bu konuda ayrıntılı bilgi için bkz. R.Jackson, Doctors and Diseases in the Roman Empire. British Museum Press 1988. s.108 – 109. aynı eserin türkçe tercümesi için bkz. R.Jackson, Roma İmparatorluğu'nda Doktorlar ve Hastalıklar. Çev. Ş.Mumcu. Homer Kitabevi İstanbul 1999. s.104-106.

[21] Bkz. J. Rachels, The End of Life. Oxford University Press. Oxford. 1986'dan aktaran Bkz. J. Areen, "Limiting Procreation". R.M.Veatch (ed), Medical Ethics, Second Edition. Jones and Bartlett Publ. Massachusetts. 1997. s. 122.

[22] Bkz. L. I. Conrad – M. Neve – V. Nutton ve ark., The Western Medical Tradition. 800 B.C. to A.D.1800. Cambridge University Press. Cambridge 1996. s.169

tedir [23]. Ancak ortaçağ düşüncesi ve onun batı sanatına yansıyan "kıyamet günü" betimlemelerinde gebeliği sonlandıranların en korkunç cezalara çarptırıldığı görülür[24].

18. ve 19. yüzyıllarda Kuzey Amerika yerlileri ile ilgili seyahatnamelerde de yerli halkın gebeliği sonlandırmaya yönelik girişimleri olduğunu, zaman zaman istenmeyen çocukları doğumdan sonra öldürdüklerini, gerek fizik unsurlarla gerekse bitkisel droglarla gebeliği sonlandırmaya çalıştıklarına yönelik bilgilere rastlanmaktadır[25].

İNANÇLARIN GEBELİĞİN SONLANDIRILMASINA YAKLAŞIMI

(i) Budizm

Klasik Hindu anlayışında enkarnasyonun gebeliğin yedinci ayından sonra gerçekleştiğine inananlar olmakla birlikte[26], Hindu öğretisinin klasik metinlerini yorumlayanların çoğunluğu enkarnasyonda döllenmeyi temel alır. Bu nedenle hangi aşamada olursa olsun gebeliğin sonlandırılması insan öldürmekle eş anlam taşır[27]. Japonya'da ise bu konudaki düşünce farklıdır; Japonya'da gebeliğin sonlandırılmasına "üzücü bir gereklilik" olarak bakılır. Kadının veya doğacak olan çocuğun hakları hiç tartışılmaz. Tapınaklarda anne–babanın sonlandırılacak olan gebelikle ölecek olan çocuğa karşı üzüntülerini ve özürlerini dile getirebilecekleri ritüllerde kullanılacak heykelcikler satılır. Anne-baba bu ritüellerde çocuğun bir sonraki yeniden doğuşunda çok daha nitelikli, merhametli ve cömert bir ortamda dünyaya gelmesi için dua ederler[28].

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[24] Bkz. T.S.Miller, The Birth of the Hospital in the Byzantine Empire. John Hopkins University Press. 2nd Edition Baltimore 1997. s.213.

[24] Batı ortaçağ düşüncesinde gebeliği sonlandıranların "kıyamet günü"de görecekleri cezalarının tanımı için bkz. A. Rouselle, Body Politics in Ancient Rome. A History of Women in the West. Vol. I., From Ancient Goddessess to Christian Saints., Ed. by P. S. Pantel., The Belknap Press of Harvard University Press. Massachusets., 1992., s.335-336. ayrıca Bkz. C. Opitz, Life in the Late Middle Ages. A History of Women in the West. Vol. II Silences of the Middle Ages. Ed. by C. Klapish-Zuber., The Belknap Press of Harvard University Press. Massachusets., 1992.s. 290-291.

[25] A. Hrdlicka, Disease, Medicine and Surgery Among the American Aborigines., JAMA vol XCIX No 20 (November 12, 1932) 1661 – 66 ve E.Stiles, Extracts from the Itenararies and Other Miscellanies of Ezra Stiles 1755-1794 .... Ed. by Franklin Bowditch Dexter. New Haven Yale University Press 1916'dan aktaran V.J.Vogel, American Indian Medicine. University of Oklahoma Press. 5th ed. 1986. Norman. s.238-239.

[26] Bkz. J.J.Lipner, "The Hindu View on Abortion and the Moral Status of the Unborn" Hindu Ethics. Ed. H.G.Coward – J.J.Lipner – K.K.Young, Albany, New York State Un. Of New York Press, s. 41-69'dan aktaran J.J.Huges - D.Keown, Buddhism and Medical Ethics: A Bibliographic Introduction. J. of Buddhist Ethics 1995:(2).,
ayrıca bkz http://www.changesurfer.com/Bud/BudBioEth.html

[27] Bkz. J.J.Huges - D.Keown, Buddhism and Medical Ethics: A Bibliographic Introduction. J. of Buddhist Ethics 1995:(2).,
ayrıca bkz http://www.changesurfer.com/Bud/BudBioEth.html

[28] Bkz. W.A.LaFleur, "Contestation and Confrantation: The Morality of Abortion in Japan" Philosophy East and West 1990:40:529-42. ve W.A.LaFleur, Liquid Life: Abortion and Buddhism in Japan. Princeton Un.Press., Princeton 1990.'dan aktaran J.J.Huges - D.Keown, Buddhism and Medical Ethics : A Bibliographic Introduction. J. of Buddhist Ethics 1995:(2)., ayrıca bkz http://www.changesurfer.com/Bud/BudBioEth.html Budizmin gebeliğin sonlandırılmasına yaklaşımı için ayrıca bkz. M.G.Barnhart, Buddhism and the Morality of Abortion. http://jbc.la.psu.edu/5/barnh981.htm. W.R.LaFleur, Abortion, Ambiguity and Exorcism
http://jbc.la.psu.edu/5/LaFleur.htm

(ii) Musevilik

Musevi dünyasının kutsal kitabı Talmud'da "*ubar yerekh imo*" batı dünyasında latince karşılığı "*pars viscerum matris* " olarak yer alan anlayış geçerlidir. Bir başka deyişle fetüs bağımsız bir varlık değil "annenin bir parçası" olarak.kabul edilir[29]. Fetüsün annenin bir parçası olarak kabul edilmesi göreceli olarak daha liberal bir yaklaşım olarak düşünülse bile bu musevilerin üremeye olan geleneksel tutumları ile çelişir[30]. Museviler yaşamın doğumdan sonra başladığına inandığından[31] gebeliğin sonlandırılmasına olan temel yaklaşım annenin korunmasıdır. Bu nedenle annenin yaşamı tehlikede olduğu zaman gebeliğin sonlandırılmasına izin verilir[32] .

(iii) Hristiyanlık

Eski Ahit'de kürtaj ile ilgili açık bir hüküm yoktur. Buna karşın –bugünkü bilgilerimize göre- 1. yüzyıl ile 2. yüzyıl başlarından günümüze kalan belgelerde gebeliğin sonlandırılmasına açık olarak karşı çıkıldı. Bu tutumun nedeninin Roma döneminde gebeliğin sonlandırılması ve çocukların öldürülmelerine (*infantisid*) hoşgörü ile yaklaşılmasına duyulan tepkinin olduğu düşünülebilir. Hiristiyanlığın erken dönemlerinde görülen katı tutum zaman içinde yumuşamaya başladı. Örneğin gebeliğini sonlandıran bir kadın yaşamı boyunca kiliseye kabul edilmezken 4. yüzyıldan itibaren bu ceza 10 yıl ile sınırlandırıldı. Önceleri fetüsün şekillenip şekillenmemesi konusunda bir ayrım yapılmazken, 12. ve 13. yüzyıldan sonra ruhun insan bedenine girebilmesi için fetüsün şekillenmesinin gerektiği görüşü kabul edildi. Embriyoloji konusundaki bilgilerin sınırlı olması nedeni ile, Aristonun yanlış olan erkeklerin 40. kızların ise 90. günde ana rahminde hareket etmeye başladığı düşüncesi hiristiyan dünyasında da kabul gördü. 14. yüzyıl başlarında Dominiken tarikatı fetüsün hareket etmemesi ve annenin yaşamının tehlikede olduğu durumlarda gebeliğin sonlandırılabileceğini tartışmaya başladı. Aynı görüşün Fransiskenler arasında tartışılması ise ancak 16. yüzyılda gerçekleşti. 17.yüzyıl başında kuzeyli hekim Thomas Fienus fetüsün oluşumu ile ilgili bir risale yazdı. Fienus eserinde ruhun döllenmeden en geç 3 gün sonra fetüsün içine girdiğini söylüyordu. Rönesansda Antik çağ düşüncesine olan ilgi Aristo'nun yanlış olan düşüncesinin yeniden etkili olmasına neden oldu. Bunun bir uzantısı olarak da gebeliğin sonlandırılmasının her türü Papa XI. Innocent tarafından yasaklandı[33]. 18.yy.da Aristo'nun döllenme ile ilgili fikir-

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29 Bkz. D.M.Feldman, Abortion: Jewish Perspectives. Encyclopedia of Bioethics. Vol I., Editor in Chief W.T.Reich. The Free Press New York 1982., s. 5.

30 Bkz. J.R.Connerry, Abortion: Roman Catholic Perspective. Encyclopedia of Bioethics. Vol I., Editor in Chief W.T.Reich. The Free Press New York 1982., s. 9-13.

31 Bkz. D.M.Feldman, Abortion: Jewish Perspectives. Encyclopedia of Bioethics. Vol I., Editor in Chief W.T.Reich. The Free Press New York 1982., s. 8

32 Bkz. D.M.Feldman, Abortion: Jewish Perspectives. Encyclopedia of Bioethics. Vol I., Editor in Chief W.T.Reich. The Free Press New York 1982., s. 5-8.

33 Bkz. J.R.Connerry, Abortion: Roman Catholic Perspective. Encyclopedia of Bioethics. Vol. I., Editor in Chief W.T.Reich. The Free Press New York 1982., s. 9-13. Batı dünyasında hiristiyanlığın gebeliğin sonlandırılmasına karşı tutumunun kapsamlı tarihçesine örnek olarak bkz. J.T.Noonan, An Almost Absolute Value in History. The Morality of Abortion. Legal and Historical Perspectives. Ed..by J.T.Noonan. 4th ed., Harvard University Press., Cambridge 1977. s.1-59.

lerinin ağırlığı azaldı. 19.yy'da ise Avrupa'da iyi eğitim görmüş kesimlerde bu görüş genellikle reddedilmeye başladı[34].

Günümüzde katolik görüş, kürtajın her türüne karşıdır. 1965'de toplanan II. Vatikan Konsülü gebeliğin sonlandırılmasını yasaklar ve fetüsün döllenme anından itibaren korunmasına olabilecek en büyük özenin gösterilmesini ister[35]. Ancak annenin tedavisi sırasında fetüsün öleceği biliniyorsa annenin tedavisine izin verilir. Çünkü burada amaç fetüsü öldürmek değil annenin tedavi edilmesidir[36].

Diğer yandan Protestanlar da gebeliğin sonlandırılması ve ruhun bedenle birleşmesi konusunda Katolik'ler gibi tutucu bir görüş benimsediler. Bu konuda Martin Luther (1483-1546) ve John Calvin'nin (1509-1564) görüşleri katolik görüşten pek de farklı değildi. 16. yüzyıldaki reformculara göre de fetüs döllenme anından itibaren bir insandı. Aristo ve Galen'in embriyoloji konusundaki görüşleri hala etkili olduğundan, bir başka deyişle yaşamın spermin içinde olup kadının rahminin sadece bu yaşamın gelişmesi için ortam hazırladığına inanıldığından temel anlayış ruhun tanrı tarafından yaratılarak erkekden gelen spermin içinde saklı olması idi. Bu nedenle fetüsün tüm gebelik boyunca insan ruhuna sahip olduğuna inanıyorlardı. Bunun bir uzantısı olarak da gebeliğin sonlandırılmasına gebeliğin her aşamasında karşı oldular . Embriyolojideki bilgilerin zaman içinde değişmesine rağmen, Protestanlar gebeliğin sonlandırılmasına karşı olan görüşlerini korudular.

(iv) İslam

Müslümanların genel inancına göre ruh ile beden 40. günde birleşmektedir[38]. Hadislere göre ruhun bedenle birleşmesi için üç aşamadan geçmesi gerekir. Bunlar *nutfa* (zygote), *alaka* (implantasyon) ve *mudga* (kas ve iskelet sisteminin oluşmaya başlaması)dır[39]. Bunun dışında 120. günde ruhun bedenle birleştiği inancı da vardır. Bu konuda

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[34] Bu konuda ayrıntılı bilgi için bkz. M.Mori, Abortion and Health Care Ethics I : A Critical Analysis of the Main Arguments. Principles of Health Care Ethics ed. by R.Gillon, John Wiley & Sons Chichester 1994., s.533-538.

[35] Bkz. J.R.Connerry, Abortion: Roman Catholic Perspective. Encyclopedia of Bioethics. Vol. I., Editor in Chief W.T.Reich. The Free Press New York 1982., s. 9-13.

[36] Bkz. R.Munson, Intervention and Reflection. Basic Issues in Medical Ethics., Wadsworth Publ. Company. 3rd.Edition., Belmont 1979. s. 57. katolik görüş için ayrıca bkz. B.Haring, A Teological Evaluation. The Morality of Abortion. Legal and Historical Perspectives. Ed..by J.T.Noonan. 4th ed., Harvard University Press., Cambridge 1977. s.123-145.

[37] Bkz. J.B.Nelson, Abortion. Protestant Perspectives. Encyclopedia of Bioethics. Vol. I., Editor in Chief W.T.Reich. The Free Press New York 1982. Bu konuda ayrıca bkz. J.M.Gustafson, A Protestant Ethical Aproach. The Morality of Abortion. Legal and Historical Perspectives. Ed..by J.T.Noonan. 4th ed., Harvard University Press., Cambridge 1977. s.101-122.

[38] Bkz. Ş.Aksoy. Can Islamic Texts Help to Resolve the Problem of the Moral Status of the Prenate ? Eubios Journal of Asian and International Bioethics 1998:8:76-79. veya http://www.biol.tsukuba.ac.jp/~macer/EJ83/ej83d.html ayrıca Bkz. M. Şehiraltı (Ilgıcı), Aile Planlaması Uygulamalarında Tıp Etiği ile İlgili Sorunların İncelenmesi. (Basılmamış Doktora Tezi) İ.Ü.Sağlık Bilimleri Enstitüsü Deontoloji Anabilim Dalı. Danışman A.Altıntaş. İstanbul 1993. s.8

[39] Bkz. Ş.Aksoy, Can Islamic Texts Help to resolve the Problem of the Moral Status of the Prenate ? Eubios Journal of Asian and International Bioethics 1998:8:76-79. veya
http://www.biol.tsukuba.ac.jp/~macer/EJ83/ej83d.html

farklı mezhepler farklı günü temel almaktadır[40]. Bugün islam dünyasında gebeliğin sonlandırılmasının kabul edilmediği ancak annenin yaşamının veya sağlığının tehlikede olduğu durumlarda veya ağır özürlü bir doğum sözkonusu olduğunda gebeliğin sonlandırılmasına izin verildiği söylenebilir[41].

İslamiyetin gebeliğin sonlandırılmasına daha hoşgörülü yaklaşması tıp tarihinde bazı müslüman hekimlerin bu konuda çeşitli yöntemleri tanımlanmasını da beraberinde getirmiştir. Örneğin batı ortaçağında pekçok hekimin, gebeliğin sonlandırılmasına yönelik teknikleri 1150 yılları civarında Cremona'lı Gerard tarafından arapçadan latinceye çevrilen İbni Sina'nin Kanun adlı eserinden öğrendiği söylenir[42]. Bu konuda 9. yy'da Razi (854-932)'nin getirdiği yöntem[43] ise 17.yy'la kadar etkili olmuştur[44]. Bununla beraber Osmanlı döneminde 18.yy.da Abbas Vesim Efendi "Düstur ül Vesim" adlı eserinde Hipokrat gibi hekimlerin çocuk düşürmeye yarayan şeyleri vermemelerini öğütlemiş, 19.yy ise Hayrullah Efendi hekimin kan dökmekten kaçınmasını ve çocuk almak ve benzeri işler yapmaması gerektiğini söylemiştir[45].

FETÜSÜN DURUMU

Gebeliğin sonlandırılmasının ahlaka uygun olup olmadığına karar verebilmek için "*fetus*" kavramını çözmek gerekir. Bir başka deyişle insan yaşamı ne zaman başlar? fetus bir insan (*human being*) mıdır değil midir ? döllenmeden doğuma kadar olan sürecin neresinde "insan" oluruz ? ne zaman "kişi (*person*)" oluruz ? sorularının yanıtlanması gerekir. Ancak bu soruları yanıtlamak kolay olmadığı gibi bu konuda bir fikir birliğinden de söz etmek mümkün değildir.

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[40] I.Rabab, "Islam and Unwanted Pregnancy". J.F. Hodgson (ed) Abortion and Sterilisation. Medical and Social Aspects., Academic Press. London 1981'den aktaran G.I.Serour, Life: Its Meaning and Sanctity. A Muslim Perspective. Bioethica e Cultura 2. The Sanctity of Life. Physical, Cultural and Religious Problems. Second Mediterranean Meeting on Bioethics. 1994. s.74-75. Bu konuda ayrıca bkz. A.Gürsoy, Abortion in Turkey : A Matter of State, Family or Individual Decision. Soc.Sci.Med. 1996:42(4):534-535.

[41] G.I.Serour – A.R.Omran, Ethical Guidelines for Human Reproduction Research in the Muslim World. IICPSR. Cairo'dan aktaran G.I.Serour, Life: Its Meaning and Sanctity. A Muslim Perspective. Bioethica e Cultura 2. The Sanctity of Life. Physical, Cultural and Religious Problems. Second Mediterranean Meeting on Bioethics. 1994. s.75. ayrıca bkz. G.I.Serour, Reproductive Choice : A Muslim Perspective. The Future of Human Reproduction. Ed. by J Harris – S.Holm. Issues in Biomedical Ethics. Clarendon Press. Oxford 1998. s. 196.

[42] Avicenna, "de regimine abortus" book 3, Fen 21, tract 2, c.12 of Canon Medicine, translation Gerard of Cremona. Venice 1608'den aktaran J.T.Noonan, An Almost Absolute Value in History. In The Morality of Abortion. Legal and Historical Perspectives. Ed..by J.T.Noonan. 4th ed., Harvard University Press., Cambridge 1977. s.21-22.

[43] Bkz. J.Camp. Magic, Myth and Medicine. Priory Press Limited. London 1973. s.41

[44] M.Şehiraltı (Ilgıcı), Aile Planlaması Uygulamalarında Tıp Etiği ile İlgili Sorunların İncelenmesi. (Basılmamış Doktora Tezi) İ.Ü.Sağlık Bilimleri Enstitüsü Deontoloji Anabilim Dalı. Danışman A.Altıntaş. İstanbul 1993. s.8

[45] N.Akdeniz, Osmanlılarda Hekim ve Deontolojisi, İ. Ü. Cerrahpaşa Tıp Fakültesi Tıp Tarihi ve Deontoloji Kürsüsü. Doktora Tezi İstanbul 1977 s. 118-119, 123'den aktaran M.Şehiraltı (Ilgıcı), Aile Planlaması Uygulamalarında Tıp Etiği ile İlgili Sorunların İncelenmesi. (Basılmamış Doktora Tezi) İ.Ü.Sağlık Bilimleri Enstitüsü Deontoloji Anabilim Dalı Danışman A.Altıntaş. İstanbul 1993. s.11

Bugünkü bilgilerimize göre ovuma bir sperm hücresinin girmesi ile birlikte *"döllenme"* gerçekleşir. Döllenen yumurta *zygot*'u oluşturur ve yeni hücre bölünmeleri ile çoğalır. Fallop kanalından uterusa ulaşan hücre kümesine *blastocyte* denir. Bu hücre kümesi 2.haftanın sonunda uterus duvarına yerleşir ve bu aşamadan 8. haftanın sonuna kadar olan dönemde *embryo* olarak adlandırılır. 4. ve 8. haftalar süresince organ sistemleri gelişerek insan şekli belirmeye başlar. 8.haftadan itibaren ise *fetüs* olarak adlandırılır.

Döllenmiş bir yumurta ile doğumundan bir kaç saat önceki bir bebeğin arasında kuşkusuz fark vardır. *Blastocyte* bir doku olarak görülebilirken, *embryo* ve *fetüs*ün bir kişi olarak yaşama hakkının olabileceği daha rahat savunulabilir. Ancak bu bir gelişim süreci olduğundan kürtaja / gebeliğin sonlandırılmasına hangi aşamaya kadar izin verilebilir ? Fetüsün insan görünümünü almasına kadar mı ? kalp atışlarının alınmasına kadar mı ? yoksa uterus dışında yaşayabilecek (*viable*) aşamaya gelinceye kadar mı ?

"(insan) yaşam(ı) ne zaman başlar ? " sorusuna tekrar dönersek, sorunun yanıtlanmasının güçlüğü bir yana sorulmasında bile farklılıklar olduğu görülür; Bir başka deyişle soru "insan yaşamının ne zaman başladığı" olarak mı sorulacaktır yoksa "bireyin yaşamının ne zaman başladığı" olarak mı sorulacaktır. Bu durumda insanın "biolojik olarak varolmasının" veya "birey olarak varolmasının" sorgulanması sözkonusudur ki bu da değerler ve haklar ile de ilgili bir sorgulamayı beraberinde getirecektir[46]. İnsanın varoluşu ile ilgili bir sorunun yanıtı kuşkusuz sadece biolojik, genetik veya bilimsel verilerle sınırlı kalmayacak, bu yanıta felsefenin yaklaşımı da eklenecektir. Günümüzde bu soruya verilmeye çalışılan yanıtlar şu şekilde özetlenebilir;

(i) *bireyci – biolojik (individual – biological criterion) yaklaşım* : Bu yaklaşım insanın varoluşunu açıklamada genelde bireyin fiziksel, biolojik ve genetik yönünü temel alır ve yaşamın başlangıcı olarak doğumu kabul eder. Ancak yeni doğan bir bebek ile bebeğin doğumundan bir gün önceki durumu arasında nitelik olarak anlamlı bir farklılık yoktur. Diğer taraftan yeni doğan bir bebek de pek bağımsız olmayıp annesine ve çevresine bağımlıdır[47].

Yaşayabilirlik (viability), bir başka deyişle dünyaya gelen bebeğin ana rahmi dışında yaşayabilmesi, insan yaşamının gerçek anlamda başlaması olarak sıklıkla temel alınan kriterlerden biridir. Bu kriter de tıp ve bilim dünyasındaki hızlı teknolojik ilerlemelerle ilgili olarak sıklıkla değişebilecek bir kriterdir[48].

Fetüsün anne karnında hareket etmeye başlamasını (*animation*) yaşamın başlangıcı olarak kabul eden görüş ise fetüsün hareketinin ruhun bedene girmesi olarak algılayan

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[46] Bkz. C.E.Curran, Abortion : Contemporary Debate in Philosophical and Religious Ethics. Encyclopedia of Bioethics. Vol. I., Editor in Chief W.T.Reich. The Free Press New York 1982. s.18-20.

[47] Bkz. C.E.Curran, Abortion : Contemporary Debate in Philosophical and Religious Ethics. Encyclopedia of Bioethics. Vol. I., Editor in Chief W.T.Reich. The Free Press New York 1982. s. 18-20

[48] Bkz. C.E.Curran, Abortion : Contemporary Debate in Philosophical and Religious Ethics. Encyclopedia of Bioethics. Vol. I., Editor in Chief W.T.Reich. The Free Press New York 1982. s.18-20.

Thomas Aquinas ve diğer ortaçağ din bilimcileri ve düşünürleri tarafından kabul edilen ve temeli ortaçağa dayanan bir yaklaşımdır[49].

Benzer bir başka yaklaşım ise insan yaşamının başlangıcında korteksin oluşumunu temel alır. Beynin eletriksel faaliyetleri sekizinci haftada başlar. Eğer yaşam bilinç ile başlarsa o zaman beynin eletriksel faaliyetlerinin başlangıcı da yaşamın başlangıcı olarak temel alınmalıdır. Bu görüş EEG'nin düz bir çizgi oluşturmasını ölüm olarak kabul edenlerle de bir bütünlük oluşturur[50].

Günümüzde bireyci-biyolojik yaklaşımı benimseyenlerin bir bölümü ise yaşamın başlangıcını döllenmiş yumurtanın ana rahminin duvarına tutunmasını (*implantasyon*) temel almaktadır[51].

John Harris ise yaşamın bir süreklilik oluşturduğunu iddia eder, Harris'e göre yaşam döllenme anında ortaya çıkmaz. Onun öncesinde de zaten vardır. Çünkü gerek yumurta gerekse sperm hücresi canlıdır ve bir gelişim ve olgunlaşma evresinden geçerler. Yaşam kesintisiz olarak devam eden bir süreçtir. Bir başka deyişle döllenme ile başlayan yaşam değil, yeni bir bireydir[52]

(ii) ilişki / iletişim kurabilmeyi temel alan yaklaşım : Bu görüşe göre insan yaşamı ve bireyin yaşamını çeşitli ilişki türleri oluşturur. Bedenin biyolojik olarak yaşamasına rağmen beyin dalgalarının alınamaması ölüm olarak kabul ediliyorsa, biyolojik kriterler de yaşam olarak kabul edilmemelidir. Bu bakış açısına göre gerçek anlamda insan ilişkileri doğuma kadar hatta doğumdan bir yıl sonrasına kadar başlayamaz. Ancak bu görüşte olanlar yeni doğanı her ne kadar bir birey olarak kabul etmese de aile ve toplum içinde bir işlevi ve rolü olduğunu yadsımaz[53].

(iii) Çok yönlü yaklaşım : Bu yaklaşım bir anlamda ilk iki görüşün sentezinden oluşur. Callahan tarafından savunulan bu görüşte yaşamın başlangıcının biyoloji ve psikoloji açısından açıklanmasının yanısıra "kültür" boyutunun da önemini vurgular[54].

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[49] Bkz. C.E.Curran, Abortion : Contemporary Debate in Philosophical and Religious Ethics. Encyclopedia of Bioethics. Vol. I., Editor in Chief W.T.Reich. The Free Press New York 1982. s.18. Thomas Aquinas gibi ortaçağ düşünürlerine göre yaşam semen ve menstural kanamadan oluşurdu. Bunların ikisi de cansız olup semenin içindeki güç kanı beden haline sokar bu da önceleri bir bitki daha sonra da hayvana benzer bir şekilde gelişip beslenirdi. Bkz. J.Finnis, Abortion and Health Care Ethics II. Principles of Health Care Ethics ed. by R.Gillon, John Wiley & Sons Chichester 1994., s.548.

[50] Bkz. C.E.Curran, Abortion : Contemporary Debate in Philosophical and Religious Ethics. Encyclopedia of Bioethics. Vol. I., Editor in Chief W.T.Reich. The Free Press New York 1982. s.18-20.

[51] Bkz. C.E.Curran, Abortion : Contemporary Debate in Philosophical and Religious Ethics. Encyclopedia of Bioethics. Vol. I., Editor in Chief W.T.Reich. The Free Press New York 1982. s.18-20.

[52] Bkz. J.Harris, The Value of Life, Routledge. 2nd ed. London 1991. s. 10. aynı eserin türkçesi için bkz. J.Harris, Hayatın Değeri. Tıp Etiğine Giriş. Çev. S.Sertabiboğlu. Ayrıntı Yayınları. 1998. s. 31-32.

[53] Bkz. C.E.Curran, Abortion : Contemporary Debate in Philosophical and Religious Ethics. Encyclopedia of Bioethics. Vol. I., Editor in Chief W.T.Reich. The Free Press New York 1982. s.20-21.

[54] Bkz. C.E.Curran, Abortion : Contemporary Debate in Philosophical and Religious Ethics. Encyclopedia of Bioethics. Vol. I., Editor in Chief W.T.Reich. The Free Press New York 1982.s. 21.

İnsan yaşamının ne zaman başladığı ve ne zaman "insan" olarak kabul edileceğimiz sorusunun yanıtı bu denli güç ve farklı görüşleri içerir. Kuşkusuz bu yanıt bizim bireysel değer yargılarımıza, yaşam ve dünya görüşümüze göre de değişkenlik gösterecektir.

FETÜS(ÜN) HAKLARI

Fetüsün "değeri (*value*)" ve "hakları" da "yaşamın ne zaman başladığı" sorusuna verilen yanıt ile yakından ilgilidir. Fetüs bir "insan" olarak kabul edenlere göre fetüs de bir insan ile aynı haklara ve onun değerine eş bir değere sahip olacaktır[55].

Fetüsün hukuk açısından konumu ise ülkelere göre farklılıklar göstermektedir[56]. Bu bağlamda bazı ülkelerde doğmamış çocuğa (*unborn child*) bağış ve vasiyet yapılabilmesi bile mümkün olmaktadır[57].

Son-yıllardaki yayınlarda dondurulmuş olan embriyoların (*frozen embryos*) hakları da incelenmeye başlamıştır. ABD'de embryo üzerindeki hak kadının temel hakları arasında kabul edilmekle birlikte dondurulmuş embryolarda erkeğin de hakkı olduğu kabul edilmiştir. Eşlerin boşanması veya ölümü halinde ortaya çıkan yasal sorunlarla, dondurulmuş embriyoların miras yolu ile mirascılara geçip geçemeyeceği gibi önemli sorunlar da ortaya çıkabilmektedir[58]. Bu konuda Broekhuijsen-Molenaar'ın görüşü ise "embryonun bir "kişi" olmasa da gelecekte bir "hukuk nesnesi"olacağından "belirli bir saygıya ve korumaya" layık olacağı yönündedir. Embriyoya eşler ortak olarak sahip olduklarından her eşin embriyo üzerinde bölünmez payı vardır. Bu nedenle embriyo miras yolu ile başkalarına geçebilir ancak mirasçı olamaz[59] şeklindedir.

GEBELİĞİN SONLANDIRILMASINA KARŞI OLAN GÖRÜŞLER

Fetusü insan olarak tanımlayanlar kürtaja kesinlikle karşı çıkarlar. Bu görüşe sahip olanlar fetüsü bilinci kapalı olan ve yaşama hakkını savunamayan kişilerle eş tutarlar ve fetüsün yaşama hakkı olduğunu savunurlar[60]. Bu görüşe taraftar olanlara göre kürtaj, "in-

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55 Bkz. C.E.Curran, Abortion : Contemporary Debate in Philosophical and Religious Ethics. Encyclopedia of Bioethics. Vol. I., Editor in Chief W.T.Reich. The Free Press New York 1982.s. 22.

56 Bu konuda İngiltere'nin yaklaşımı, ABD ve Kanada'daki bazı mahkeme kararları için bkz. J.K.Mason – R.A.McCall Smith – G.T.Laurie, Law and Medical Ethics. Butterworths., London 1999. s.124-138., Anglo Sakson Hukuk sisteminin fetüs haklarına yaklaşımı için bkz. D.W.Louisell – J.T.Noonan, Constitutional Balance. In The Morality of Abortion. Legal and Historical Perspectives. Ed.,by J.T.Noonan. 4th ed., Harvard University Press., Cambridge 1977. s.220-260.

57 Bkz. E.Özsunay, Hayatın Başlangıcı ve Sonuna İlişkin En Önemli Hukuksal Sorunlar. (Prof. Dr. Bülent Davran'ın anısına Armağan'dan ayrı bası) s.12

58 Bkz. E.Özsunay, Hayatın Başlangıcı ve Sonuna İlişkin En Önemli Hukuksal Sorunlar. (Prof. Dr. Bülent Davran'ın anısına Armağan'dan ayrı bası) s.12-14.

59 A.M.L.Broekhuijsen-Molenaar; The Legal Status of the Embryo in Vitro, Council of Europe, 3rd Symposium on Bioethics : Medically Assisted Procreation and the Protection of the Human Embryo, Strasbourg 13-15 December 1990 CDBI / SPK(96)'dan aktaran Bkz. E.Özsunay, Hayatın Başlangıcı ve Sonuna İlişkin En Önemli Hukuksal Sorunlar. (Prof. Dr. Bülent Davran'ın anısına Armağan'dan ayrı bası) s.14-15.

60 Bkz. R.Munson, Intervention and Reflection. Basic Issues in Medical Ethics., Wadsworth Publ. Company, 3rd.Edition., Belmont 1979. s. 55.

san öldürme"nin bir türüdür ve kesinlikle yasaklanmalıdır. Çünkü fetüs masum bir insandır. Kürtaj yolu ile masum bir insanın öldürülmesi ise cinayettir ve hiçbir zaman kabul edilemez[61].

Devin'e göre fetüs döllenme anından itibaren doğmuş olan bir insanla aynı statüdedir. Çünkü insan türünün bir örneğidir (*tür ilkesi*), zaman içinde düşünecek, konuşacak, sevecek ve adalet duygusuna sahip olacaktır (*potansiyellik ilkesi*). Bu ilkeler gereği fetüsler döllenme anından itibaren korunmalı ve gebeliğin sonlandırılması cinayet olarak kabul edilmelidir[62]. Bu görüşte olanlar annenin yaşamı tehlikede olsa bile gebeliğin sonlandırılmasına karşıdır. Bir başka deyişle kadının -kendi yaşamı için bile olsa- gebeliğini sonlandırması doğru değildir[63].

Gebeliğin sonlandırılmasına karşı olanlara göre gebelik, tecavüz, ensest ilişki vb. sonucunda oluşsa bile gebelik sonlandırılamaz. Bu görüşü inançlar temelinde katolik inancı savunur[64].

GEBELİĞİN SONLANDIRILMASINA TARAFTAR OLAN GÖRÜŞLER

Gebeliğin sonlandırılmasına taraftar olanlar ise "sosyal nedenler" veya "psikolojik unsurlar" da dahil "kadının sağlığının korunmasına" öncelik verirler. Hatta bu görüşü paylaşanların bir kısmı "sadece kadının kürtaj istemini" yeterli bulurlar[65]. Bu görüşte olanların bazılarına göre fetüs bir insan / kişi (*person*) değildir. Dolayısı ile kürtaj apendektomi gibi organik bir maddenin bedenden ayrılması ile eşdeğerdir. Fetüs kadının bedeninin bir dokusu, bir parçasıdır. Bu nedenle üreme konusunda verilecek olan karar gibi fetüs hakkında verilecek karar da kadının özgürlüğünün bir parçasıdır ve kadına aittir[66].

Bir insan olarak fetüsün yaşama hakkı varsa, bir insan olarak da annenin yaşama hakkı vardır. Bu iki yaşama hakkının eşit olduğu varsayılırsa, annenin kendi bedeninde / bedenine olanlarla ilgili olarak karar verme hakkı olduğundan, kararının daha ağırlıklı olarak anneye ait olduğu savunulur[67].

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[61] Bkz. J.J. Thomson, A Defense of Abortion. In Bioethics. An Anthology., Edited by H. Kuhse – P.Singer, Blackwell Philosophy Anthologies., Blackwell Publisher 1999., s.38.

[62] P.Devine, The Ethics of Homicide. Ithaca, NY Cornell University Press 1978'den aktaran J.Areen, "Limiting Procreation". R.M.Veatch (ed), Medical Ethics, Second Edition. Jones and Bartlett Publ. Massachusetts. 1997. s. 118.

[63] B.Brody, Abortion and the Sanctity of Human Life: A Philosophical View. Cambridge, MA. MIT Press 1975'den aktaran J.Areen, "Limiting Procreation". R.M.Veatch (ed), Medical Ethics, Second Edition. Jones and Bartlett Publ. Massachusetts. 1997. s. 118.

[64] Bkz. Ş.Aksoy, Abortion: The Destruction of Life. Eubios. Journal of Asian and International Bioethics 1997:7:53-54., veya http://www.biol.tsukuba.ac.jp/~macer/EJ72/EJ72M.html

[65] Bkz. M.Mori, Abortion and Health Care Ethics I : A Critical Analysis of the Main Arguments. Principles of Health Care Ethics ed. by R.Gillon, John Wiley & Sons Chichester 1994., s.531.

[66] Bkz. C.E.Curran, Abortion : Contemporary Debate in Philosophical and Religious Ethics. Encyclopedia of Bioethics. Vol. I., Editor in Chief W.T.Reich. The Free Press New York 1982.s. 22. Bu konuda ayrıca bkz. H.V.McLachlan, Bodies, Rights and Abortion. Journal of Medical Ethics 1997:23:176-180.,

[67] Bkz. J.J. Thomson, A Defense of Abortion. In Bioethics. An Anthology., Edited by H. Kuhse – P.Singer, Blackwell Philosophy Anthologies., Blackwell Publisher 1999., s.37.

Bazı görüşler gebeliğin sonlandırılması kararını kadının mahremiyet (*privacy*) hakkının bir parçası olarak görmektedir[68]. Feminist yaklaşım olarak adlandırılabilecek bu görüşler de çeşitlilik göstermektedir. Bazı feminist yaklaşımlar sadece kadının kendi bedeni ile ilgili özgürlüğünü temel alırken, bir diğer feminist yaklaşım ise gebeliğin sonlandırılması kararında fetüsün değil kadının temel alınması gerektiğini savunur. Bir başka deyişle verilecek olan kararda fetüsün durumunu değil kadının fetüse karşı olan duyguları, partneri ile olan ilişkileri ve diğer çocuklarının içinde bulunduğu koşullar çerçevesinde kürtajı seçme hakkının temel alınması gerektiğini savunur[69]. Bazı gebeliklerin tecavüz, ensest ilişki sonucu ortaya çıktığını, bunun gerek kadın gerekse çocuk üzerindeki etkilerinin göz ardı edilemeyeceğini dile getirir. Ayrıca gerek geçmişte, gerekse günümüzde kültürel değerler nedeni ile gebeliğin sonlandırılmasının yasak / yasa dışı olduğu toplumlarda kadınların sağlıksız koşullarda gerçekleştirmek zorunda kaldıkları kürtajlar, bunların kadın sağlığına olumsuz sonuçları ve bu nedenle görülen kadın ölümlerini tartışmaların temeline alır[70].

ARA GÖRÜŞ

Bu görüşte olanlar gebeliğin sonlandırılmasına karşı olanların savundukları fikirlerin pek çoğuna katılmazlar. Gebeliğin sonlandırılmasına karşı olmakla birlikte annenin sağlığının tehlikede olduğu durumlarda gebeliğin sonlandırılmasını kabul ederler[71].

Bu görüşte olanlara göre ise fetüs bir kişi (*person*) olmamakla birlikte bu potansiyeli taşır. Bu nedenle herhangi bir organik madde ile eş tutulamaz. Gebeliğin sonlandırılması kişi olma potansiyelini taşıyan bir dokunun ortadan kaldırılması anlamına geleceğinden ahlaki sorunlara neden olabilir. Bu nedenle gebeliğin sonlandırılmasının savunulabilir nedenleri olmalıdır[72].

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[68] Bu konuda verilmiş olan bazı mahkeme kararları için bkz. G.J.Annas. The Impact of Medical Technology on the Pregnant Woman's Right to Privacy. American Journal of Law & Medicine 1987 vol XIII no 2-3., s.213-232., J.A.Robertson, Gestational Burdens and Fetal Status . Justifying Roe v.Wade. American Journal of Law & Medicine 1987 vol XIII no 2-3., s.189-212.

[69] Bkz. S.Sherwin, Abortion : A Feminist Perspective. J.D.Arras – B.Steinbock, Ethical Issues in Modern Medicine. 4th Edition., Mayfield Publishing Company. Toronto 1995. s. 361-369. Gebeliğin cerrahi girişim yerine ilaçla sonlandırılması konusu ve getirdiği etik sorunlara burada yer verilmeyecektir. Bu konuda bkz. R.J.Cook –D.A.Grimes, Antiprogestin Drugs . Ethical, Legal and Medical Issues. Law, Medicine & Health Care 1992:20(3):149-153., R.Macklin, Antiprogestin Drugs : Ethical Issues. Law, Medicine & Health Care 1992:20(3):215-219., R.Boland, RU 486 in France and England: Corporate Ethics and Compulsory Licensing. Law, Medicine & Health Care 1992:20(3):226-234., S.S.Banwell – J.M.Paxman, The Research for Meaning. RU 486 and the Law of Abortion. Am.J.of Public Health 1992:82(10):1399-1406.

[70] Bkz. S.Sherwin, Abortion : A Feminist Perspective. J.D.Arras – B.Steinbock, Ethical Issues in Modern Medicine. 4th Edition., Mayfield Publishing Company. Toronto 1995. s. 361-369.

[71] Bkz. J.J. Thomson, A Defense of Abortion. In Bioethics. An Anthology., Edited by H. Kuhse – P.Singer. Blackwell Philosophy Anthologies., Blackwell Publisher 1999., s.39-42.

[72] Bkz. R.Munson, Intervention and Reflection. Basic Issues in Medical Ethics., Wadsworth Publ. Company. 3rd.Edition., Belmont 1979. s. 55.

Yine bu görüşe göre tecavüz, insest vb. trajik olguların varlığında[73] kürtaj uygulanması kabul edilir[74]. Ancak hemen her zaman kürtaj uygulanmasını da kabul etmezler. Önceden planlanmamış bir gebelik veya başlangıçta istenmeyen bebeklerin doğumlarından sonra çok sevilebildiklerini savunurlar. Gerek giderek gelişen fetüs hakları gerekse kadın, hekim, diğer çocuklar ve eşin olası psikolojik sorunlardan etkilenmemeleri için gebeliğin olabildiğince erken dönemde sonlandırılması gerektiği görüşündedirler[75].

Bu görüşte olanlar günümüzde yasa ile ahlakın birbirinden ayrı düşünülmesi gerektiğini, kürtajın yasaklanması ile bu uygulamaların yasadışı olarak uygunsuz koşullarda yapılmaya devam edeceğini ve kadınların sağlıklarının ciddi tehlikelerle karşı karşıya kalacağını savunurlar[76]. Bu nedenle gebeliğin sonlandırılmasının yasallaşmasını, böylece kadınların -uygun olmayan, sağlıksız koşullarda gerçekleştirilen kürtaj uygulamaları (*back-street practices*) ile- yaşamlarının ve sağlıklarının tehlikeye atılmasının önleneceğini savunurlar[77].

Bu görüşü paylaşanlar "istenmeyen gebeliklerin ciddi sorunlar getirebileceğini kabul etmekle birlikte, fetusün yaşama hakkının kadının özerkliği ve sosyal koşullardan daha önemli olduğunu"[78] savunurlar.

TEDAVİ AMACI İLE KÜRTAJ UYGULANMASI (*Therapeutic Abortion*)

Bazı durumlarda annenin yaşamını kurtarmak için kürtaj uygulanması gerekebilir. Bu olgularda kürtaj annenin korunması için zorunludur. Bu nedenle gerçekleştirilen kürtaj genelde tüm dünyada kabul görür. Dünya Tıp Birliğinin 1970 yılında yayınladığı *Oslo Bildirgesi* "Tedavi Amacı ile Kürtaj Uygulanması" ile ilgilidir. Bu bildirgede *Cenevre Bildirgesi*'nde belirtilen "insan yaşamına döllenme anından itibaren saygı göstereceğim" cümlesi vurgulandıktan sonra, ilgili ülkenin yasalarının izin vermesi durumunda, gebeliği sonlandırmanın gerekli olduğunu iki hekimin yazılı olarak belirtmesi ve gebeliğin sonlandırılmasının yetkili mercilerce, yetkinlikleri kabul edilmiş hekimler tarafın-

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[73] Tecavüz veya ensest ilişki sonucu oluşan gebeliklerin sonlandırılmasına karşı çıkanların savundukları düşünceler genelde, "tecavüzün sonucu olarak da oluşsa onların da yaşama hakları vardır" veya " her insanın yaşama hakkı vardır. Ancak tecavüz sonucu oluşmuşlarsa bunların daha az yaşama hakkı vardır" görüşü ile karşı çıkarlar. Bkz. J.J. Thomson, A Defense of Abortion. In Bioethics. An Anthology., Edited by H. Kuhse – P.Singer, Blackwell Philosophy Anthologies., Blackwell Publisher 1999., s.37.

[74] Bkz. M.Mori, Abortion and Health Care Ethics I : A Critical Analysis of the Main Arguments. Principles of Health Care Ethics ed. by R.Gillon, John Wiley & Sons Chichester 1994., s.532.

[75] Bkz. BMA's Ethics, Science and Information Division (Head of Division F.Fisher), Medical Ethics Today : Its Practice and Philosophy. 2nd. Ed., Published by BMJ Publishing Group., London 1995. s.104-105.

[76] Bkz.M.Mori, Abortion and Health Care Ethics I : A Critical Analysis of the Main Arguments. Principles of Health Care Ethics ed. by R.Gillon, John Wiley & Sons Chichester 1994., s.532.

[77] Bkz. BMA's Ethics, Science and Information Division (Head of Division F.Fisher), Medical Ethics Today : Its Practice and Philosophy. 2nd. Ed., Published by BMJ Publishing Group., London 1995. s.104-105.

[78] Bkz. M.Mori, Abortion and Health Care Ethics I : A Critical Analysis of the Main Arguments. Principles of Health Care Ethics ed. by R.Gillon, John Wiley & Sons Chichester 1994., s.532.

dan gerçekleştirilmesi koşulu ile kürtaj uygulamalarını kabul etmektedir. Bununla birlikte hekimlerin özerkliğine saygı olarak, "inancı gereği kürtaj uygulamak veya önermek istemeyen" hekimlere, hastanın bakımının devamlılığının güvence altına alınması koşulu ile, hasta bir başka hekimin sorumluğuna verildikten sonra tedaviden çekilme hakkı tanınmıştır[79].

Annenin "yaşamını kurtarmak" için kabul edilen kürtaj, annenin "sağlığının tehlikede olduğu" durumlar için de geçerli midir? Eğer anneye uterus kanseri tanısı konmuş ve annenin yaşamını kurtarmak için uygulanacak olan cerrahi girişim fetüsün ölümü ile sonuçlanacaksa kürtaj uygulanmasını kabul edebiliriz. Ancak annenin psikolojik sorunları söz konusu olduğunda durum ne olacaktır? Annenin ruh sağlığı ile kürtaj arasında bir ilinti olması gebeliğin sonlandırılmasına gerekçe oluşturur mu ? Eğer bir psikiyatrist kadının gebeliğin getirebileceği psikolojik sorunların üstesinden gelemeyeceğine inanıyorsa, bunun ağır psikiyatrik sorunlar oluşturacağını düşünüyorsa, gebeliğin sonlandırılmasını düşünebilirmiyiz?

Bazı araştırmacılar kadının sağlığının tehlikede olduğu durumlarda yasal olarak gebeliğinin sonlandırılması talebinin geçerli olmasına rağmen sözü edilen sağlık riskinin ne denli önemli olduğunu da sorgulamaktadır. Sözü edilen sağlık riskinin çok önemli boyutlarda olmaması durumunda, kendi değerleri açısından gebeliği sonlandırmak istemeyen bir hekim, hastayı başka bir hekime yönlendirse bile, bunun doğacak olan çocuğun ölümüne neden olacağını bildiği için kendi değerlerini zedeleyeceğini savunmaktadır[80].

KÜÇÜKLERİN (MİNORS) GEBELİĞİN SONLANDIRILMASINDA KARŞILAŞILAN ETİK SORUNLAR

Küçüklerin (*minors*) gebeliklerinin sonlandırılmasına yönelik talepleri, gebeliğin sonlandırılmasında karşılaşılan etik sorunların yanısıra meslek sırrının korunması konusunda da önemli etik ikilemleri beraberinde getiren bir konudur. Diğer konularda olduğu gibi küçükler yetişkin olmamaları, deneyimsizlikleri veya sorunlarla ilgili yargılarında yetersiz olabileceklerinden seçeneklerini değerlendiremeyebilirler. Bu durumda ebeveynler danışılabilecek en uygun kişilerdir. Bununla beraber bazı durumlarda ebeveynlerin gebeliğin sonlandırılması ile ilgili olarak verilecek karara katılmalarının istenmesi hastanın fizik veya ruhsal olarak zarar görmesine neden olabilmektedir. Bu durumda ebeveynlerin bilgilendirilmesi ile bireyin cinselliği ile ilgili olan mahremiyet hakkı (*privacy*) çatışabilmektedir.

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[79] Bkz Statement on Therapeutic Abortion. Declaration of Oslo. World Medical Association Inc. Handbook of Declarations., ayrıca bkz. A.G.Johnson, Pathways in Medical Ethics, Edward Arnold. London 1990.s.101-102. Adı geçen bildirgenin türkçe örneği için bkz. Oslo Bildirgesi. Tedavi Amaçlı Düşüğe İlişkin Duyuru. Sağlıkla İlgili Uluslararası Belgeler. Dünya Tabipler Birliği Avrupa Konseyi, Birleşmiş Milletler, Unesco, Avrupa Tabip Birlikleri Forumu. Yayına Hazırlayan F.Sayek. Türk Tabipler Birliği. Haziran 1998., s.21.

[80] Bkz. R.M.Veatch, The Patient – Physician Relationship. The Patient as Partner. Part 2., Indiana University Press. Bloomington., 1991. s.152-153.

Amerikan Tıp Birliği'nin Etik ve Yasal İşler Konseyi (*American Medical Association. Council on Ethical and Judicial Affairs*) 1992 yılında Küçüklerin (*Minors*) tıbbi bakımlarında meslek sırrı kavramını incelemiştir. Konsey "küçüklerin mental hastalıklar, cinsel yolla bulaşan hastalıklar ve uyuşturucu kullanımı gibi duyarlı konularda tıbbı bakımdan vazgeçmemeleri için meslek sırrının korunmasında güvence verilmesinin önemini vurgulamış" ve "çocukların tıbbi bakımlarına ebeveynlerin katılımının her zaman önemli ve genellikle gerekli olmakla birlikte, temel amaca zarar verebilen bazı koşullarda, yasa gerektirmedikçe zorunlu olmamasına" karar vermiştir[81]. Günümüzde küçüklerin gebeliklerinin sonlandırılması konusunda ABD'de bazı eyaletler ebeveynlerin bilgilendirilmesini yasal bir zorunluluk olarak öngörürken bazı eyaletler böyle bir zorunluluk getirmemektedir .

DOĞACAK ÇOCUĞUN CİNSİYETİNİN VE KÜLTÜREL DEĞERLERİN GEBELİĞİN SONLANDIRILMASI KARARINA ETKİSİ VE ETİK SORUNLAR

Gebeliğin sonlandırılması için öne sürülen bazı gerekçeler gerçekten sorun oluştururlar. Bu gerekçelerde içinde yaşanılan kültür de belirleyici olur[83]. Örneğin kadının herhangi bir genetik hastalığı sözkonusu olmadığı halde sadece doğacak çocuğun cinsiyeti nedeni ile kürtaj talebinde bulunması -ülkemiz de dahil- bazı kültürlerde hekimlerin karşılaştıkları ciddi bir sorundur. Kültürel nedenlerle erkek çocukların daha çok önemsendiği veya daha önce doğan çocukların tümünün aynı cinsiyeti taşıması bazı ebeveynler için gebeliğin sonlandırılmasına bir gerekçe oluşturabilir[84]. Sağlıklı bir fetüsün sadece cinsiyeti nedeni ile yaşamının sonlandırılması etik açıdan kabul edilemez. Bu durumda ebeveynin kararlarının hekim tarafından etkilenmesi ve yönlendirilmesi etik açıdan kabul edilebilir. Eğer hekim kadının kürtaj talebinden vazgeçmesini sağlayamaz ise hastanın tedavisinden çekilmesi ise etik açıdan kabul edilmelidir[85]. Bunun yanısıra bazı ülkelerde gebeliğin sonlandırılmasının bir doğum kontrol yöntemi olarak algılanması ve bu

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[81] Bkz. American Medical Association. Council on Ethical and Judicial Affairs, Mandatory Parental Consent to Abortion. JAMA 1993:269(1):82-86. Amerikan Tıp Birliğinin bu konudaki görüşü için ayrıca bkz. American Medical Association. Council on Ethical and Judicial Affairs. Code of Medical Ethics. Current Opinions with Annotations. 1994. Edition., Chicago Illinois, 1994., s.2-3.

[82] 1993 yılında ABD'de eyaletlerin bu konudaki yasal yaklaşımının dökümü için bkz American Medical Association. Council on Ethical and Judicial Affairs, Mandatory Parental Consent to Abortion. JAMA 1993:269(1):85.

[83] İçinde yaşanılan kültürün özelliklerinin kürtaj kararına olan etkisi için bkz. B.Rylko-Bauer, Abortion From A Cross Cultural Perspective . An Introduction. Soc.Sci.Med. 1996:42(4):479-482.

[84] Örneğin Hindistan'da 1978 – 1983 yılları arasında 78.000 fetüsün cinsiyeti nedeni ile yaşamlarına son verilmiştir. Bkz. M. Parikh, Sex Selective Abortions in India : Parental Choice or Sexist Discrimination ? Fem. Issues 1990;10(2):19-32'den aktaran S.K.Khanna, Traditions and Reproductive Technology in an Urbanizing North Indian Village. Soc.Sci.Med 1997:44(2):171-180.

[85] Bkz. B.Lo, Resolving Ethical Dilemmas. A Guide for Clinicians. 2nd ed. Lippincott Williams & Wilkins. Philadelphia 2000. s. 306.

amaçla geleneksel yöntemlerin kullanılması[86] gerek etik açıdan gerekse kadın sağlığı açısından önemli bir sorundur.

ETİK İLKELER AÇISINDAN GEBELİĞİN SONLANDIRILMASI

Gebeliğin sonlandırılmasını etik ilkeler açısından incelediğimizde ortaya çıkabilecek ikilemler şöyle özetlenebilir;

Özerklik ilkesi açısından baktığımızda gebe kadının hekim tarafından tüm tıbbi olasılıklar hakkında bilgilendirildikten sonra kendi bedenini tıbbi açıdan ilgilendiren bir konuda karar verme hakkı vardır. Fetüsün lehine kadının davranışını veya kararını etkilemek kadının özerkliğini de ihlal edeceğinden özerklik ilkesi açısından sorun oluşturur. Bunun yanısıra özerklik ilkesi hekim özerkliği açısından da değerlendirilmelidir. Bu bağlamda hekimin etik olmayan veya yasadışı uygulamaları reddetme hakkı da dahil hekimin, mesleğinin kabul edilmiş standardları içinde hekimliğini uygulaması konusundaki duyarlılığı da dikkate alınmalıdır[87]. Ayrıca hekimin kendi değerleri nedeni ile gebeliği sonlandırmayı reddetme hakkına da saygı gösterilmelidir.

Fayda ilkesi ise gebelik sürecinin her aşamasında söz konusu olan bir ilkedir. Bu ilke hekimi gebe kadını gebeliği sürecinde her türlü zarardan koruma yükümlülüğünü vurgular. Hekimin aynı zamanda fetüse karşı faydalı olma yükümlülüğü de vardır. Zaman zaman hekimin fetüse karşı fayda yükümlülüğü ile annenin özerkliği ve faydası birbiri ile çelişebilir. Bu durumda fayda ödevi hangi taraf için daha çok gerekli ise, o taraf lehine kullanılarak dengelenmelidir. Fayda ilkesi aynı zamanda fetüsün babası veya ailenin diğer bireyleri içinde söz konusudur. Ancak bu bireylerin esenliği (*well-being*) anne ve fetüs arasındaki etik ikilemler kadar çarpıcı değildir. Tüm bunların yanı sıra hekimin esenliği de göz ardı edilmemelidir. Bu özellikle hekimin ciddi bir yasal risk alması durumunda sözkonusudur. Hekimin hastası için alabileceği olası yasal risklerin de bir sınırı olduğu unutulmamalıdır[88].

Eğer doğmamış olanlar "insan" veya "birey" ise *adalet ve zarar vermeme* ilkeleri kürtajın her türünü yasaklar. Çünkü masum bir insana zarar verme –girişimi- her zaman yanlış bir eylemdir. Doğmamış bir çocuğu öldürme istemi ve onun gelişimini engelleme de zarar verme girişimi olarak kabul edilir. Bu bağlamda her canlının *yaşama hakkı* olduğu unutulmamalıdır[89]. Bazı araştırmacılar gebeliğin sonlandırılmasını ancak hidrocephal vb. haklı gerekçeleri olan olgularda kabul eder ve zarar vermeme ilkesi açından kabul edilebilmesi için oldukça kuvvetli gerekçeleri olması gerektiğini savunur[90].

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[86] Bkz. E.P.Renne, The Pregnancy That Doesn't Stay : The Practice and Perception of Abortion by Ekiti Yoruba Women, Soc.Sci.Med. 1996;42(4):483-494.

[87] Bkz.C.Strong – G.D.Anderson, Anethical Framework for Issues During Pregnancy. Principles of Health Care Ethics ed. by R.Gillon, John Wiley & Sons Chichester 1994., s.591.

[88] Bkz. C.Strong – G.D.Anderson, Anethical Framework for Issues During Pregnancy. Principles of Health Care Ethics ed. by R.Gillon, John Wiley & Sons Chichester 1994., s.591.

[89] Bkz. J.Finnis, Abortion and Health Care Ethics II. Principles of Health Care Ethics ed. by R.Gillon, John Wiley & Sons Chichester 1994., s.551.

[90] Bkz. C.Strong – G.D.Anderson, Anethical Framework for Issues During Pregnancy. Principles of Health Care Ethics ed. by R.Gillon, John Wiley & Sons Chichester 1994., s.591.

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1960'lardan önce dünyada kürtaj -genelde- yasa dışı bir uygulama idi. 1960'lı yılların sonlarından itibaren gebeliğin sonlandırılması tartışılmaya ve daha liberal yasaların yürürlüğe girmesi talep edilmeye başlandı[91]. 1973'de Amerika Birleşik Devletlerindeki Anayasa Mahkemesinin Roe'ya karşı Wade (*Roe v. Wade*) davasında verdiği karar, kürtajın yasalaşmasında önemli bir dönüm noktası oldu.

Bazı kaynaklar günümüzde dünya nüfusunun %40'ının kürtaj isteğinde bulunmanın yasal olduğu ülkelerde yaşadığını savunuyor[92]. Kürtajın giderek daha çok ülkede yasalaşması, uygun olmayan koşullarda gebeliklerin sonlandırılmasına yönelik girişimlerin azalmasına neden olduğundan geçen süre içinde gebeliğin sonlandırılmasına bağlı anne ölümlerinde de önemli bir düşüş görülmektedir[93].

ABD

1800'lü yıllara kadar ABD'de kürtaj ile ilgili herhangi bir yasal düzenleme yoktu. Amerikan iç savaşının ardından 1900'lerden sonra kamuoyunun baskısı ile her eyalet kendi içinde kürtajı bir tür cinayet olarak değerlendiren yasalarını oluşturmaya başladı[94].

Gebeliğin sonlandırılmasının yıllarca -politik platformlar da dahil- tartışıldığı[95] ABD'de 1973 yılında Roe'ya karşı Wade (*Roe v. Wade*) davasında Anayasa Mahkeme-

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[91] Bkz. M.Mori, Abortion and Health Care Ethics I : A Critical Analysis of the Main Arguments. Principles of Health Care Ethics ed. by R.Gillon, John Wiley & Sons Chichester 1994., s.531.

[92] Bkz. The New Dictionary of Medical Ethics. Ed.by K.M.Boyd – R.Higgs – A.J.Pinching., BMJ Publishing Group., London 1997. "Abortion" Maddesi.

[93] Bkz. R.Roemer, Equity in Abortion Services. Am. J.of Public Health 1978:68(7):629., Dünyada kürtaj ile ilgili son istatistiki veriler konusunda kapsamlı bir çalışma olarak bkz. S.K.Henshaw – S.Singh – T.Haas, The Incidence of Abortion Worldwide., International Family Planning Perspectives 1999:25:Suppl. S30-S38.

[94] J.C.Mohr, Abortion in America: The Origins and Evolution of National Policy 1800-1900. Oxford University Press, Oxford., England 1979'dan aktaran J.Areen, "Limiting Procreation". R.M.Veatch (ed), Medical Ethics, Second Edition. Jones and Bartlett Publ. Massachusetts. 1997. s. 122. ABD'deki kürtaj yasası ile ilgili gelişmeler ile ilgili olarak ayrıntılı bilgi için ayrıca bkz. G.C.Leedes, Liberalism, Republicanism and the Abortion Controversy. Medicine and the Law. Ed.by B.M.Dickens., Dartmouth. Aldershot 1993. s. 15-53., B.M.Dickens, Abortion and Distortion of Justice in the Law. Medicine and the Law. Ed.by B.M.Dickens., Dartmouth. Aldershot 1993. s. 103-114., J.A.Robetson, Gestational Burdens and Fetal Status. Justifying Roe v. Wade. Am.J. of Law & Med. 1987:XIII(2-3):189-212., C.Holden, Congress to Reexamine Antiabortion Amendment. Science 1981:212:4501., M.B.Bracken-D.H.Freeman – K.Hellenbrand, Hospitalisation for Medical – Legal and Other Abortions in the United States 1970 – 1977. Am.J. of Public Health 1982:72(1):335., The American Medical Association. Committee on Medicolegal Problems, Legal Interventions During Pregnancy. Court-Ordered Medical Treatments and Legal Penalties for Potentially Harmful Behaviour by Pregnant Women. JAMA 1990:264(20):2663-2670., A.Charo, Undue Burden of Abortion. The Lancet 1992:340:44., D.Brahams, Abortion and Assisted Parenthood in USA. The Lancet 1991:337:228-229.,G.Annas, The Supreme Court, Liberty, and Abortion. The N.Engl.J.of Med. 1992:327(9):651-654., W.K.Mariner, The Supreme Court, Abortion, and Jurispuridence of Class. Am.J.of Public Health 1992:82(11):1556-1562., G.J.Annas, Partial-Birth Abortion, Congress and the Constitution. The N. Engl. J. of Med. 1998:339:279-283., F.Charatan, Missouri Passes Antiabortion Law. BMJ 1999:319:874., Bazı mahkeme kararları için bkz. A.Zucker, Abortion. Death Studies. 1990:14:93-96., A.Zucker, Abortion. Death Studies. 1991:15:503-506., A.Zucker, Abortion. Death Studies. 1992:16:463-464., Abortion on the Supreme Court Agenda : Planned Parenthood v. Casey and Its Possible Consequences. Law, Medicine & Health Care 1992:20(3):243-248.

[95] Bu konuda kapsamlı bir çalışma örneği olarak bkz. B.H.Craig – D.M.O'Brien, Abortion and American Politics. Chatham House Publishers Inc. Chatham, New Jersey 1993. ayrıca bkz. D.S.Greenberg, Abortion Politics The Lancet 1991:338:435-436.

sinin verdiği karar[96], bu ülkede gebeliğin sonlandırılmasının toplum tarafından kabul edilebilir olmasında önemli rol oynadı[97]. Mahkeme sözü edilen bu kararda, 1965 yılında mahremiyet hakkı (*privacy*) olarak kabul ettiği "gebeliğin önlenmesini" hamile olan kadının gebeliğinin sonlandırılmasını da içine alacak şekilde genişletti. Hamile olan kadına verilen bu hak "bir kişinin kendi bedenini dilediği gibi kullanması" gibi sınırsız bir hak olmamakla birlikte "gebeliğin ilk üç ayı içinde kürtaj uygulanması kararını hamile kadının hekiminin vereceği tıbbi karara" bırakıyordu. Böylece gebeliğin sonlandırılması kararında kadının etkisi sınırlandırılıyor ve bu karar tıp tarafından reddedilebiliyordu.

Anayasa Mahkemesinin getirdiği bir başka bakış açısı ise fetüsün insan olmadığı görüşü oldu. Eyaletler yapacakları yasal düzenlemelerde tüm diğer canlı varlıkların yaşamının ve sağlığının korunması için alacakları kararlar gibi, fetüsün canlılığı ve sağlığının korunması için de karar almakta serbest bırakıldılar. Ancak eyaletler "potansiyel bir canlı yaşamı" olarak, "yaşayabilir (*viable*)" hale geldikten sonra fetüs için kürtaj kararı ve uygulanmasına yönelik düzenleme yapamayacaklardı. Burada "yaşayabilir (*viable*)" kavramı, "ana rahminin dışında, yapay yardım ile de olsa yaşayabilme potansiyeline sahip olma" olarak tanımlanmıştır[98]. Bu aşamadan sonra alınacak kararlarda potansiyel bir insan yaşamının korunmasına öncelik verilmesi kriteri getirilmiştir. Ve bu aşamadan sonra kürtaj, ancak annenin sağlığının ve yaşamının korunması söz konusu olduğunda uygulanabilecektir[99]. 1992'de getirilen bir kriterle, kürtaj kararı verildikten ve aydınlatılmış onam sürecinden sonra kürtajın uygulanması için 24 saat bekleme zorunluluğu getirilmiştir[100].

İNGİLTERE

İngiltere'de gebeliğin sonlandırılmasında karşılaşılan sorunlarda temel alınan yasaların uzun bir geçmişi vardır. Lord Ellenborough Yasası (*Lord Ellenborough's Act*) (1803), Kişiye Karşı İşlenen Suçlar Yasası (*The Offences Against the Person Act*) (1861), Çocukların Yaşamını Koruma Yasası (*Infant Life -Preservation- Act*) (1929) gibi yasalar gebeliğin sonlandırılmasında karşılaşılan yasal sorunların çözümünde temel alınmıştır.

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[96] 410 U.S. 113 (1973)

[97] Bkz. R.Munson, Intervention and Reflection. Basic Issues in Medical Ethics., Wadsworth Publ. Company. 3rd.Edition., Belmont 1979. s. 53. Bu konuda oldukça kapsamlı bir çalışma olarak bkz. S.Clement – L.Goldstein ve ark., The Evolution of The Right to Privacy After Roe v. Wade: Am. J.of Law & Medicine.1987 Vol XIII:2-3:368-525. Ayrıca bkz. R.Colker, Abortion and Dialog. Pro-choice, Pro-life and American Law. Indiana University Press., Bloomington. 1992., C.L.Cetrulo – L.G.Cetrulo, The Legal Liability of the Medical Consultant in Pregnancy. The Medical Clinics of North America 1989:73(3):557-565.

[98] Bkz. J.Areen, "Limiting Procreation". R.M.Veatch (ed), Medical Ethics, Second Edition. Jones and Bartlett Publ. Massachusetts. 1997. s. 123.

[99] Bkz. R.Munson, Intervention and Reflection. Basic Issues in Medical Ethics., Wadsworth Publ. Company. 3rd.Edition., Belmont 1979. s. 63-68.

[100] Bkz. J.Areen, "Limiting Procreation". R.M.Veatch (ed), Medical Ethics, Second Edition. Jones and Bartlett Publ. Massachusetts. 1997. s. 123. ayrıca bkz. W.K.Mariner, The Supreme Court, Abortion, and Jurispuridence of Class. Am.J.of Public Health 1992:82(11):1559-1560.

İngiltere'de 1967 yılında Kürtaj Yasası (*Abortion Act*) yürürlüğe girmiş[101], 1990'daki İnsan Döllenme ve Embriyoloji Yasası (*Human Fertilisation and Embrylogy Act*) söz konusu yasada bazı değişikliklere neden olmuştur [102].

İngiltere'deki yasal düzenleme "liberal" anlayışın bir anlamda ortasında yer alır. Bu ülkede istem üzerine gebeliğin sonlandırılmasına izin verilmemektedir. İngiltere'deki yasal düzenlemede, kürtaj ancak iki hekimin "gebeliğin devam etmesinin kadının veya kadının diğer çocuklarının fizik veya ruh sağlığına zarar vereceği"ni belgelemeleri önkoşuluna bağlı olarak uygulanmaktadır[103].

DİĞER ÜLKELERDEKİ YASAL DURUM

1967 – 1977 yılları arasında dünyada çeşitli ülkeler gebeliği sonlandırmayı yasallaştırmaya başladılar. Arjantin, Avustralya[104] (Capital Territory, New South Wales, Northern Territory, South Australia [105], Victoria eyaletleri) Avusturya, ABD, Batı Almanya[106], Benin, Birleşik Arap Emirlikleri, Bulgaristan [107], Çekoslovakya, Danimarka[108], Doğu Al-

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[101] M.Davies, Textbook on Medical Law. Blackstone Press Limited 2nd Ed. Hants 1998. s.267-289. 1967 yılında yürürlüğe giren bu yasadaki değişiklik için bkz. An Act (Chapter 87 of 1967) to Amend and Clarify the Law Relating to Termination of Pregnancy by Registered Medical Practitioners. Dated 27 October 1967. (The Abortion Act 1967) IDHL 1969:32(1):27-29. İngiltere'deki 1967 tarihli Kürtaj yasasındaki değişikliğin yorumu için bkz. J.K.Mason – R.A.McCall Smitt – G.T.Laurie, Law and Medical Ethics. Butterworths., London 1999. s.115-118.

[102] Bkz. Human Fertilisation and Embryology Act, 1990. Summary of Changes in the Law on Abortion. BMA. Medical Ethics Committee. Professional and Scientific Division. January 1991.

[103] Bkz. The New Dictionary of Medical Ethics. Ed.by K.M.Boyd – R.Higgs – A.J.Pinching., BMJ Publishing Group., London 1997. "Abortion" Maddesi. İngiliz Tıp Birliği'nin (British Medical Association-BMA) bu konudaki görüşü için bkz. BMA's Ethics, Science and Information Division (Head of Division F.Fisher), Medical Ethics Today : Its Practice and Philosophy. 2nd. Ed., Published by BMJ Publishing Group., London 1995. s.103-109., İngiltere'deki yasal düzenlemelerle ilgili olarak ayrıca bkz. T.L.T.Lewis, Legal Abortion in England and Wales 1968-78. BMJ 1980:2 February 1980:295-296., M.H.Hall, Changes in the Law on Abortion. BMJ 1990:301:1109-1110., D.Brahams, Judicial Warning on Very Late Aboritons The Lancet 1990:February 24:464., J.Guillebaud, Medical Abortion. Safe, Effective and Legal in Britain. BMJ 1992:304:195-196., A Law to Codify and Amend the Customary Law of the Island Relating to the Termination of Pregnancy by Registered Medical Practitioners, Sanctioned by Order of Her Majesty in Council of the 19th day of December 1996. dated 23 July 1996. (The Termination of Pregnancy (Jersey) Law 1997). IDHL 1999:50(1):36-38.,

[104] Western Australia için bkz. B.Loff-S.Cordner, Western Australia Passes Liberal Abortion Law. The Lancet 1998:351:1714.

[105] Bu konuda ayrıca bkz. L.Cannold, Consequences for Patients of Health Care Proffessionals' Conscientious Actions: The Ban on Abortions in South Australia., J.of Med. Ethics 1994:20:80-86.,

[106] Almanya'daki gelişmeler için ayrıca bkz. H.L.Karcher, New German Abortion Law Agreed. BMJ 1995:311:149., J.K.Mason – R.A.McCall Smitt – G.T.Laurie, Law and Medical Ethics. Butterworths., London 1999. s.122-123.

[107] Bulgaristan'daki gelişmeler için ayrıca bkz. Degree No 2 of 1 February 1990 on the Conditions and Procedures for the Artificial Termination of Pregnancy Darzaven Vestnik, 9 february 1990, No 12 pp.4-9'dan aktaran IDHL 1990:41(4):624-625.

[108] Danimarka'da sonraki yıllardaki gelişmeler için ayrıca bkz. Law No 350 of 24 May 1989 amending the Law on the Termination of Pregnancy. Lovtidente, 1989 Part A, 27 May 1989 No 53, p.1179'dan aktaran IDHL 1989:40(3):594-595., Order No 1125 of 13 December 1996 on the Termination of Pregnancy. Lovtidente, 1996 Part A, 21 December 1996 No 194, p.6916'dan aktaran IDHL 1997:48(1):34.

manya, El Salvador, Fas, Fiji, Finlandiya, Fransa[109], Guatemala, Güney Kore, Güney Afrika[110], Hindistan, Hong Kong, İngiltere, İran[111], İsrail[112], İsveç[113], İzlanda, Kamerun, Kanada[114], Macaristan[115], Norveç, Peru, Singapur, Şili, Tunus, Yeni Zellanda, Yugoslavya, Zambia gibi ülkeler Türkiye'den önce gebeliği sonlandırmayı yasallaştırdılar. Bu ülkelerde gebeliğin sonlandırılmasına neden oluşturan gerekçeler farklı olmakla birlikte (anne yaşamının tehlikede olması, annenin fizik veya ruhsal sağlığının tehlikede olması, doğacak olan çocuğun zihin özürlü olması, tecavüz-ensest gibi sorunlar sonucu gebeliğin ortaya çıkması veya düzenli doğum kontrol yöntemini kullanmadaki başarısızlık (Hindistan) gibi) gebeliğin sonlandırılması yasal temellere dayandırıldı[116].

İlgi çekici olan bu dönemdeki yasalarda gebeliğin sonlandırılması için özel bir onam (*consent*) bölümüne yer verilmeyerek tıbbi tedaviye / cerrahi girişimlere verilecek onam kapsamında bir anlayışın geçerli olmasıdır. Yukarıda sözü edilen ülkelerdeki yasal düzenlemelerde sadece Fransa'da evli olmayan küçüklerde (*minors*) gebeliğin sonlandırılması söz konusu olduğunda ebeveyn / yasal vasisinin onamının gerekliliği, Hindistanda ise 18 yaşın altındaki kadınların gebeliklerinin sonlandırılmasında onamın önemi özellikle vurgulanmıştır. Bu dönemdeki yasal düzenlemelerde eşin (*partner*) onamına önem verilmemiştir. Bu konuda sadece Güney Kore istisna oluşturmuş, İzlanda'da -bu konuda zorunluluk olmamakla birlikte- uygulamada eşin, gebeliğin sonlandırılması sırasında bulunmasını gerekli kılmıştır[117].

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[109] Fransa için ayrıca bkz. A.Dorozynski, Paris Court Attacts Abortion Law, BMJ 1995;311:142-138, A.Fagot-Largeault, Ownership of the Human Body : Judicial and Legislative Responses in France. In Ownership of the Human Body. Philosophical Considerations on the Use of the Human Body and its Parts in Healthcare. Ed.by Henk A.M.J. Ten Have – j.Welie – with coll. S.F.Spicker., Kluwer Academic Publishers. Dordrecht. 1998. s. 99-114.

[110] Güney Afrika'daki gelişmeler için ayrıca bkz. An Act (No 92 of 1996) to Determine the Circumstances in Which and Conditions Under Which the Pregnancy of a Woman May be Terminated; and to Provide for Matters Connected Therewith. Date of Assent: 12 November 1996. (The Choice on Termination of Pregnacy Act 1996) Government Gazette 22 November 1996, vol 377, No 17602, pp. 1-10'dan aktaran IDHL 1997:48(2):178-181.

[111] İran'da gebeliğin sonlandırılması konusundaki yaklaşım için bkz. S.S.Banwell – J.M.Paxman, The Research for Meaning, RU 486 and the Law of Abortion. Am.J.of Public Health 1992;82(10):1405.

[112] İsrail'deki gelişmeler için ayrıca bkz. M.L.Gross, After Feticide : Coping with Late-Term Abortion in Israel, Western Europe, and United States. Camb.Quarterly of Health Care Ethics 1999:8:449-462.

[113] İsveç'teki gelişmeler için ayrıca bkz. Law no. 660 of 18 May 1995 amending the Abortion Law (No. 595) of 1974., Svensk Författningssamling 1995, 13 June 1995'den aktaran IDHL 1996:47(1):36-37.

[114] Kanada'daki yasal gelişmeler için ayrıca bkz. D.Brahams, Abortion Ruling in Quebec. The Lancet 1989:5 August:340-341.

[115] Macaristan'da sonraki yıllardaki gelişmeler için ayrıca bkz. Ordinance No 76 of 3 November 1988 of the Council of Ministers on the Termination of Pregnancy. Magyar Közlöny, 3 November 1988, No 52, pp.1185-1186'dan Aktaran IDHL 1989:40(3):595., Ordinance No 15 of 15 December 1988 of the Minister of Social Affairs and Health on the Termination of Pregnancy. Magyar Közlöny, 15 December 1988, No 62, pp.1379-1387'den Aktaran IDHL 1989:40(3):595-596. Law No 79 of 17 December 1992 on the Protection of the Life of the Fetus Magyar Közlöny, 23 December 1992, No 132, pp. 4705-4708.

[116] Bkz. R.J.Cook – B.Dickens, A Decade of International Change in Abortion Law. 1967-1977. Am.J.of Public Health 1978:68(7):637-644.

[117] Bkz. R.J.Cook – B.Dickens, A Decade of International Change in Abortion Law. 1967-1977. Am.J.of Public Health 1978:68(7):637-644.

Gebeliğin sonlandırılmasının yasallaşmasından günümüze bu alanda oldukça büyük bir değişim yaşandı[118]. Son 10 yıl içindeki gelişmeler, özellikle 1994'de Kahire'de gerçekleştirilen Uluslararası Nüfus ve Gelişim Konferansı ile 1995'de Pekin de gerçekleştirilen 4.Dünya Kadın Konferansından sonra gebeliğin sonlandırılması halk sağlığının temel sorunlarından biri olarak tanımlanmıştır. Günümüzde dünyada çeşitli ülkelerde yürürlükte olan kürtaj ile ilgili yasaları kapsamlı olarak inceleyenler tüm bu yasal düzenlemeleri üç temel grupta kümelendiriyorlar[119];

(i) gebeliğin sonlandırılmasını ceza hukuku çerçevesinde ele alan ülkeler; Bazı ülkeler, ülke genelindeki ahlaki değerleri ceza hukuku çerçevesinde de geçerli kılmaktadır. Örneğin Kolombiya ve Polonya [120]'da mahkeme kararlarında Papalığın öngördüğü "yaşamın döllenme anından itibaren korunması" ilkesi temel alınabilmektedir. Diğer

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[118] 1967-1977 yılları arasında gebeliğin sonlandırılması ile ilgili yasalardaki gelişmeleri ayrıntılı olarak aktaran kaynaklardan biri olarak bkz. R.J.Cook – B.M.Dickens, A Decade of International Change in Abortion Law. 1967-1977. Am.J.of Public Health 1978:68(7):640-641. Yazarlar dünyada gebeliğin sonlandırılmasına yönelik yasal düzenlemeleri belli aralıklarla incelemektedir. Aynı araştırmacıların sonraki yıllarda gebeliğin sonlandırılması ile ilgili yasalardaki gelişmeler konusundaki araştırmaları için bkz. R.J.Cook – B.M.Dickens, International Developments in Abortion Laws : 1977-1988 Am.J.Public Health 1988;78:1305-1311., R.J.Cook – B.M.Dickens, International Developments in Abortion from 1988 to 1998. Am.J.of Public Health 1999:89(4):579-586., Ayrıca Bkz. E.Kevin, The Dilemma of Abortion. Faber and Faber London 1986., Bu konuda Avrupa'daki yasal gelişmeler, özellikle Polonya, Macaristan, Arnavutluk, Almanya, Belçika ve İrlanda'daki gelişmeler için ayrıca bkz. R.Reed, Abortion Law in Europe in 1991-1992. The J. of Law, Medicine & Ethics 1993:21(1):72-93., Farklı ülkelerdeki durum için ayrıca bkz. B.M.Knoppers, Comparative Abortion Law: the Living Abortion. Pediatric Forensic Medicine and Pathology. Ed. by J.K.Mason. Chapman and Hall Ltd. London 1989. s.381-397., C.Tietze –S.Lewit, Legal Abortion. Scientific American 1977:236(1):21-27. İrlanda'daki eğilim ile ilgili olarak bkz. D.Brahams, Abortion Information, An Irish Case. The Lancet 1991:338:1006., C.Francome, Abortion in Ireland. BMJ 1992:305:436., An Act (No 5 of 1995) to prescribe the conditions subject to which certain information relating to services lawfully available outside the State for the termination of pregnancies and to persons who provide such sevices may be given to individual women or the general public, to amend the Independent Advertisements Act 1889, and the Censorship of Publications Acts, 1929 to 1967 and to provide for related matters. Dated 12 May 1995 (The regulation of Information (Services Outside the State for Termination of Pregnancies) Act 1995). IDHL 1995:46(4):481-482., K.Birchard, Irish Election date Sparks Off Abortion Debate. The Lancet 1997:349:1528., K.Birchard, New Ethical Guidelines on Abortion in Ireland. The Lancet 1998:352:1840., K.Birchard, Abortion Issues Highlighted in Ireland. The Lancet 1999:353:131. Kuzey İrlanda ve Commonwealth Ülkelerindeki yasal durum için bkz. J.K.Mason – R.A.McCall Smitt – G.T.Laurie, Law and Medical Ethics. Butterworths., London 1999. s.118-119, 121-122. Hollanda'daki durum için bkz. J.Welie – H.A.M.J.Ten Have, Ownership of the Human Body : The Dutch Context. In Ownership of the Human Body. Philosophical Considerations on the Use of the Human Body and its Parts in Healthcare. Ed.by Henk A.M.J. Ten Have – j.Welie – with coll. S.F.Spicker., Kluwer Academic Publishers. Dordrecht. 1998. s. 99-114.

[119] Bkz. R.J.Cook – B.M.Dickens, International Developments in Abortion from 1988 to 1998. Am.J.of Public Health 1999:89(4):579-586.

[120] Polonya'daki gelişmeler için ayrıca bkz. Ordinance of 30 April 1990 of Minister of Health and Social Welfare Concerning the Proffessional Qualifications Required by Physicians Performing Operations for Termination of Pregnancy and the Procedure for the Issuance of Medical Ruling Permitting such Operations. Dziennik Ustaw Rzeczypospolitej Polskiej 7 May 1990, No 29, serial No 178. pp. 382-383'den aktaran IDHL 1991:42(3):463-466., V.Rich Poland:Split Over Abortion 1992:339:295., Law of 7 January 1993 on Family Planning, Protection of Human Fetuses and the Conditions Under Which Pregnancy Termination is Permissible. IDHL 1993:44(2):253-255., Law of 30 August 1996 amending the Law on Family Planning, Protection of Human Fetuses and the Conditions Under Which Pregnancy Termination is Permissible, and amending other Laws Dziennik Ustaw Rzeczypospolitej Polskiej 4 December 1996, No 139, text No 646 pp. 2885-2888'den aktaran IDHL 1997:48(2):176-178.

yandan bazı ülkelerde düşüğe neden olan ilaçlar yasaklanmaktadır. Doğacak olan çocuğun cinsiyeti nedeni ile gebeliğin sonlandırılması ciddi bir sorun olduğundan Çin ve Hindistan gibi bazı ülkeler doğacak olan çocuğun cinsiyeti nedeni ile gebeliğin sonlandırılmasını yasaklamıştır[121].

(ii) gebeliğin sonlandırılmasını bir halk sağlığı sorunu olarak gören ülkeler; Özellikle uygun olmayan koşullarda gebeliğin sonlandırılması nedeni ile anne ölümlerinin yüksek olduğu ülkeler bu eğilimi benimsemektedir. Bu eğilim özellikle eski doğu avrupa ülkeleri[122] ve yasaların kısıtlayıcı etkisi nedeni ile gebeliğin sonlandırılmasının uygun olmayan koşullarda gerçekleştirilmesine bağlı anne ölümlerinin yüksek olduğu Latin Amerika ülkelerinde geçerlidir [123].

(iii) gebeliğin sonlandırılmasını insan hakları ve sosyal adalet çerçevesinde ele alan ülkeler; Son 10 yıl içinde kadınların üreme sağlığı (*reproductive health*) ve kendi bedenleri üzerinde karar verme hakları (*self-determination*) konusunda önemli gelişmeler olmuştur. Bazı ülkelerde güvenli koşullarda kürtaj hizmetinden yararlanmak da bu hakların önemli bir parçası olarak görülmektedir[124].

Gebeliğin sonlandırılmasının yasal boyutunda "cezalandırma" eğilimi etkisini yitirerek devam etmekle birlikte günümüzde pek çok ülkenin gebeliğin sonlandırılmasına, kadının sağlığının korunması olarak algıladığını, sayılı bazı ülkenin ise bu konuya kadının üreme hakkı ve kendi bedeni üzerinde karar verme hakkı bağlamında insan haklarının bir parçası olarak görmeye başladığını söyleyebiliriz.

TÜRKİYE

Osmanlı döneminde hekimler genelde gebeliğin sonlandırılmasına karşı olmuş, bu nedenle gebeliğin sonlandırılması genelde ebeler tarafından gerçekleştirilmiştir. Bu uy-

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121 Bkz. R.J.Cook – B.M.Dickens, International Developments in Abortion from 1988 to 1998. Am.J of Public Health 1999:89(4):579-580. Çin'de kürtaj'a yaklaşım için ayrıca bkz. S.M.Rigdon, Abortion Law and Practice in China: An Overview with Comparisons to the United States, Soc.Sci.Med. 1996:42(4):543-560., J.Nie, The Problem of Coerced Abortion in China and Related Ethical Issues. Camb. Quarterly of Health Care Ethics 1999:8:463-479.

122 Örneğin Romanya'da 1989 yılında kürtaj nedeni ile görülen anne ölümleri diğer avrupa ülkelerinden 10 kat daha fazla idi . Bkz. R.J.Cook – B.M.Dickens, International Developments in Abortion from 1988 to 1998. Am.J.of Public Health 1999:89(4):579-586. Eski Doğu Avrupa ülkelerinde anne ölümlerinin yüksek olmasının bir başka nedeni de bu ülkelerde geçmişte kürtajın bir "doğum kontrol yöntemi" olarak algılanmasıdır. Bazı kaynaklar geçmişteki bu yapının bir tür "kürtaj kültürü" olarak tanımlamaktadır. Bkz. P.Tichtchenko-B.Yudin, The Moral Status of Fetuses in Russia. Cambridge Quarterly of Health Care Ethics 1997:6:31-38.

123 Bkz. R.J.Cook – B.M.Dickens, International Developments in Abortion from 1988 to 1998. Am.J.of Public Health 1999:89(4):579-586. Latin Amerika ülkelerinden Arjantin, Uruguay, Brezilya ve Meksika'da gebeliğin sonlandırılması ile ilgili yasalar için ayrıca bkz. R.Boland, The Current Status of Abortion Laws in Latin America : Prospect and Strategies for Change. The J.of Law, Medicine & Ethics 1993:21(1):67-71. Bu konuda SSCB'nin yaklaşımını yansıtan bir yasal düzenleme örneği için bkz. Decree of December 1987 of the USSR Ministery of Health Confirming the Instruction on the Procedure for Authorizing Operations for the Artificial Termination of Pregnancy on the Basis of Nonmedical Indications. IDHL 1991:42(2):267.

124 Bkz. R.J.Cook – B.M.Dickens, International Developments in Abortion from 1988 to 1998. Am.J.of Public Health 1999:89(4):580-583.

gulama anne ölümlerine neden olduğundan gebeliğin sonlandırılmasının da cezalandırıldığını arşiv belgelerinden öğreniyoruz[125]. Önceleri şeriat hükümlerine göre verilen cezalar, 9 Ağustos 1858 tarihli Ceza Kanunnamei Humayunu'ndaki çocuk düşürme ve düşürtme cezaları ile netlik kazanmıştır[126]. 1810 tarihinde Napolyon tarafından çıkarılan yasalardan esinlenildiği söylenen bu yasal düzenlemede gebe kadına çocuğunu düşürmesi için yardım eden veya ilaç verenler hapis veya ağır işlerde çalışma cezası ile cezalandırılıyordu[127]. Bunun yanısıra çeşitli yayınlarda kürtajın ahlak dışı ve yasak bir uygulama olduğu vurgulanıyordu. 19. yüzyılda yabancı gözlemciler de raporlarında bu konudaki gözlemlerini aktarmışlardır[128].

Cumhuriyet Döneminin ilk yıllarında Osmanlı dönemindeki politikalar bir anlamda devam etmiştir. Savaş yıllarında ülkenin nüfusu azaldığından[129] Cumhuriyetin ilk yıllarında nüfus artışı teşvik edilmiş, çocuk düşürme ve düşürtme ile ilgili cezalar da Türk Ceza Kanununda yerini almıştır. Özellikle 1950'li yılların ikinci yarısından sonra nufüs artışının hızlanması devletin bu alandaki politikasını değiştirmesine neden olmuştur. Buna bağlı olarak 1966 yılında 557 sayılı nüfus planlaması yasası kabul edilmiştir[130].

1970'li yıllarda Türkiye'de kürtajın yasalaşması tartışılmaya başlanmıştır. Kürtajın yasalaşmasına karşı olanlar bu uygulamanın Türk toplumunun ahlak değerlerini ve aile yapısını bozacağını, henüz alt yapısı olmayan koşullarda kürtaj uygulamalarına zemin hazırlayarak anne ölümlerinin artacağını savunurken karşı görüşte olanlar kürtajın zaten yasal olmasa da yaygın olarak uygulandığını savunmuşlardır [131]. Tüm bu tartışmaların ardından kürtaj "Rahim Tahliyesi ve Sterilizasyon Hizmetlerinin Yürütülmesi ve denetlenmesine İlişkin Tüzük" ile 1983 yılında yasalaşmıştır[132].

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[125] Başbakanlık Osmanlı Arşiv Belgesi . Cevdet, Sıhhıye Def., No:437 (1827)'den aktaran M.Şehiraltı (Ilgıcı), Aile Planlaması Uygulamalarında Tıp Etiği ile Ilgili Sorunların İncelenmesi. (Basılmamış Doktora Tezi) İ.Ü.Sağlık Bilimleri Enstitüsü Deontoloji Anabilim Dalı. Danışman A.Altıntaş. İstanbul 1993. s.11

[126] Bkz. M.Şehiraltı (Ilgıcı), Aile Planlaması Uygulamalarında Tıp Etiği ile İlgili Sorunların İncelenmesi. (Basılmamış Doktora Tezi) İ.Ü.Sağlık Bilimleri Enstitüsü Deontoloji Anabilim Dalı. Danışman A.Altıntaş. İstanbul 1993. s.11-13. ayrıca bkz. A.Gürsoy, Abortion in Turkey : A Matter of State, Family or Individual Decision. Soc.Sci.Med. 1996:42(4):532.

[127] Memalik-i Osmaniye'de tezayüd ve tenakis-i nüfus. Sabah 346. 1 Muharrem 1307 / 28 Ağustos 1889. s. 2-3'den alıntı yapan A.Duben-C.Behar, Istanbul Households, Marrige, Family and Fertility 1880-1940. Cambridge University Press. 1991,s 181-182'den aktaran A.Gürsoy, Abortion in Turkey : A Matter of State, Family or Individual Decision. Soc.Sci.Med. 1996:42(4):532.

[128] A.Duben-C.Behar, Istanbul Households, Marrige, Family and Fertility 1880-1940. Cambridge University Press. 1991,s 181'den aktaran A.Gürsoy, Abortion in Turkey : A Matter of State, Family or Individual Decision. Soc.Sci.Med. 1996:42(4):532.

[129] A.Gürsoy, Abortion in Turkey : A Matter of State, Family or Individual Decision. Soc.Sci.Med. 1996:42(4):532.

130 Bkz. M.Şehiraltı (Ilgıcı), Aile Planlaması Uygulamalarında Tıp Etiği ile İlgili Sorunların İncelenmesi. (Basılmamış Doktora Tezi) İ.Ü.Sağlık Bilimleri Enstitüsü Deontoloji Anabilim Dalı. Danışman A.Altıntaş. İstanbul 1993. s.11-13.

[131] A.Gürsoy, Abortion in Turkey : A Matter of State, Family or Individual Decision. Soc.Sci.Med. 1996:42(4):532.

132 Buna rağmen 1996 yılında yayınlanan bir araştırmaya göre Türkiye'de düşük gelir düzeyine sahip kadınların güvenli koşullarda kürtajdan yararlanmalarının hala sınırlı olduğu belirtilmektedir. Bkz. D.Huntington – A.A. Dervişoğlu ve ark., The Quality of Abortion Services in Turkey. Int.J.Gynecol. Obstet. 1996:53:41-44'den aktaran R.J.Cook – B.M.Dickens, International Developments in Abortion from 1988 to 1998. Am.J.of Public Health 1999:89(4):580.

"RAHİM TAHLİYESİ VE STERİLİZASYON HİZMETLERİNİN YÜRÜTÜLMESİ VE DENETLENMESİNE İLİŞKİN TÜZÜK"ÜN TIP ETİĞİ AÇISINDAN DEĞERLENDİRİLMESİ

1983 yılında yürürlüğe giren *Rahim Tahliyesi ve Sterilizasyon Hizmetlerinin Yürütülmesi ve Denetlenmesine İlişkin Tüzük* hukukçularımız tarafından da ayrıntılı olarak incelenmiştir[133]. Adı geçen tüzüğünün "onam" bölümü tıp etiğindeki "özerklik ilkesi" açısından incelediğimizde özellikle "özerklik" ilkesi konusunda sorun olduğu söylenebilir.

Bu bölümde "*Müdahaleden önce görevli doktorun tüm açıklamalarını dinledik. Rahim tahliyesine rıza ve iznimiz olmadan girişilemiyeceği, bu işlemin tıbbi sonuçları ve muhtemel komplikasyonlar bize etraflıca anlatıldı. Bu konuda sorumlulukların bize ait bulunduğu bilincinde olduğumuzu, hiçbir şiddet, tehdit, telkin ya da maddi ve manevi baskı altında olmaksızın rahim tahliyesini kabul ettiğimizi, gebeliğe son verme nedeniyle doğacak sonuçları gerek birbirimiz ve gerek doktor ve hastane aleyhine kullanmıyacağımızı, sonucuna katlanacağımızı ve gebeliğe son verme işlemine rıza gösterdiğimizi beyan ederiz.*" denmektedir. Bu aydınlatılmış onam metninde gebeliği sonlandırılacak olan kadının ve eşinin aydınlatıldığını görüyoruz. Ancak "*gebeliğe son verme nedeniyle doğacak sonuçları gerek birbirimiz ve gerek doktor ve hastane aleyhine kullanmıyacağımızı, sonucuna katlanacağımızı*" şeklindeki bir söylemin[134], hukuk sistemi içinde geçerliliğini değerlendirmek kendi alanımızı aşmakla birlikte, tıp etiği açısından kabul edilemez olduğunu dile getirmemiz gerekir. Böyle bir söylem Avrupa Konseyi'nin Bioetik Sözleşmesinin 24. Maddesi ile de çelişmektedir. Sözü edilen Sözleşme hastaların zarar görmeleri durumunda ilgili ülkenin yasal düzenlemeleri çerçevesinde tazminat talep etmek haklarını güvence altına almaktadır[135].

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[133] Bu konuda kapsamlı bir çalışma olarak bkz. E. Yurtcan, Türk Hukunda Kürtaj ve Uygulanması. Beta Basım Yayım Dağıtım Anonim Şirketi. İstanbul 1984. aynı eserin genişletilmiş baskısı için bkz. E. Yurtcan, Türk Hukunda Kürtaj ve Uygulanması. Yeni Yargıtay Kararları İşlenmiş ve Gözden geçirilmiş 2. Bası. Kazancı Hukuk Yayınları No 79. İstanbul 1990.

[134] İlgi çekici olan bu "onam formu formatı"nın sonraki yıllarda yürürlüğe giren İnvitro Fertilizasyon ve Embryo Transferi Merkezleri Yönetmeliği'nde (Resmi Gazete, 21 Ağustos 1987 sayı 19551) de kullanılmış olması, adı geçen yönetmelikte 1996 yılında değişiklik yapılmasına rağmen (İnvitro Fertilizasyon ve Embriyo Transferi Merkezleri Yönetmeliğinde Değişiklik Yapılmasına Dair Yönetmelik. Resmi Gazete 19 Kasım 1996. sayı 22822) aydınlatılmış onam bölümünde herhangi bir değişiklik yapılmamış olmasıdır. İnvitro Fertilizasyon ve Embryo Transferi Merkezleri Yönetmeliğinin aydınlatılmış onam bölümünün tıp etiği açısından değerlendirilmesi için bkz. Ş.Görkey, In Vitro Fertilization and Embryo Transfer Centers – Amendment in Turkey (An Ethical Evaluation) Council of Europe 3rd Symposium on Bioethics. Medically Assisted Procreation and the Protection of the Human Embryo. Strasbourg 15-18 December 1996. Communication of the Participants p.30., ayrıca Bkz Ş.Görkey, Centers de Fecondation in Vitro et de Transfert d'Embryon – Legislation en Vigueur en Turquie (evaluation ethique) 3rd Symposium sur la Bioethique. L'Assistance Medicale a la Procreation et la Protection de l'Embryon Humain. Strasbourg 15-18 Decembre 1996 Communication des Participants p.31

[135] Council of Europe. Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine. Article 24.

SONUÇ

Gebeliğin sonlandırılması "yaşamın başlangıcı" ve "yaşam" ın sorgulanmasını da beraberinde getirdiğinden çağlar boyunca tartışılmış ve hala tartışılmaya devam edilen bir konudur. Gebeliğin sonlandırılmasının yasalaşması göreceli olarak oldukça yeni olmasına rağmen günümüzde pekçok ülkede belli koşullar ve gebeliğin belli dönemi içinde gerçekleşmesi koşulu ile yasallık kazanmıştır. Bu sürece içinde gebeliğin sonlandırılmasına bağlı olan anne ölümlerinde önemli bir düşüş de görülmektedir.

Yaşamı ve *yaşamın başlangıcını* sorgulayan bir konudaki tartışmaların pek de kolay sonlanacağını sanmıyoruz.

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VIDEOS for ICP 2

1) Language http://www.euprimarycare.org/video-role-plays-primary-care-subthemes
2) Say this not that: https://www.youtube.com/watch?v=r842YIpanQ
3) Headcahe: https://www.youtube.com/watch?v=S4wWClQhZaA
4) Chief concern: https://www.youtube.com/watch?v=IViQKF9qFaw
5) Past Medical History: https://www.youtube.com/watch?v=YjC7iZ_aDq8
6) History takin, whole process: https://www.youtube.com/watch?v=sbJZCjyEWwI&list=PLC7A2A3A140D0391B
7) Difficult topics: https://www.youtube.com/watch?v=0zBMZCzeQO4

Readings for ICP 2

8) Summary of history taking: http://www.egyankosh.ac.in/bitstream/123456789/33888/1/Unit1.pdf
9) Sensitive Issues: https://www.glowm.com/section_view/heading/History Taking%20and%20Interview%20Techniques%20and%20the%20Physician-Patient%20Relationship/item/410