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Appendix 2

Recommended Definitions, Standards, and Reporting Requirements for ICD-10 Related to Reproduction

Fetal, Perinatal, Neonatal, and Infant Mortality Definitions¹

Live birth. Live birth is the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of the pregnancy, which, after such separation, breathes or shows any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached; each product of such a birth is considered liveborn.

Fetal death (deadborn fetus). Fetal death is death prior to the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of pregnancy; the death is indicated by the fact that after such separation the fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles.

Birthweight. The first weight of the fetus or newborn obtained after birth.

Low birthweight. Less than 2,500 g (up to, and including 2,499 g).

Very low birthweight. Less than 1,500 g (up to, and including 1,499 g).

Extremely low birthweight. Less than 1,000 g (up to, and including 999 g).

Gestational age. The duration of gestation is measured from the first day of the last normal menstrual period. Gestational age is expressed in completed days or completed weeks (e.g., events occurring 280 to 286 completed days after the onset of the last normal menstrual period are considered to have occurred at 40 weeks of gestation).

Preterm. Less than 37 completed weeks (less than 259 days) of gestation.

Term. From 37 completed weeks to less than 42 completed weeks (259 to 293 days) of gestation.

¹ World Health Organization. International Conference on the Tenth Revision of the International Classification of Diseases, Geneva: World Health Organization, In Press 1991.

Recommended Definitions, Standards, and Reporting Requirements Related to Reproduction

Postterm. 42 completed weeks or more (294 days or more) of gestation.

Perinatal period. The perinatal period commences at 22 completed weeks (154 days) of gestation (the time when birth weight is normally 500 g), and ends seven completed days after birth.

Neonatal period. The neonatal period commences at birth and ends 28 completed days after birth. Neonatal deaths (deaths among live births during the first 28 completed days of life) may be subdivided into early neonatal deaths, occurring during the first seven days of life and late neonatal deaths, occurring after the seventh day but before 28 completed days of life.

Notes on Definitions

For live births, birth weight should preferably be measured within the first hour of life before significant postnatal weight loss has occurred. Whilst statistical tabulations include 500 g groupings for birth weight, weights should not be recorded in those groupings. The actual weight should be recorded to the degree of accuracy that it is measured.

The definitions of *low*, *very low*, and *extremely low* birthweight do not constitute mutually exclusive categories. Below the set limits they are all-inclusive and therefore overlap (i.e., *low* includes *very low* and *extremely low*, while *very low* includes *extremely low*).

Gestational age is frequently a source of confusion when calculations are based on menstrual dates. For the purposes of calculation of gestational age from the date of the first day of the last normal menstrual period and the date of delivery, it should be borne in mind that the first day is day zero and not day one; days 0-6 therefore correspond to *completed week zero*, days 7-13 to *completed week one*, and the 40th week of actual gestation is synonymous with *completed week 39*. Where the date of the last normal menstrual period is not available, gestational age should be based on the best clinical estimate. In order to avoid misunderstanding, tabulations should indicate both weeks and days.

Age at death during the first day of life (day zero) should be expressed in units of completed minutes or hours of life. For the second (day 1), third (day 2), and subsequent days of life, age at death should be expressed in days.

Reporting Requirements

It is recognized that legal requirements for the registration of fetal deaths and live births still vary from country to country and even within countries. However, it is recommended that, wherever possible, all fetuses and infants delivered weighing at least 500 g, whether alive or dead, be included in the statistical tabulations. When birth weight is unavailable, the corresponding criteria for gestational age (22 completed weeks), or body length (25 cm crown-heel) should be used. The criteria for deciding whether an event has taken place within the perinatal period should be applied in the order 1) birth weight, 2) gestational age, 3) crown-heel length. The inclusion of fetuses and infants weighing between 500 g and 1,000 g in national statistics is recommended both because of its inherent value and because this inclusion improves the completeness of reporting at 1,000 g and over.

In statistics for international comparison, inclusion of this group of births of extremely low birth weight disrupts the validity of comparisons and is not recommended. Countries should therefore arrange registration and reporting procedures so that the events and the criteria for their inclusion in the statistics can be easily identified. Less mature fetuses and infants not corresponding to these criteria should be excluded from perinatal statistics unless there are legal or other valid reasons to the contrary, in which case this inclusion must be explicitly stated. Where these characteristics are unknown, the event should be included in, rather than excluded from, mortality statistics of the perinatal period. Countries should also present standard statistics in which both the numerator and the denominator of all ratios and rates are restricted to fetuses and infants weighing 1,000 g or more (weight-specific ratios and rates); where birth weight is unavailable, the corresponding gestational age (28 completed weeks) or body length (35 cm crown-heel) should be used.

In reporting fetal, perinatal, neonatal and infant mortality statistics the number of deaths due to malformations should whenever possible be identified for live births and fetal deaths and in relation to birth weight of 500-999 g and 1,000 g or more. Neonatal deaths due to malformations should be subdivided into early and late neonatal deaths. The availability of this information enables perinatal and neonatal mortality statistics to be reported with or without the deaths from malformations. A malformation is defined as a congenital morphological anomaly, regarded as the underlying cause of death during the fetal and neonatal period.

Recommended Definitions, Standards, and Reporting Requirements Related to Reproduction

Ratios and Rates

Published ratios and rates should always specify the denominator that has been used, i.e., live births or total births (live births plus fetal deaths). Countries are encouraged to provide the ratios and rates listed below, or as many of them as their data collection systems permit:

$$\text{Fetal death ratio: } \frac{\text{Fetal deaths}}{\text{Live births}} * 1,000$$

$$\text{Fetal death rate: } \frac{\text{Fetal deaths}}{\text{Total births}} * 1,000$$

$$\text{Fetal death rate, weight-specific: } \frac{\text{Fetal deaths weighing 1,000 g and over}}{\text{Total births weighing 1,000 g and over}} * 1,000$$

$$\text{Early neonatal mortality rate: } \frac{\text{Early neonatal deaths}}{\text{Live births}} * 1,000$$

Early neonatal mortality rate, weight-specific:

$$\frac{\text{Early neonatal deaths of infants weighing 1,000 g and over at birth}}{\text{Live births weighing 1,000 g and over}} * 1,000$$

$$\text{Perinatal mortality ratio: } \frac{\text{Fetal deaths and early neonatal deaths}}{\text{Live births}} * 1,000$$

$$\text{Perinatal mortality rate}^1: \frac{\text{Fetal deaths and early neonatal deaths}}{\text{Total births}} * 1,000$$

¹ The perinatal mortality rate is the number of fetal deaths weighing at least 500 g (or, when birth weight is unavailable, after 22 completed weeks of gestation or with a crown-heel length of 25 cm or more), plus the number of early neonatal deaths, per 1,000 total births. Because of the different denominators in each component, this is not necessarily equal to the sum of the fetal death rate and the early neonatal mortality rate.

Perinatal mortality rate, weight-specific:

$$\frac{\text{Fetal deaths weighing 1,000 g and over, plus early neonatal deaths of infants weighing 1,000 g and over at birth}}{\text{Total births weighing 1,000 g and over}} * 1,000$$

$$\text{Neonatal mortality rate: } \frac{\text{Neonatal deaths}}{\text{Live births}} * 1,000$$

Neonatal mortality rate, weight-specific:

$$\frac{\text{Neonatal deaths of infants weighing 1,000 g and over at birth}}{\text{Live births weighing 1,000 g and over}} * 1,000$$

$$\text{Infant mortality rate: } \frac{\text{Number of deaths under one year of age}}{\text{Live births}} * 1,000$$

Infant mortality rate, weight-specific:

$$\frac{\text{Infant deaths among live births weighing 1,000 g and over at birth}}{\text{Live births weighing 1,000 g and over}} * 1,000$$

Maternal Mortality Definitions

Maternal death. The death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and the site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes.

Late maternal death. The death of a woman from direct or indirect obstetric causes more than 42 days but less than one year after termination of pregnancy.

Pregnancy-related death. The death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the cause of death. This definition is provided to permit calculation of an alternative to the *maternal death* rate in countries that wish to identify deaths occurring in pregnancy, childbirth and the puerperium, but cannot distinguish direct and indirect maternal deaths as defined.

Recommended Definitions, Standards, and Reporting Requirements Related to Reproduction

Maternal deaths should be subdivided into two groups:

Direct obstetric deaths: those resulting from obstetric complications of the pregnant state (pregnancy, labor and puerperium), from interventions, omissions, incorrect treatment, or from a chain of events resulting from any of the above.

Indirect obstetric deaths: those resulting from previous existing disease or disease that developed during pregnancy and which was not due to direct obstetric causes, but which was aggravated by physiologic effects of pregnancy.

Reporting Requirements

For the purposes of the international reporting of maternal mortality only those maternal deaths occurring before the end of the 42-day reference period should be included in the calculation of the various ratios and rates, though the recording of later deaths is useful for national analytical purposes.

Late maternal deaths should not be included in the calculation of the maternal mortality rate.

Published maternal mortality rates should always specify the numerator (number of recorded maternal deaths), which can be given as:

- the number of recorded direct obstetric deaths, or
- the number of recorded obstetric deaths (direct plus indirect).

The denominator used for calculation should likewise be specified as either the number of live births or the total number of births (live births plus fetal deaths). Where both denominators are available, a calculation should be published for each.

Ratios and Rates

These should be expressed as a ratio of the numerator to the denominator, multiplied by k (where k may be 1,000, 10,000, or 100,000 as preferred and indicated by the country). Maternal mortality ratios and rates can thus be expressed as:

Maternal mortality rate¹: $\frac{\text{Maternal deaths (direct and indirect)}}{\text{Live births}} * k$

Direct obstetric mortality ratio: $\frac{\text{Direct obstetric deaths only}}{\text{Live births}} * k$

Pregnancy-related mortality ratio: $\frac{\text{Pregnancy - related deaths}}{\text{Live births}} * k$

¹ The use of the term *rate*, although inexact in this context, is maintained for the sake of continuity.

Appendix 3

Life-Table Analysis

Introduction

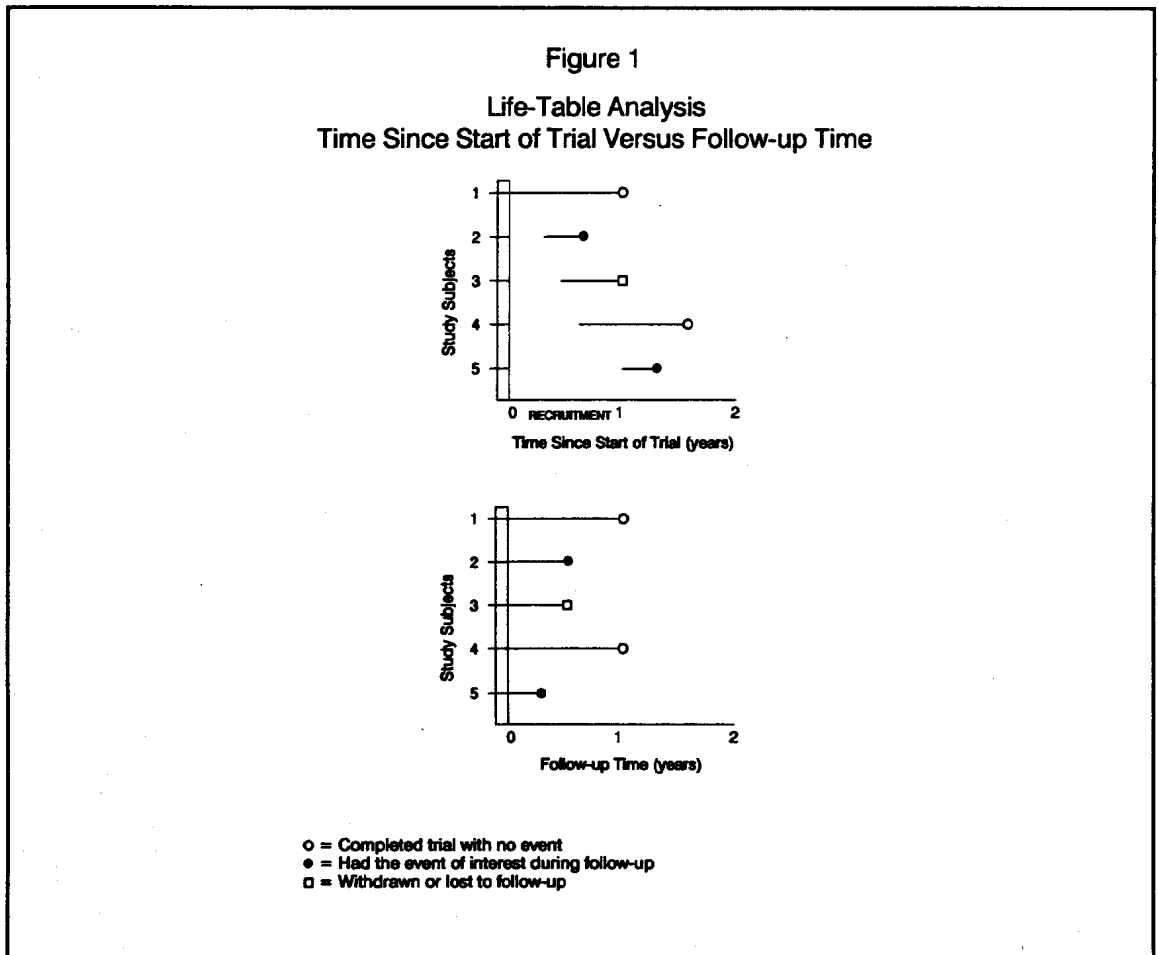
Life-table analysis is a method of summarizing the results of a study by time, that is, by grouping into smaller intervals the time between admission to a study and the end of the designated follow-up period. For each time interval, life-table analysis records the number of study subjects who are still in the study at the start of the interval, the number who experience the outcome of interest during the interval (e.g., pregnancy, intrauterine device (IUD) expulsion, continuation of contraceptive use), and the number of study subjects who discontinue participation during the interval without having had the outcome of interest (i.e., because they are lost to follow-up or no longer participate in the study for a reason other than the outcome of interest). From these numbers, the probability of the outcome event occurring in each interval is estimated.

The major advantage of the life-table approach is that it takes into account how long each participant is in the study. Life tables take advantage of the experience of individuals even though they do not complete the study. This establishes the period of time within the study when each participant was at risk of exhibiting the outcome of interest.

Grouping observations into fixed time periods of follow-up. In most clinical trials, the subjects do not enter the study at the same time. Their entry is staggered. In life-table analysis, however, all entry times are considered time zero. In Figure 1, study subjects were recruited during a one-year time period and followed up for one year. Their staggered entry is shown in the upper panel of the figure. Study subjects 1 and 4 completed the trial without experiencing the event of interest (i.e., pregnancy). Study subject 3 was lost to follow-up and study subjects 2 and 5 experienced the event of interest during the follow-up. For life-table analysis, the time of follow-up observation for the five study subjects are shown in the lower panel of Figure 1. All entry times are at time zero.

Study subjects who do not experience the event of interest while they are being followed up are said to survive (without the event). They could complete the study without the event or drop out (be withdrawn because they have an event that disqualifies them from the study or be lost to follow-up). Some study subjects enter the study near its conclusion and do not complete the full time period before the conclusion of the study. In these situations, the follow-up experience of all study subjects who survive is said to be censored before we can observe the event of interest. Note, however, that the term *censored* as used for any particular time period includes only those lost or discontinued during the interval for some reason other than the event of interest, not those who complete the interval without the event.

Life-table Analysis



The steps and formulas required for life-table calculations are:

Step 1. Group the observations into fixed time periods of follow-up.

Step 2. Compute the probability of surviving any time interval, the i th interval, given survival up to the beginning of the interval as:

$$(8.33.1) \quad q_i = \frac{n_i - d_i - (c_i / 2)}{n_i - (c_i / 2)}$$

where n_i = number of subjects entering the i th interval; d_i = number of events of interest in the i th interval; c_i = number of subjects censored in the i th interval (lost-to-follow-up or discontinuing for a reason other than the event of interest); q_i is also called the survival rate for the i th interval; and $n_i - (c_i / 2)$ is the group at risk for the event of interest during the i th interval.

Step 3. Compute the probability of not surviving the i th interval as:

$$(8.33.2)$$

$$p_i = 1 - q_i$$

$$= \frac{d_i}{n_i - (c_i/2)}$$

p_i is also called the event rate for the i th interval.

Step 4. Compute the probability of surviving from the beginning of the study until the end of each time interval. The probability of surviving from the beginning of the study until the end of the i th interval is:

$$(8.33.3)$$

$$S_i = q_1 * q_2 * \dots * q_i$$

S_i is also called the cumulative survival rate.

Step 5. Compute the probability of experiencing the event of interest sometime from admission to the study until the end of the i th interval, $1 - S_i$. This is also called the cumulative event rate.

Step 6. Compute the variance of the cumulative event rate for the i th interval as:

$$(8.33.4)$$

$$\text{Variance } (1 - S_i) = \text{Variance}(S_i)$$

$$= S_i^2 * \sum_{k=1}^i \left[\frac{1}{n_k - d_k - (c_k/2)} - \frac{1}{n_k - (c_k/2)} \right]$$

Step 7. Compute the Standard Error (SE) for $1 - S_i$ as:

$$(8.33.5)$$

$$\text{SE } (1 - S_i) = \text{SE } (S_i)$$

$$= \sqrt{\text{Variance } (S_i)}$$

Recall that the SE of the cumulative event rate is also known as the standard deviation. Steps 3, 5, and 7 are required for the life tables in Table 2. The other steps, however, are needed to calculate these items.

Table 2						
Life Table						
Sponge Users						
Follow-up Month <i>i</i>	Number Entering <i>n_i</i>	Number Pregnant <i>d_i</i>	Number Censored <i>c_i</i>	<u>Step 3</u> Monthly Pregnancy Proba- bility <i>p_i</i>	<u>Step 5</u> Cumulative Pregnancy Proba- bility <i>1 - S_i</i>	<u>Step 7</u> SE of Cumulative Pregnancy Proba- bility SE (<i>1 - S_i</i>)
1	723	15	104	0.0224	0.0224	0.0057
2	604	8	35	0.0136	0.0357	0.0073
3	561	12	26	0.0219	0.0568	0.0094
4	523	10	41	0.0199	0.0756	0.0109
5	472	11	31	0.0241	0.0979	0.0125
6	430	10	31	0.0241	0.1196	0.0140
7	389	6	23	0.0159	0.1336	0.0149
8	360	6	8	0.0169	0.1482	0.0158
9	346	5	11	0.0147	0.1607	0.0165
10	330	4	24	0.0126	0.1713	0.0171
11	302	1	12	0.0034	0.1741	0.0173
12	289	<u>0</u>	85	0.0000	0.1741	0.0173
		88				
Diaphragm Users						
1	717	5	102	0.0075	0.0075	0.0033
2	610	9	14	0.0149	0.0223	0.0059
3	587	12	39	0.0211	0.0430	0.0083
4	536	4	49	0.0078	0.0505	0.0090
5	483	6	36	0.0129	0.0627	0.0102
6	441	7	31	0.0165	0.0781	0.0116
7	403	3	24	0.0077	0.0852	0.0122
8	376	5	16	0.0136	0.0977	0.0132
9	355	3	23	0.0087	0.1055	0.0139
10	329	3	25	0.0095	0.1140	0.0146
11	301	0	24	0.0000	0.1140	0.0146
12	277	<u>4</u>	63	0.0163	0.1284	0.0160
		61				

For month 1:

$$\begin{aligned} q_1 &= \frac{n_1 - d_1 - (c_1/2)}{n_1 - (c_1/2)} \\ &= \frac{723 - 15 - (104/2)}{723 - (104/2)} \\ &= \frac{656}{671} \\ &= 0.9776 \end{aligned}$$

$$p_1 = 1 - q_1 = 1 - 0.9776 = 0.0224$$

$$S_1 = q_1 = 0.9776$$

$$1 - S_1 = 0.0224$$

$$\begin{aligned} \text{Variance } (1 - S_1) &= S_1^2 * \left[\frac{1}{n_1 - d_1 - (c_1/2)} - \frac{1}{n_1 - (c_1/2)} \right] \\ &= 0.9776^2 * \left[\frac{1}{723 - 15 - (104/2)} - \frac{1}{723 - (104/2)} \right] \\ &= (0.9557) * \left[\frac{1}{656} - \frac{1}{671} \right] \\ &= 0.00033 \end{aligned}$$

$$\text{SE } (1 - S_1) = \sqrt{\text{Variance } (1 - S_1)} = 0.0057$$

For month 2:

$$\begin{aligned} q_2 &= \frac{n_2 - d_2 - (c_2/2)}{n_2 - (c_2/2)} \\ &= \frac{604 - 8 - (35/2)}{604 - (35/2)} \\ &= \frac{578.5}{586.5} \\ &= 0.9864 \end{aligned}$$

$$p_2 = 1 - q_2 = 0.0136$$

$$\begin{aligned} S_2 &= q_1 * q_2 = 0.9776 * 0.9864 \\ &= 0.9643 \end{aligned}$$

$$1 - S_2 = 0.0357$$

$$\text{Variance } (1 - S_2) = 0.9643^2 * \left[\frac{1}{656 - 671} - \frac{1}{578.5 - 586.5} \right] = 0.000054$$

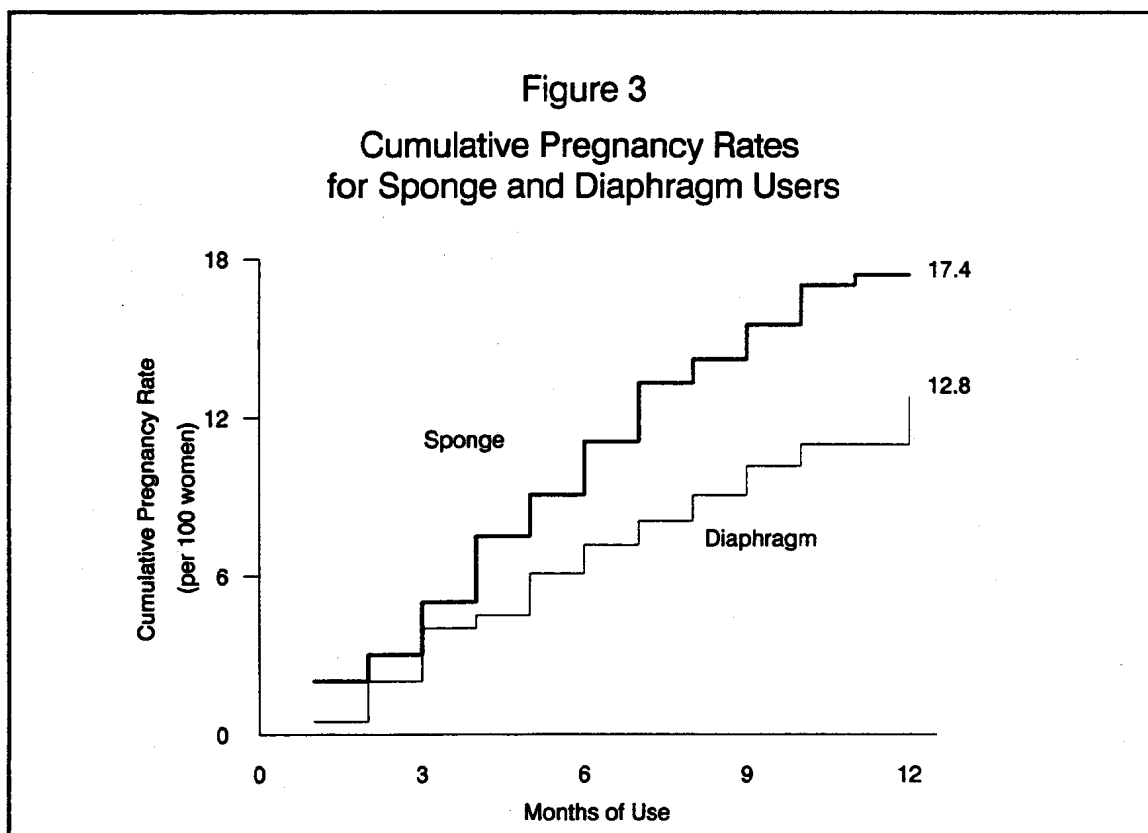
$$\text{SE } (1 - S_2) = \sqrt{\text{Variance } (1 - S_2)} = 0.0073$$

Life-table Analysis

Table 2 contains follow-up data from the randomized parallel clinical trial of the contraceptive sponge and the diaphragm in Example 8.32 (Edelman et al., 1984). The format for Table 2 is a good working format. To illustrate the calculations, consider the first two months of follow-up for sponge users (Use formulas 8.33.1 through 8.33.5).

In reporting the results of a life-table analysis, the emphasis is on the cumulative event rate (cumulative pregnancy probability $(1 - S_i)$ in Table 2). With the cumulative event rate, the probability of having the event of interest within the first k months of use of a treatment can be estimated. For example, the probability of becoming pregnant in the first six months is 0.1196 for sponge users and 0.0781 for diaphragm users. The SE for the cumulative event rate measures the precision of the estimate.

For comparative trials, the interest is usually in comparing cumulative event rates or probabilities between treatments. This is the probability calculated in Step 5 as shown in Table 2. A useful way to compare cumulative event rates is to plot them. The method of plotting is illustrated in Figure 3. Since the estimates of cumulative event rates are made at the end of each month, the plotted points are joined by steps rather than by straight lines. The joined, plotted points are called cumulative event rate curves.



The rates are expressed as pregnancies per 100 women. For the contraceptive sponge, the annual pregnancy rate is estimated at about 17 per 100 women. For the diaphragm, approximately 13 of 100 users will become pregnant within one year. The plots show that throughout the follow-up, sponge users have a higher pregnancy rate than diaphragm users.

Point Estimates and Confidence Intervals

The primary point estimate from the life table is the cumulative event rate at different times during the follow-up. By combining the point estimates of the cumulative event rate with the corresponding standard error of the estimate of the cumulative event rate, a confidence interval for the cumulative event rate at a specific time during the follow-up can be calculated. The formula for a 95% confidence interval is:

(8.34.1)

$$\text{Lower Limit} = (1 - S_i) - 1.96 * SE_i(1 - S_i)$$

$$\text{Upper Limit} = (1 - S_i) + 1.96 * SE_i(1 - S_i)$$

For the contraceptive sponge data in Table 2, the 95% confidence interval for the 12-month cumulative pregnancy probability is:

$$\text{Lower Limit} = 0.1741 - 1.96 * 0.0173 = 0.1402$$

$$\text{Upper Limit} = 0.1741 + 1.96 * 0.0173 = 0.2080$$

Note that the values for $(1 - S_i)$ and $SE_i(1 - S_i)$ to be used in formula 8.34.1 are from the last line of the upper panel in Table 2.

<u>Follow-up Month</u>	<u>Cumulative Pregnancy %</u>	<u>95% CI for the Cumulative Probability</u>
1	2.24	(1.12, 3.36)
3	5.68	(3.84, 9.52)
6	11.96	(9.22, 14.70)
9	16.07	(12.84, 19.30)
12	17.41	(14.02, 20.80)

Life-table Analysis

In reports and publications, it is useful to present an abbreviated version of the working life table that includes a column for the confidence interval for the cumulative event rate. The cumulative event rate and confidence intervals may be expressed as percentages or proportions. Table 4 presents the cumulative pregnancy probability and confidence intervals expressed as percentages.

Statistical Comparison. The relative effectiveness of two treatments is best evaluated statistically by comparing the cumulative rate curves for the total study period. The logrank method uses a chi-square (χ^2) statistic to compare the number of observed events for each treatment with the number of events expected if the treatments were equally effective. For purposes of illustration, assume that we are comparing treatment A with treatment B. The calculations are made easier by using a table that requires the following entries:

i = the number of the follow-up interval (e.g., month i where $i = 1, 2, \dots, 12$).

d_i = total number of events observed in interval i (both treatments combined).

n_{Ai} = number at risk in treatment group A in interval i .

= number in group A entering the interval $- 1/2$ the number in group A censored during the interval.

n_{Bi} = number at risk in treatment group B in interval i .

= number in group B entering the interval $- 1/2$ the number in group B censored during the interval.

E_{Ai} = expected number of events in group A in interval i .

(8.36.1)

$$= \frac{n_{Ai}}{n_{Ai} + n_{Bi}} * d_i$$

E_{Bi} = expected number of events in group B in interval i .

(8.36.2)

$$\frac{n_{Bi}}{n_{Ai} + n_{Bi}} * d_i = d_i - E_{Ai}$$

In the sponge and diaphragm example, consider the first month in Table 2:
 $d_1 = 15$ sponge pregnancies + 5 diaphragm pregnancies = 20 pregnancies.

During the first month of follow-up, 723 sponge users entered the trial, 104 quit the trial for a reason other than pregnancy or were lost to follow-up (censored) during the month.

$$n_{s1} = 723 - (104/2) = 671 \text{ where S refers to sponge usage.}$$

During the first month of follow-up, 717 diaphragm users entered the trial, 102 quit the trial or were lost to follow-up (censored) during the month.

$$n_{D1} = 717 - (102/2) = 666 \text{ where D refers to diaphragm usage.}$$

$$E_{s1} = \frac{n_{s1}}{n_{s1} + n_{D1}} * d_1 = \frac{671}{671 + 666} * 20 = 10.04$$

$$E_{D1} = d_1 - E_{s1} = 20 - 10.04 = 9.96$$

The calculations in Table 5 are used to determine E_s and E_D , the expected number of pregnancies among the sponge and the diaphragm users, respectively. The expected values are compared to the observed values using the following chi-square (χ^2) statistic with 1 degree of freedom (df):

(8.37.1)

$$\begin{aligned} \chi_{1df}^2 &= \frac{(O_s - E_s)^2}{E_s} + \frac{(O_D - E_D)^2}{E_D} \\ &= \frac{(88 - 73.79)^2}{73.79} + \frac{(61 - 75.21)^2}{75.21} \\ &= 5.42 \end{aligned}$$

where O_s and O_D are the observed number of pregnancies among the sponge and the diaphragm users, respectively (see Table 2). The example $\chi_{1df}^2 = 5.42$ has a p-value slightly less than 0.025. This is a small p-value and indicates a statistically significant probability that the two treatments are not equally effective. The small p-value taken together with the life-table displays and the plot of the cumulative pregnancy curves suggests that the sponge is less effective than the diaphragm in preventing pregnancy.

Life-table Analysis

Table 5					
Logrank Test					
Month i	Total Pregnancies d_i	n_{Si}	n_{Di}	E_{Si}	E_{Di}
1	20	671	666	10.04	9.96
2	17	586.5	603	8.38	8.62
3	24	548	567.5	11.79	12.21
4	14	502.5	511.5	6.94	7.06
5	17	456.5	465	8.42	8.58
6	17	414.5	425.5	8.39	8.61
7	9	377.5	391	4.42	4.58
8	11	356	368	5.41	5.59
9	8	340.5	343.5	3.98	4.02
10	7	318	316.5	3.51	3.49
11	1	296	289	0.51	0.49
12	4	246.5	245.5	2.00	2.00
				E_S = 73.79	E_D = 75.21

Practice Exercises

1. Circle true (T) or false (F).
 - (a) T/F In life table analysis, we are interested in how long persons in the trial do not have the outcome.
 - (b) T/F Life tables summarize results of the study according to time intervals.
 - (c) T/F Life tables take advantage of the experience of individuals even though those persons do not complete the study.
 - (d) T/F Life tables provide a method of recording the actual time when study subjects enter the trial.
 - (e) T/F Life-table analysis permits estimates of the probability that an individual who follows a particular treatment regimen will have the outcome within 3 months.
 - (f) T/F The results of life tables are usually analyzed by visual methods alone.
 - (g) T/F The logrank method is used to compare cumulative event rate curves.

Suggested Answers to Practice Exercises

1. True or false.

(a) T

(b) T

(c) T Any length of time in the study is recorded in the life table.

(d) F No. In the analysis, all participants are treated as if they enter the study at the same time.

(e) T

(f) F No. Visual methods and formal statistical tests are used to analyze life tables.

(g) T