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# Use of Circadian Rhythms to Screen for Fever: A Replication

Michele S. Heckman  
*Grand Valley State University*

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USE OF CIRCADIAN RHYTHMS TO SCREEN FOR FEVER:  
A REPLICATION

By

Michele S. Heckman, B.S.N., R.N.

A THESIS

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Thesis Committee Members:  
Emily Droste-Bielak, Ph.D., R.N.  
Katherine Kim, Ph.D., R.N.  
William C. Bell, Ph.D.

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## ABSTRACT

### USE OF CIRCADIAN RHYTHMS TO SCREEN FOR FEVER: A REPLICATION

By

Michele S. Heckman, B.S.N., R.N.

There are inconsistent guidelines for, and consequently, inconsistent practice in the screening of hospitalized adults for fever. Using the predictive knowledge of circadian thermal rhythms, the purposes of this study were to identify 1) the hour of the day in which most fevers occurred and 2) the necessary frequency of measurement to detect fever. The sample consisted of 35 subjects, ages 22-62. Temperatures were measured at 6 p.m., 10 p.m., 6 a.m., 10 a.m., 2 p.m., and 6 p.m. for 24 hours. Eighteen (51.42%) of the 35 subjects had fevers during the 24-hour measurement period. Fourteen (77.78%) initial fevers were detected at each of the 6 p.m. measurements. Two (11.11%) initial fevers were detected at 10 p.m. These two subjects continued to be febrile at 6 p.m. the following day. No initial fevers were detected at 6 a.m., 10 a.m., or 2 p.m.

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## Chapter One

### Introduction

The first thermometer developed for human use was demonstrated in 1732 (Boerhhave, 1732/1977). In current nursing practice, the procedure for temperature measurement for the purpose of screening for fever has become a basic, almost ritualistic, task in the nursing assessment of hospitalized patients. The presence of fever is a diagnostic cue in a variety of conditions and disease states. Temperature measurement is an essential tool in monitoring the course of these diseases and conditions as well as the efficacy of the treatment regimen.

Temperature measurement of hospitalized patients is performed en masse on a twice-daily (early a.m. and early p.m.) or a thrice-daily (once per shift) schedule. Temperatures of post-operative or post-procedural patients are often measured every four hours. These schedules are often based on reasons of tradition or convenience rather than on a scientific framework. In addition, these schedules fail to detect initial temperature elevations (Bell, 1969; Sims,

1965). Undetected fevers may lead to inappropriate discharges and subsequent readmissions, financial implications in a system of prospective payment.

Overall incidence of fever in hospitalized patients was reported to be quite low in two previous studies, 1.28% and 2.8% (Angerami, 1980; Schmidt, 1958). In view of this fact, the necessity for a schedule that coincides with patterns of fever development becomes apparent. The low incidence of fever also suggests that multiple daily mass screenings are unnecessary for fever detection and, therefore, waste nursing time and equipment. This practice also adds interruptions to the patients' resting and visiting periods.

Inconsistent guidelines for a temperature measurement schedule are presented in basic nursing skills texts (Nurse's Reference Library, 1983; Potter & Perry, 1985; Wolff, Weitzel, Zornow, & Zsohar, 1983). These inconsistencies may be reflective of inconsistencies in practice and demonstrate that not many of the research findings have disseminated to education and practice.

#### Problem Statement

Mass temperature measurement in the early morning and early afternoon is a procedure that is inaccurate because it fails to accomplish the purpose of fever detection. Consequently, this schedule is costly in

terms of wasted nursing time and supplies. Therefore, it is necessary to determine a schedule that more accurately identifies initial fever elevations. More specifically, at what time of day do most patients develop fever? And, how often must patients' temperatures be measured to detect initial temperature elevations?

#### Purpose

Using the predictive knowledge of circadian thermal rhythms, this study attempted to identify the hour(s) most sensitive for fever detection in a system of mass screening. In addition, it was hoped that a recommendation for the necessary frequency of measurement of body temperatures could be developed based on the findings of this study.

This study tried to replicate and extend the findings of DeRisi (1968), and Samples, Van Cott, Long, King, and Kersenbrock (1985) in order to expand nursing's knowledge base.

## Chapter Two

### Literature Review and Conceptual Framework

#### Literature Review

The review of the literature included studies that explored patterns of initial fever development and determined appropriate times to screen hospitalized adults for fever. In addition, studies that examined various factors affecting temperature measurement were reviewed.

DeRisi (1968) randomly sampled 100 hospitalized male adults and measured temperatures at 6 a.m., 10 a.m., 2 p.m., 6 p.m., and 10 p.m. for three consecutive days. Results indicated that a 0.68° F. difference between the 2 and 6 p.m. grand means was significant statistically ( $z = 22.7, p < .0001$ ) and clinically. DeRisi (1968) determined that 48% of the temperature elevations or fever found in this study would have gone undetected without the 6 p.m. measurement.

In a similar study, Samples, VanCott, Long, King, and Kersenbrock (1985) selected 107 hospitalized adults by screening Kardexes and measured temperatures at the same times for the same duration. They reported that 60% of the febrile measurements occurred at 6 p.m.

There were no controls for shiftworkers or for premenopausal women who would have normal variations in circadian thermal rhythm. The researchers also included elderly individuals (sample ages 18-91), which was a potential source of error, as temperature declines with age (Higgins, 1983).

Angerami (1980) attempted to determine the hour that presents the greatest sensitivity and the greatest specificity for detection of fevers. Temperatures of every person over the age of 12 hospitalized at the institution selected for the study were measured every two hours for 24 hours over an eight day period. Because an incidence of fever of 1.28% was found, Angerami (1980) questioned the routine performance of temperature measurement. The most sensitive hour for fever detection was calculated to be 7 p.m., and the least sensitive was 7 a.m.; specificity was calculated to be between 90% and 100% at all hours. Angerami (1980) concluded that, in a system of mass screening, only the time of 7 p.m. is most sufficient.

In an early nursing study, Schmidt (1958) surveyed temperature records to find 132 elevated temperatures out of a total of 1876 taken. The early morning temperature measurements were then eliminated on all but post-surgical or post-procedural patients to appreciate a time-savings of 62 hours in a 21-day

period. Sims (1965) retrospectively studied temperature records of 485 patients to find that the highest rate of fever occurred between 2 p.m. and 6 p.m. Results indicated 8500 hours per year were spent on taking and recording temperatures. Consequently, a routine schedule of temperature measurement at 7 a.m., 2 p.m., and 7 p.m. was introduced. A savings of 3500 hours in nursing time was reported, but the percentage of fevers detected with the new schedule was not reported.

Bell (1969) also studied temperature records retrospectively, sampling the first, third, fifth, and seventh post-operative or hospital day. Included were the 4 p.m. temperatures of the previous day and the 8 a.m. and 4 p.m. temperatures of the sample day. Slightly more than 2% of the subjects had an elevated temperature at 8 a.m. that had not been preceded by an elevation at 4 p.m. the previous day. Bell (1969), therefore, recommended temperatures be taken once per day, between 4 p.m. and 8 p.m., and recommended nursing judgment be used when more frequent measurement might be indicated.

In summary, a wide variation of recommended times for temperature screening exists. The finding that a greater percentage of fevers occurs in the late afternoon to early evening was consistent. The

inability to pinpoint an exact time for the peak and trough in the circadian thermal rhythm may be due to differences in geographical location (Palmer, 1976).

Nurses have also studied the temperature-taking procedure itself, variables affecting temperature measurement, and differences in measurement at sites and for type of thermometer. Unless stated otherwise, the studies cited in this review utilized an electronic thermometer.

Boerhhave (1732/1977) was the first scientist to develop the clinical thermometer for human temperature measurement. Its use was demonstrated by measuring the heat produced by mixing water and spirits of wine. Over the next two hundred years, thermometers were refined and redesigned to measure temperature at various sites of the human body.

Beck and St. Cyr (1974) reviewed the oral thermometers in current use and listed advantages and disadvantages of the electronic, mercury-in-glass, and the chemical dot thermometers. Although they did not offer a specific recommendation, they credited the chemical dot thermometer to "be the most advantageous, simple, accurate, and safe method of the three." Its primary disadvantage was stated to be that it was disposable, adding to the problem of what to do with our single-use disposable plastic items. The glass thermometer was least simple to use, provided a



potential source of injury to the patient in the event of breakage, and provided a potential source of contamination. In addition, the authors reported in vitro inaccuracies. The electronic thermometer presented the greatest accuracy in vitro and great inaccuracy in vivo. They believed the inaccuracy was due to slow insertion into the heat pocket. The electronic thermometer also offered the possibility of contamination.

Beck and Campbell (1975) reported confirming a "heat pocket" at "the junction of the base of the tongue at the floor of the mouth on either...side of the frenum" (p. 176). They described average temperatures at alternative oral sites of measurement, and advocated the posterior sublingual pocket.

In a study of 50 hospitalized adults, Erickson (1976) also demonstrated the posterior sublingual pocket yielded higher temperature measurements. These subjects were 25 males and 25 females between the ages of 20 and 81 who were known to be febrile. A mean temperature difference of  $0.37^{\circ}$  F. between the left front area and posterior sublingual pockets and  $0.34^{\circ}$  F. between the right front area and posterior sublingual pockets was statistically significant at the 0.01 level using the Bonferoni t-test. The values of  $0.3-0.4^{\circ}$  F. also have clinical importance. A mean temperature difference between the left and right

posterior sublingual pockets of  $0.04^{\circ}$  F. was neither statistically significant ( $p > .05$ ) or clinically significant. A mean difference of  $.08^{\circ}$  F. between mouth closed and mouth open measurements was statistically significant (no  $p$  level reported), but clinically insignificant. Also, of interest for further study, a difference of  $0.73^{\circ}$  F. was determined between the highest and lowest temperatures in subjects with full dentition. Four subjects were edentulous. They showed a difference of  $1.18^{\circ}$  F. between their highest and lowest readings. Sixteen subjects with either full or partial dentures showed a difference of  $0.62^{\circ}$  F. Beck and St. Cyr (1974) also cited dentures as a possible source of measurement error because of their heat-absorbing capacity. In a subsequent study, Erickson (1980) again demonstrated higher temperature readings in the posterior sublingual pocket. A slow-slide insertion, a pre-warming technique, was used to yield higher temperature readings and shorter reading times. This technique was recommended for use in research. In a more recent publication, however, Erickson (1983) abandoned the recommendation of the slow-slide technique, stating the advantage of the technique may be offset by the need to instruct personnel and patients and by the discomfort of holding the mouth open for the time necessary for the technique.

Cooper and Abrams (1984) compared vaginal temperatures with temperatures obtained at four different oral locations in a repeated measures design of 11 women aged 21 to 43 years. They demonstrated each of the oral locations: the anterior sublingual pocket, the posterior sublingual pocket, the dorsal tongue, and the buccal trough, produced different temperatures, even early in the morning before arising. Temperatures taken in the posterior sublingual pocket yielded the highest readings. The authors believed this location related measurements closest to the body core temperature. They also referred to the fact that early morning temperatures rise as much as one degree during and after ovulation.

In a study to determine the relationship of several variables affecting perioperative body temperature, Closs, Macdonald, and Hawthorn (1986) found the amount of body fat, age, and operating room temperature to be statistically related to hypothermia. However, they did not indicate at what point after surgery temperatures returned to normal.

Tachypnea has been shown to affect oral temperature measurement in two studies. Tandberg and Sklar (1983) demonstrated that for every increase of respirations by 10, the decreased difference in temperature measurement approaches 0.5° C. Durham, Swanson, and Paulford (1986) replicated their study and

obtained similar results. They believed the difference to be due to the cooling effects produced by the tachypnea and that the time for the electronic thermometer to equilibrate was not enough to accurately measure the oral temperature in the presence of tachypnea. Both studies recommended rectal temperature measurement for tachypneic patients (respiratory rate > 22).

Ingestion of ice water was demonstrated to lower oral temperature by as much 5.5° F. and that temperature returned to the pre-ingestion state in 15 minutes (Forster, Adler, & Davis, 1970). Using mercury-in-glass thermometers, Woodman, Parry, and Sims (1967) found elevations of 0.2° F. after smoking, but did not study the duration of the elevation. They questioned the clinical significance of the elevation. No studies of the effects of smoking on temperature measurement with the electronic thermometer were found.

Higgins (1983), using a mercury-in-glass thermometer, measured oral temperatures of 60 male and female subjects over the age of 65 between 9:00 a.m. and 12:00 noon. A mean temperature of 97.7° F. was demonstrated. The nine male subjects in the 80-90 years of age group had a mean temperature of 97.1° F. The author asserted, then, that body temperature

decreases with age and advocated that a temperature of 98.6° F. in an individual aged 65 or older be classified as fever.

In a study exploring the effects of air and water mattresses on body temperature, Wirtz (1987) measured sublingual and skin temperatures of 20 men over the age of 62 who were residents of a chronic care geriatric hospital. These temperatures were measured each morning before arising and two hours after retiring for a 72-hour period. Ten subjects were using alternating air mattresses and ten were using nonheated water mattresses. The mean sublingual temperature of the air mattress group was 98.2° F.; mean temperature of the water group was 97.1° F. The difference was determined to be statistically significant ( $t(18) = 3.2$ ,  $p = .005$ ). The author concluded that water mattresses exert more of a cooling effect on body temperature than alternating air mattresses. This may be deleterious in a geriatric population. This study raises the question of effects of circulating air mattresses on body temperature regulation in a younger age group as well.

By far, the largest body of research related to variables affecting temperature measurement was the effect of oxygen therapy. Graas (1974) measured oral and rectal temperatures of nine nursing students before and 15 minutes after oxygen administration by nasal cannula at three liters per minute. A mercury-in-glass

thermometer was used. Both oral and rectal temperatures decreased  $0.2^{\circ}$  F. Again, the clinical significance was questioned.

Yonkman (1982) studied 30 healthy volunteer subjects for the effect of cooled and heated aerosol on the measurement of oral temperature in a repeated measures design. Statistically significant decreases ( $p < .005$ ) of  $0.21-0.24^{\circ}$  F. heated and  $0.27-0.31^{\circ}$  F. cooled were found. The researcher determined that these were clinically insignificant. In similar studies with similar designs, Hasler and Cohen (1982) and Lim-Levy (1982) obtained similar results for oxygen delivered by aerosol, venti-mask, mask, and nasal cannula to healthy volunteers for a period of 15 and 30 minutes. All authors suggested that the short administration times may not be enough to effect any temperature measurement difference and recommended studies be conducted with long-term oxygen administration.

In a clinical study, Dressler, Smejkal, and Ruffolo (1983) measured oral and rectal temperatures of 30 post-cardiac surgery patients who were receiving oxygen by mask. They demonstrated a decreased difference of  $1.46^{\circ}$  F. between oral and rectal temperatures. They also demonstrated greater decreased differences with increases in age.

Felton (1978) wondered whether removing the oxygen mask for temperature measurement had any adverse effect on the patients' oxygenation status. With a small sample of 10 hospitalized subjects, clinically significant decreases in PaO<sub>2</sub> were demonstrated. Nine out of ten subjects experienced a drop in PaO<sub>2</sub> ranging from 7 to 53 mmHg. In five subjects, the PaO<sub>2</sub> did not return to baseline in twenty minutes. Felton recommended, therefore, that rectal temperatures be taken in patients receiving oxygen by mask.

In summary, body temperature and oral temperature measurement are affected by several variables. Individuals over age 60 have lower body temperatures, which implies that the point at which temperature becomes fever is also lower (Higgins, 1983). Ovulatory females have early morning temperatures that are elevated by as much as one degree (Cooper & Abrams, 1984). The use of a nonheated water mattress was shown to decrease body temperature in comparison to use of an alternating air mattress (Wirtz, 1987). Because the effects of circulating air mattresses on body temperature are unknown, use of these mattresses was considered an extraneous variable in this study.

Other variables have been shown to affect the accuracy of temperature measurement. These variables were considered as extraneous in this study. Oxygen delivered by mask has a cooling effect (Dressler,

Smejkal, & Ruffolo, 1983). Removing a mask for temperature measurement will decrease PaO<sub>2</sub>, creating a potential harm (Felton, 1978). The ingestion of hot or cold substances and smoking has been shown to affect the accuracy of temperature measurement (Forster, Adler, & Davis, 1970; Woodman, Parry, & Sims, 1967). Respiratory rates greater than 22 per minute also having a cooling effect on temperature measurement (Durham, Swanson, & Paulford, 1986; Sklar, 1983). Temperatures are significantly reduced in the immediate post-operative period, presumably due to the ambient temperature of the operating room (Closs, Macdonald, & Hawthorn, 1986).

Finally, oral temperature measurement is affected by the location of the probe in the oral cavity. Use of the posterior sublingual pocket is recommended, as that location yields the highest readings. The length of time over which the probe is inserted has an effect on temperature measurement. However, the value of this effect is minimized by the cost in comfort to and cooperation of the subject.

#### Conceptual Framework

The conceptual framework for this study was taken from the sciences related to biological rhythms and nursing science. Also included is a review of the physiology of thermoregulation and fever production.



Kluger (1979) has conceptualized body temperature regulation as consisting of three general components: 1) sensors, 2) integrators, and 3) effectors. Sensors are nerve cells that detect temperatures externally (skin) as well as internally (hypothalamus, spinal cord, and abdomen). The sensors then convert the temperatures into signals and send them along the afferent nerves to the hypothalamus. The hypothalamus is the integrator of all thermal responses and acts much like a thermostat. This integrator "considers" all of the thermal information with which it has been presented, "selects" the appropriate physiological response, and sends the appropriate information along the efferent nerves to the effectors, physiologic structures which actively control the raising or lowering of body temperature. Some of these effectors are skeletal muscle (shivering), skin blood vessels (vasodilatation or vasoconstriction) and sweat glands (sweating).

It is known that some activities (e.g. physical exercise and the ingestion of food) increase body temperature for a short period of time, until the effectors have responded effectively to return the temperature to its normal range. This increase in body temperature is a direct result of the heat produced by an increase in the body's metabolic rate (Hensel, 1973;

Kluger, 1979; Memler & Wood, 1983; Moore-Ede, Sulzman, & Fuller, 1982). Body temperature, then, is a result of the balance between heat production and heat loss.

Fever occurs when toxins stimulate the release of an endogenous pyrogen. It is believed that this chemical acts upon the hypothalamus to cause an elevation in temperature and that the degree of fever is mediated by the release of prostaglandins. The antipyretic effect of aspirin and other nonsteroidal antiinflammatory agents is thought to be due to the suppression of prostaglandin synthesis (Kluger, 1979; Flower, Moncada, & Vane, 1985).

Early physiologists inductively explained the circadian thermal rhythm as a consequence of heat production and heat loss; the late afternoon peak was produced by the accumulation of heat caused by the activities of the day, and the morning nadir was due to the absence of activity during the sleeping hours. Palmer (1976) refers to uncited studies that disproved these early beliefs. One study involved "subjects confined to bed and fed identical meals at regularly spaced intervals throughout the day, ...(who) still displayed the rhythm with no decrease in amplitude." The other study was a case study of a man paralyzed with polio for sixteen months who displayed a normal temperature rhythm throughout his illness (p. 133).

Two other situations exist that subtract support from the early physiological theory described above. When the hypothalamus has been destroyed or damaged, the absence of any thermal rhythm is observed (Reinberg & Ghata, 1964). Secondly, the absence of the circadian thermal rhythm at birth in the presence of daily physical activity and food intake patterns negates the theory (Reinberg & Ghata, 1964). One might argue, within the framework of the theory, that an infant's temperature rhythm is not developed because the thermoregulatory effector mechanisms are also not yet developed. However, the effector mechanisms of the elderly are also inefficient and inconsistent, and yet the rhythm persists, albeit with decreased amplitude (Bassler, 1976; Palmer, 1976; Prinz, Christie, Smallwood, Vitialiano, Bokan, Vitiello, & Martin, 1984; Reinberg & Ghata, 1964; Touitou, Reinberg, Bogdan, Auzeby, Beck, & Touitou, 1986).

Aschoff (1976) credits Professor Franz Halberg with the introduction of the term "circadian" (from the Latin circa, about and dies, day) to describe diurnal rhythms. These biological rhythms are endogenous, adaptive, and reflect synchronization with the day-night cycle generated by the rotation of the earth around the sun (Palmer, 1976). Conditions caused by

this cycle act as "cues"; these cues act as entraining agents to synchronize the organism with the environment.

In humans, the most researched cue is the light-dark cycle. Diurnal vibrations in environmental temperature and social activities also serve as cues (Aschoff, 1976). It has been necessary, then, to isolate human subjects from light-dark cycles, knowledge of time, and social activities to study "free-running" (in the absence of cues) rhythms. Experiments under these conditions demonstrate that when humans are allowed to free-run, circadian rhythms extend from 24 hours to about 25 hours. Temperature rhythms, as well as urine excretion and cortisol secretion, remain synchronized with the free-running rhythm. The other rhythms became desynchronized with the environment. Almost every physiologic function studied in man demonstrates circadian rhythmicity (Aschoff, 1976).

These findings led to the largely-accepted hypothesis that there are two oscillators in humans (Aschoff, 1965, 1976; Lobban, 1960; Moore-Ede, Sulzman, & Fuller, 1982; Palmer, 1976). The first controls the sleep-wake cycle and has a weak power for being self-sustaining. The other controls the rhythms of body temperature, urine excretion, hormone secretion, cell division, enzyme synthesis, and others. This

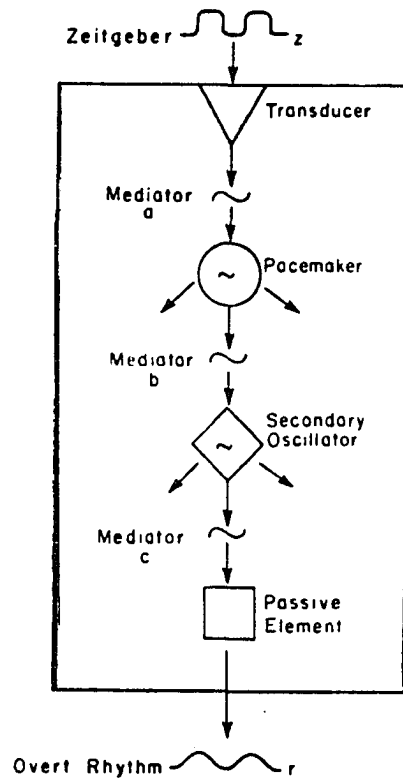
oscillator has a strong power for sustaining itself. The sleep-wake oscillator is believed to be located in the suprachiasmatic nuclei of the hypothalamus. The oscillator for body temperature and others is thought to be located in the hypothalamus also, but its exact location is unknown (Moore-Ede, Sulzman, & Fuller, 1982). The findings of the temporal isolation studies described previously also lend support to the belief that human circadian rhythms are synchronized by internal cues as well (Aschoff, 1976; Halberg, 1960b).

It should be noted here that, while circadian rhythms have been studied separately, they do in fact operate in synchrony with each other and in coordination with the metabolic processes of the organism. Alterations in one circadian rhythm have been demonstrated to effect alterations in another rhythm (Aschoff, 1965; Halberg, 1960a; Lobban, 1960).

Moore-Ede, Sulzman, and Fuller (1982) have developed a simplified diagram of the components of the major elements of a circadian system (as seen in Figure 2). The "cue" (zeitgeber) in the diagram is the environmental cue of light, temperature, or social activities. This cue is converted by the transducer to a signal that is meaningful to the circadian system. The retina, for example, is the transducer for light

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Figure 1. Major elements of a circadian rhythm system



Note. From The Clocks That Time Us: Physiology of the Circadian Timing System (p. 140) by M. Moore-Ede, F. Sulzman, and C. Fuller, 1982, Cambridge, MA: Harvard University Press. Reprinted by permission.

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signals. The pacemaker is the primary oscillator, the timekeeper in the absence of environmental cues. An analogous example is provided in the physiological rhythm system of the cardiovascular system in which the sinoatrial node is the pacemaker. Little is known about the construction or location of the pacemakers of the circadian system, as has already been discussed. The secondary oscillators are self-sustaining and are responsible for driving the overt rhythm. The adrenal cortex is thought to be a secondary oscillator because of its ability to maintain its rhythmicity in vitro. Passive elements are tissues or physiologic subsystems that are not capable of self-sustaining rhythms. Mediators transmit temporal information from one site in the body to another. The neural and endocrine systems are the most obvious mediators. For example, adrenocorticotrophic hormone (ACTH) is produced by the pituitary to stimulate the circadian rhythmicity of the adrenal cortex.

The components described above interact to produce an overt rhythm. Overt rhythms are defined as "measurable periodic outputs of the circadian timing system" (Moore-Ede, Sulzman, & Fuller, 1982, p. 147). As has already been stated, these rhythms are a combination of endogenous activity and a response to exogenous stimuli.

Felton (1986) studied 39 nurses to determine the effect of rotating work shifts on circadian rhythms. The hypothesis for the study was that social activities were a more dominant synchronizer than the day-night cycles. Results demonstrated that the rhythms of physiologic functions shifted toward the night activity period when the nurses attempted to adapt to the night rotation over a one-day lag. A period of ten days was observed to be required to adapt to a day rotation after having worked nights. These findings are consistent with others reported by Aschoff (1976), Conroy and Mills (1970), Moore-Ede, Sulzman, and Fuller (1982), Palmer (1976), and Reinberg and Ghata (1964).

The term "circadian thermal rhythm" refers to the daily variation of body temperature which is characterized by one peak (4-6 p.m.) and one trough (4-6 a.m.) approximately every 24 hours (DeRisi, 1968; Selle, 1952). It is one of several circadian rhythms exhibited by humans (Aschoff, 1965; Conroy & Mills, 1970; Hockey & Colquhoun, 1972; Reinberg & Ghata, 1964).

Conroy and Mills (1970) and Palmer (1976) credit John Davy, a British army physician, as the first researcher to describe circadian thermal rhythms in 1845, who used himself as the subject. Wunderlich and Seguin (1871) advocated twice daily temperature measurement, between 7 and 9 a.m. and between 4 to



6 p.m., "repeated oftener in important cases, in very acute cases, in cases of doubtful diagnosis, and deviations from the normal type" (p. 27). In 1873, Seguin published an open letter to "mothers, nurses, and all who have charge of the young and the sick." The letter instructed: "In ordinary cases, a serial observation of the sickly fluctuations is taken at the very hours in which the regular undulations are expected in health...from 8-10 a.m. and from 4-6 p.m." (p. 21). Normal temperatures read "0"; degrees or fractions of degrees above zero indicated fever, below indicated morbidity. The letter continued with the following instructions: "so that if, during a succession of three mornings you read zero or a few tenths of a degree more or less, and if in the ensuing afternoons till bed-time the rise does not exceed the half of a degree (.5), you can pronounce all danger over, the patient cured, and kept only under the restraint of hygienic and recuperative measures" (p. 22).

Over the next century, the circadian rhythm has been validated through research many times. Now it is accepted that the human thermal rhythm first becomes noticeable at an age of four to five weeks, becomes entrained between the ages of five and nine months (Bassler, 1976; Palmer, 1976), and continues into old age (Prinz, et al., 1984; Touitou, et al., 1986). It

is also common knowledge that body temperature ranges from a mean of 97.2° F. in the early morning hours to a mean peak of 99.5° F. in the late afternoon to early evening hours (Conroy & Mills, 1970; Moore-Ede, Sulzman, & Fuller, 1982; Palmer, 1976; Selle, 1952).

Prinz et al. (1984) and Touitou et al. (1986) demonstrated that, although the mean body temperature decreases with age, the rhythmicity persists. They also found that mean body temperatures of elderly women were consistently higher than those of elderly men and that there were no significant changes in temperature rhythms in subjects with senile dementia of the Alzheimer's type. The investigator was unable to identify any studies that have been published which explored the effects of a hypothalamic lesion on circadian thermal rhythm.

Touitou et al. (1986) measured the rectal temperatures of six elderly men, six elderly women, and six elderly patients with diagnosed Alzheimer's dementia during the same 24-hour period in January, March, June, and September. They reported peak seasonal temperatures in March and trough seasonal temperatures in June. In contrast, Renbourne (1963) reported that early morning temperatures were lower on cold mornings, required longer equilibration times with the mercury-in-glass thermometer, and were higher with shorter equilibration times on warmer mornings.

Hejl (1977) studied 2044 subjects between the ages of 14 and 74 over a nine-year period in Czechoslovakia to determine the existence of a rhythmicity in the appearance of symptoms of viral and bacterial illnesses. Subjects were selected if they were presented with an acute fever (above 37° C.) and symptoms suggesting an upper respiratory infection. They were then classified as tonsillitis or virosis by the presence or absence of specified diagnostic criteria. The analysis of the data indicated that tonsillitis (bacterial infection) occurred more frequently in the morning in both males and females, around ovulation in women, at the time of the full moon in both males and females, and in the summer for both males and females. A reverse correlation existed for virosis. The process of detecting the fever was not described. Therefore, it is unknown whether it was controlled. Hejl (1977) extended the implications of the findings to all bacterial and viral infections, and suggested that patterns inconsistent with the findings of the study have diagnostic importance.

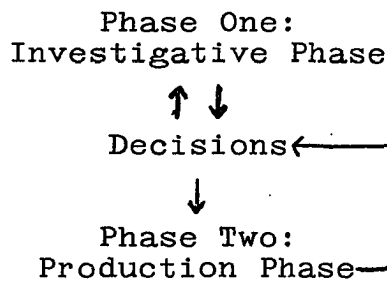
#### Nursing Framework

The nursing framework for this study is gleaned from Orem's (1985) theory of nursing. In this theory, nursing is conceptualized as a deliberate action, a purposive goal-seeking activity.

There are two phases of deliberate action. Phase one is the investigative and decision-making phase. The second phase is the production phase (see Figure 2).

Briefly, in phase one, the care provider has investigated health care needs and environmental conditions. Available courses of action and relative effectiveness and risks have been investigated as well. The phase is closed when a health care action has been chosen. Phase two involves the implementation of the chosen course of action in relation to the specific demands for care.

Figure 2. Phases of Deliberate Action



Nursing assessment of temperature is a phase one activity. Temperature measurement investigates the presence or absence of fever and the results are used to classify the patient as febrile or afebrile. This information is then used to diagnose a condition or to

monitor a condition or the effectiveness of a treatment. This information is also used to decide on the adoption or alteration of a course of action.

The results of a temperature measurement and the succeeding classification may be influenced by many factors, as have been discussed. The unrecognized influence on the accuracy of temperature measurement or the misinterpretation of the level of significance of the accurate measurement will lead to misinformed decision-making about courses of action. For example, a temperature of 99.6° F. at 6 p.m. may not be considered febrile, whereas the same measurement would be considered febrile at 6 a.m.

#### Summary

In summary, the circadian thermal rhythm is characterized by a peak in the late afternoon and a nadir in the early morning. It is stable in individuals aged nine months to 65 years. The rhythm persists in situations of fever and is altered by damage to the hypothalamus and alterations in sleep-activity patterns. Such alterations may be induced by hospitalization in intensive care or constant care units.

The accuracy of temperature measurement is affected by respiratory rate, oxygen therapy, ingestion of hot or cold fluids and food, smoking, and ambient temperature. In addition, the naturally occurring

processes of age and ovulation effect body temperature. The presence of fever may be altered by the use of nonsteriodal antiinflammatory agents. Normal thermoregulation may be altered by use of air or water mattresses, as well. And finally, the accuracy of the measured temperatures, as well as the interpretation of significance affects the investigative and decision-making phases of deliberate nursing action described by Orem (1985).

#### Implications for the Study

Although much is known about circadian thermal rhythms, there is little evidence that this knowledge is incorporated into nursing practice. Nursing practice within a scientific framework encourages efficient and effective decision-making and management of patient care. Nurses must utilize the concept of circadian thermal rhythms in the adoption of a schedule for fever screening and in the interpretation of measured temperatures.

#### Research Questions

Utilizing the knowledge of circadian thermal rhythms, the following research questions were examined:

- 1) At which hour(s) of the day do most fevers occur in a system of mass screening?

2) How many times per day is temperature measurement necessary for fever detection in a system of mass screening?

Definitions

Fever: an oral temperature at 99.6° F. or greater.

Electronic thermometer: the IVAC TEMP PLUS II Model 2080.

Posterior sublingual pocket: "the pockets of tissue located well back under the tongue where it joins the floor of the mouth on either side of the frenulum" (Erickson, 1983, p. 14).

## Chapter Three

### Methodology

#### Study Design

A descriptive study, using repeated measures, served as the method to investigate the time of day when most fevers first appear, based on the circadian thermal rhythm framework. This study partially replicated the studies of DeRisi (1968) and Samples et al. (1985).

#### Research Variables

The independent variable was time of measurement and the dependent variable was oral temperature. Extraneous variables were the sleep-wake schedule, age, menstrual phase, respiratory rate, oral pathology, post-operative time status, admission to a critical care or constant care unit, the use of circulating or alternating air mattresses, the ingestion of nonsteriodal antiinflammatory drugs, the ingestion of hot or cold substances and smoking prior to temperature measurement, and the administration of oxygen by mask.

#### Sample

All patients, aged 18-65, were considered for participation in the study. Subjects who were able to physically hold the electronic thermometer probe in



place for the minute necessary for measurement and were afebrile for, at most, three days prior to the time of selection were included. Subjects in the critical care or constant care units, in isolation requiring the use of a mercury-in-glass thermometer, on aspirin, on acetaminophen or nonsteroidal antiinflammatory agents, on Mediscus, Clinitron, or alternating air mattresses, on oxygen by mask, having a respiratory rate greater than 22/minute, less than 24-hours postoperative, with central nervous system surgery or pathology, and with oral surgery or pathology were excluded from the study.

A sampling frame was constructed by reviewing the Kardexes and charts for eligibility. Subjects were then systematically assigned to the study.

#### Site

This study was conducted at a 462-bed midwestern teaching hospital. This private hospital maintained a trauma center with extensive networking to rural communities via helicopter transport and was equipped and staffed for open heart surgery, kidney transplant, and neurological care. The hospital also offered programs in mental health, alcohol and substance abuse, and physical wellness. Patient care areas were designated by the medical/surgical specialty for which they were maintained. In addition to these units, several critical care and constant care areas were also operated on the basis of specialty.

## Instruments

Temperatures were measured orally with the IVAC TEMP PLUS II Model 2080 in use at the hospital. This model was battery powered and able to display information indicating that the battery was low, that the probes were out of the units, the absence of tissue contact with the probe, and included a pulse/respiration timer clock. This unit was also capable of measuring temperature in two different modes. The predictive mode sensed the rate of temperature rise and calculated the final reading. The unit then displayed the prediction, usually in 25-50 seconds (Erickson, 1983). The "steady-state" mode, or monitor mode, read the actual temperature. The predictive mode was used in this study.

The circuitry of this model calibrated itself prior to each temperature measurement. It would not allow a temperature to measure (appear on the display) if calibration was not achieved. Inter-instrument calibration was not considered necessary by the manufacturer because of the consistency of the circuitry within the model (Steve Windsor, personal communication, July 24, 1987). No malfunctions with the thermometer were encountered during the study. The hospital provided one new thermometer for exclusive use in the study.

The data collection record was designed for use in this study (see Appendix A). The information recorded on the upper portion of the record included age, sex, sleep schedule, date of last menstrual period, dentition, and the temperature, pulse, and respiration measurements. The lower portion of the data collection record was blank, designed to record the addressograph of the subject for the purposes of identification prior to measurement. The upper and lower portions were perforated to allow separation prior to analysis.

#### Pilot Study

A pilot study was conducted utilizing the participation criteria for the larger sample. The purpose of the pilot study was to test the data collection procedure, the data collection record, and the data analysis procedure. Also, the number of temperatures that could feasibly be measured by one collector in a 30-minute time period was determined.

Six patients were inducted into the pilot study; one patient expired prior to completion of the study. It was determined that 15 temperatures could be measured and recorded by one collector in a one-hour period. The measurement period was extended to one-hour to decrease attrition due to the ingestion of food or smoking. In addition, minor changes were made in the data collection record to facilitate its ease of use.

It was also discovered that respirations measured for 15 seconds and multiplied by four differed by as much as four respirations per minute when measured for a full minute. It was, therefore, determined that respirations would be measured for a full minute during this study to decrease exclusion due to false calculation.

#### Procedure

Two baccalaureate nursing students and one master's prepared nurse were recruited as data collectors. Monetary compensation for their services was provided through a grant from the Kalamazoo Nursing Research Collective. Instructions in the use of the electronic thermometer and identification of the posterior sublingual pocket were given as well as an opportunity for practice. Interrater reliability was measured by a return demonstration and comparison of the consistency of results with a standard. Standards for interrater reliability were the 100% achievement of each step of the checklist, as determined by the primary researcher (see Appendix B). Hospital units were notified by memorandum of the purpose of the study, names of the data collectors, and expectations of the staff.

Potentially eligible subjects were approached to ascertain their willingness to participate. The primary investigator explained the study and obtained a

signed consent. Subjects were assured verbally and in writing that they could withdraw from the study at any time and that confidentiality would be maintained (see Appendix C).

After consent was obtained, a code number was assigned to the data collection record. The lower portion of the data collection record was stamped with the addressograph card of each patient for the purpose of identification prior to measurement. The data collection records were provided to the collector in a notebook format.

Temperature measurement began at 6 p.m. and continued at 10 p.m., 6 a.m., 10 a.m., 2 p.m., and 6 p.m. for 24 hours. Temperature measurement began 30 minutes prior to the hour and ended 30 minutes after the hour.

Prior to temperature measurement, data collectors verified that the subject had refrained from drinking or smoking. He/she then asked the subject to open his/her mouth and elevate the tongue so that the posterior sublingual pocket could be identified. The probe was placed in the pocket and the subject was asked to close his/her mouth snugly around the probe until the unit indicated that measurement was completed. Before removing the probe, the data collector counted respirations and pulse utilizing the unit's clock timer.

Data collectors recorded temperatures, pulses, and respirations on the data collection record and hospital records. Hospital staff were asked to omit the temperature-taking routine for the subjects participating in the study to eliminate any extra interruptions to the patient's day. This request was facilitated by flagging the chart and Kardex with a note indicating the patient's participation in the study. Data collectors also verbally reported any detected fevers to the nurse caring for the patient and documented this notification in the patient's record.

## Chapter Four

### Data Analysis

#### Data Preparation

The data collection records were reviewed to ensure that all data entered into the analysis phase were consistent with the sample characteristics already described. Only records with complete data for the collection period (i.e., one temperature for each of six measurement periods) were analyzed. The ovulatory phase of female subjects could not be determined for slightly more than half of the female subjects. Most of these women had past histories of hysterectomies and were unable to identify their ovulatory phases in the absence of menstrual periods. Therefore, the ovulatory phase of female subjects was not considered in the analysis.

In preparation for computer analysis, these data (temperatures) were then entered onto a coding sheet as they appeared on the data collection record, each column representing the time of day. The first two columns were age and sex respectively; the third through eighth columns represented the temperature

measurements; the ninth, tenth, and eleventh columns represented the sleep schedule, the ovulatory phase, and the type of dentition.

### Data Analysis

Data analysis was completed with the use of Abstat software by Anderson Bell. Temperatures were classified as fever if they were 99.6° F. or greater. Frequency and percentages of fever for each measurement period were calculated. Confidence intervals were constructed on the means for each measurement period. Two 6 p.m. measurements were collected to determine the numbers of fevers that would have gone undetected with only a once-daily 6 p.m. measurement. All other computations utilized only the second 6 p.m. measurement, as the first 6 p.m. measurement was considered a baseline for developing the recommendation for frequency of temperature assessment.

### Results

Characteristics of the sample. Fifty-one individuals were eligible for participation in the study. Five of these patients declined to participate for unknown reasons. Forty-six subjects agreed to participate in the study. Eleven subjects (23.9%) were excluded from the study because of the development of one or more of the extraneous variables. Of these 11 subjects, 3 subjects were unavailable for temperature measurements while undergoing diagnostics or therapies,



1 subject went home, 2 subjects developed respiratory rates greater than 22 per minute, and the remaining subjects (5) received an antipyretic analgesic.

The 35 subjects remaining ranged in age from 22 to 62 years (mean age = 43.6). There were 22 females and 17 males. All subjects claimed a night-time sleeping schedule.

Research Question #1: At what hour of the day do most first fevers occur? A total of 175 temperatures was taken in the five measurement periods for the 35 subjects. Eighteen (51.42%) of the 35 subjects (afebrile at the beginning of the study) had fevers during the 24-hour measurement period.

There were no first fevers revealed at 6 a.m., at 10 a.m., or at 2 p.m. The distribution of initial fevers detected at 6 p.m. and 10 p.m. are presented in Table 1.

Table 1. Distribution of Initial Fevers

<u>Time</u>	<u>6 p.m.</u>	<u>10 p.m.</u>	<u>6 a.m.</u>	<u>10 a.m.</u>	<u>2 p.m.</u>	<u>6 p.m.</u>	<u>Total</u>
% of Initial Fevers	77.78	11.11	0.00	0.00	0.00	11.11	100%
No. of Initial Fevers	14	2	0	0	0	2	18

Research Question #2: How many times per day is temperature measurement necessary for fever detection in a system of mass screening? All of the 18 fevers were detected at 6 p.m. The two subjects whose initial fevers were detected at 10 p.m. continued to be febrile at 6 p.m. the following day.

Forty-one (23.42%) fevers were detected in total in each of the measurement periods. The frequencies and percentages for each measurement period are presented in Table 2.

Table 2. Distribution of Overall Fevers Observed

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<u>Time</u>	<u>10 p.m.</u>	<u>6 a.m.</u>	<u>10 a.m.</u>	<u>2 p.m.</u>	<u>6 p.m.</u>	<u>Total</u>
Proportion of Fevers	26.82%	9.76%	12.19%	17.07%	34.15%	100%
No. of Fevers	11	4	5	7	14	41

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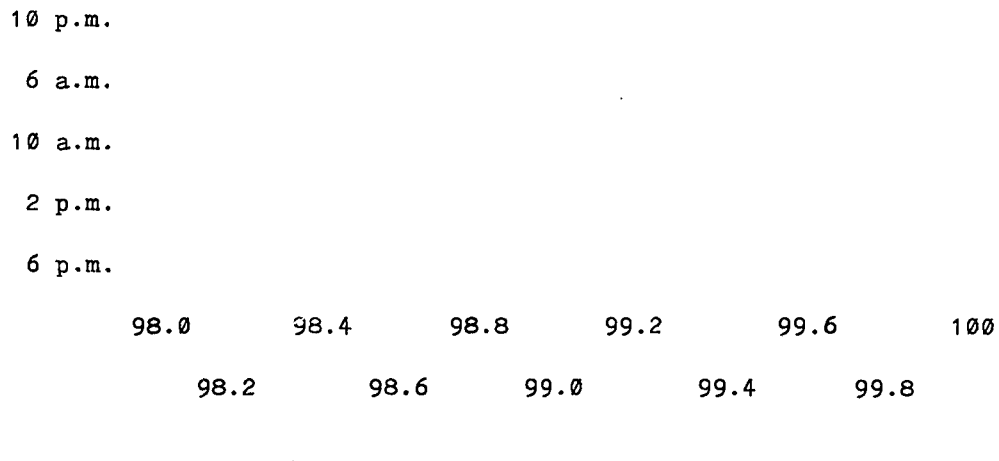
Ninety-nine percent confidence intervals on the means were constructed for each of the measurement periods. These intervals, means, and observed temperature ranges are presented in Table 3.

Table 3. Confidence Intervals (99%) on the Means

	<u>Interval</u>	<u>Mean</u>	<u>Range</u>
10 p.m.	98.6, 99.4	99.0	97.3-101.3
6 a.m.	98.4, 99.0	98.6	97.4-100.4
10 a.m.	98.4, 99.0	98.6	97.2-100.1
2 p.m.	98.6, 99.0	98.8	97.9-100.1
6 p.m.	99.0, 99.6	99.2	97.1-100.9

A diagram of the intervals is presented in Figure 3.

Figure 3. Confidence Intervals (99%) on the Means



### Other Findings of Interest

Ninety-five to ninety-eight percent of potentially eligible subjects were excluded from the sampling frame because of the extensive use of aspirin, acetaminophen, and nonsteroidal antiinflammatory agents. As has already been stated, the use of these drugs also contributed to the exclusion of participating subjects during this study.

Eight subjects (22.86%) admitted not being able to read when they were asked to sign the consent. One of these subjects refused to participate in the study. Consents were read to and then signed by the participants.

Twenty-one subjects in the study had natural dentition, 11 subjects had artificial dentition, and two subjects had no teeth at all. The mean temperature for the natural dentition group was 98.9° F., for the artificial dentition group was 98.9° F., and for the group without dentition was 98.8° F. An independent  $t$ -test of the difference of the means (natural and artificial  $t(30) = 0.136130$ ) was insignificant at the .01 level. This finding was inconsistent with the findings of others (Beck & St. Cyr, 1974; Erickson, 1976). A  $t$ -test on the difference of the means between natural dentition and no dentition was not completed because of the low number of subjects without dentition.

## Chapter Five

### Discussion and Implications

#### Discussion

The findings of this study support previous recommendations (DeRisi, 1968; Samples et al., 1985) for a once daily temperature measurement at 6 p.m. as adequate in screening adult hospitalized patients for fever. Changes in body temperature are frequently accompanied by other symptoms routinely assessed by nurses. Therefore, body temperature may be assessed more frequently, based on professional nursing judgment about patient status.

These data demonstrate that most initial fevers and the largest overall proportion of fevers occur at 6 p.m., the peak of the circadian thermal rhythm. Furthermore, the two subjects whose fevers were first detected at 10 p.m. continued to be febrile at the second 6 p.m. measurement. These subjects may have displayed objective symptoms or reported subjective symptoms associated with fever, prompting the nurse to measure temperature prior to 6 p.m.

The confidence intervals provide a framework for the interpretation of temperature measurement in clinical practice (see Table 3 and Figure 3). For

example, a temperature of 99.6° F. measured at 6 p.m. exceeds the upper limits of the intervals by a margin of clinical significance. The same temperature detected at 6 p.m. has no clinical significance as it meets the upper boundaries of the interval.

In addition, the confidence intervals support this study's definition of 99.6° F. as fever. Not one of the upper limits of the confidence intervals exceeds 99.6° F. Moreover, the highest temperatures observed in each of the measurement periods exceeds the upper limits of the confidence intervals by a margin of clinical significance.

The high rate of illiteracy found in this study was unexpected. This finding has tremendous implications for nurses when interacting with patients in situations requiring reading. Examples of such situations are patient education with printed materials and circumstances requiring written consent.

The extensive use of antipyretic analgesic medications was also unexpected. This factor greatly reduced the sample size of this study.

Rapid respiratory rates also reduced the sample size. During the study, it became apparent that the rates recorded in the patients' charts were frequently different from what was observed by the data collectors. Based on this observation, respiratory rates were measured at the time of induction into the

study to determine eligibility for entry into the study on that criteria. This greatly reduced potential exclusion during the collection period.

Inaccuracy or inconsistency of measurement may also be a factor in the difference of initial fevers observed at the two 6 p.m. measurements (see Table 1). Hypothetically, any difference observed between the two 6 p.m. measurements should be much smaller.

#### Limitations

Limitations of this study are its small sample size and its high exclusion rate. A larger sample size would have increased the strength of the results and may have decreased the difference in observed frequency of fever between the two 6 p.m. measurements.

#### Recommendations

The adoption of a daily 6 p.m. measurement policy for fever screening would result in a tremendous savings in nursing time without reducing the diagnostic base. In fact, the diagnostic cue of fever could be more accurately interpreted if measured once daily at the peak of the circadian rhythm. In addition, a once daily temperature measurement could also result in cost savings in terms of probe covers and breakdown of the electronic units from overuse.

The upper limits of the confidence intervals (see Table 3 and Figure 3) may be utilized by nurses in determining the significance of temperatures in the

decision step of Phase one as described by Orem (1985). Accuracy in temperature measurement and classification will lead to the selection of a more effective course of action (see Figure 2).

Nurse educators should incorporate the theoretical concept of circadian thermal rhythm with the psychomotor skills of temperature measurement. Recommendations for schedules for screening for fever should appear in nursing skills texts, as well. Patients should be taught to monitor their own temperatures at 6 p.m. when it is necessary to do so. This would not only increase diagnostic accuracy, but could also improve patient compliance.

Nurses must become skilled in assessing the literacy of patients. This is essential, especially in situations requiring reading by patients.

Certainly, replication of this study in other institutions is recommended. Efforts should be made to recruit a larger sample size and to decrease attrition. Replication comparing a group of patients receiving antipyretic analgesic medications to a control group would reveal the significance of the differences in temperature measurement. In addition, replication of this study using populations of subjects over age 65, of subjects with neurological impairment, and of subjects with various mattress therapies is also recommended.



Physiological functions other than body temperature must also be studied utilizing the circadian rhythm framework. Examples are the effects of continuous intravenous fluids on fluid and electrolyte balance or urinary output, the effects of drug administration at various times of day, and the effect of continuous tube feedings on blood sugars or gut function.

In summary, then, the findings of this study provide a scientific basis for the practice of screening for fever. The results support the recommendations of previous researchers for a once-daily temperature measurement at 6 p.m. for the purposes of screening for fever. The adoption of such a policy should result in time and cost savings. In addition, the findings offer a framework for the classification of temperatures as fever at various hours of the day.

## Appendices

Appendix A

Data Collection Record

Subject No. \_\_\_\_\_ Date of LMP \_\_\_\_\_

Age \_\_\_\_\_ Dentition:

Gender \_\_\_\_\_ artificial \_\_\_\_\_

Sleep Schedule \_\_\_\_\_ natural \_\_\_\_\_

Wake Schedule \_\_\_\_\_ none \_\_\_\_\_

6pm    10pm    6am    10am    2pm    6pm

temp \_\_\_\_\_

pulse \_\_\_\_\_

resp \_\_\_\_\_

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Addressograph

## Appendix B

### Checklist

1. Request each participant to refrain from drinking/smoking.
2. Identify participant.
3. Measure temperature.
  - a. verify that no drinking/smoking has occurred in the last half hour.
  - b. remove probe and apply probe cover.
  - c. ask participant to open mouth and elevate tongue.
  - d. identify sublingual pocket (use left side throughout study).
  - e. place probe in pocket in contact with tissue. Hold probe by collar throughout the measurement period.
  - f. ask participant to close lips around probe until measurement is completed.
  - g. read temperature display at the signal.
  - h. engage clock timer and count resp. and pulse.
  - i. remove probe, eject cover and discard, replace probe in unit.
4. record temp., resp., and pulse on
  - a. data collection record
  - b. patient chart
5. notify nurse of record of fever and document notification in nurses' notes section of patient chart.

## Appendix C

### Consent

In signing this document, I am giving my consent to be a participant in a research project about body temperature that is being conducted by Michele Heckman, a graduate student in nursing at Grand Valley State College, Allendale, Michigan. The purpose of the study is to identify patterns of fever development and to determine the significant hours for temperature measurement.

I understand that my temperature will be measured orally at 6 p.m., 10 p.m., 6 a.m., 10 a.m., 2 p.m., and 6 p.m. for twenty-four hours by trained volunteers. I have been informed that I will be asked to refrain from smoking or drinking any liquids for at least one-half hour prior to temperature measurement. In addition, I understand that my participation in the study may be terminated by the investigator for my welfare or if I develop any characteristic(s) that may affect accurate temperature measurement (e.g., rapid breathing, oxygen by mask, etc.).

Risks of participation in the study have been identified to me as interruptions necessitated by the temperature measurement. While no direct benefits to myself have been identified, I understand the overall benefits of the study are predicted to be the development of a more precise schedule for fever screening with a decrease in the total number of times temperatures are measured for the average hospitalized person.

#### PATIENT ACKNOWLEDGMENT

"I have been given an opportunity to ask questions regarding this research study, and these questions have been answered to my satisfaction. I understand that if I have any additional questions, I can contact Michele Heckman at (616) 323-3752.

"In giving my consent, I understand that my participation in this research project is voluntary, and that I may withdraw at any time without affecting my future medical care. I also understand that Borgess Medical Center, with my welfare as a basis, may decide at any time that I should no longer participate in this study.

"I hereby authorize the investigator, Michele Heckman, to release the information obtained in this study to the medical science literature. I understand that I will not be identified by name. Additionally, I understand that the Food and Drug Administration (FDA) may inspect Borgess Medical Center research files and may wish to interview me regarding my participation in this study.

"I acknowledge that I have read and understand the above information, and that I agree to participate in this study. I have received a copy of this document for my own records."

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Signature of Investigator

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Signature of Participant

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Date

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