Durham University

Insights

Institute *of* Advanced Study

Choosing the Gold Standard: Subjective Report vs Physiological Measure

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Volume 5 **2012** **Number 3**

ISSN 1756-2074

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CHOOSING THE GOLD STANDARD: SUBJECTIVE REPORT VS PHYSIOLOGICAL MEASURE

This essay approaches the broad topic of whether to privilege subjectivity or objectivity in the measurement of physical experience. The topic is approached from a relatively narrow focus on the measurement of hot flashes during the menopausal transition. Hot flashes are experienced as sudden, generally unpleasant, sensations of heat by up to 75% of women in the US. They are caused by transient episodes of sweating and vasodilation. Numerous surveys have been carried out with standardized questionnaires to query hot-flash experience (presence/absence) and bothersomeness. Biometric measurement of skin temperature, pulse or sweating provides an alternative source of information about symptom experience. At times, women demonstrate hot flashes that are biometrically documented, but do not experience, identify or label the phenomenon to be a hot flash. This may be because self-reported hot-flash frequencies are influenced by personal perceptions and by the cultural significance applied to subjectively perceived phenomena. In contrast, objective measures of hot flashes are largely unbiased by cultural context. Which is the true measure of a hot flash – subjective report or a change in the level of sternal skin conductance? The literature of phenomenology is explored with an emphasis on the problem of hot-flash assessment. This interest in hot flashes can be applied to the measurement of other conditions that can be both subjectively experienced and objectively measured, such as pain, stress, memory and sleep quality.

Introduction

This essay approaches the broad topic of whether to privilege subjectivity or objectivity in the measurement of physical experience. The topic is approached from a relatively narrow focus on the measurement of hot flashes during the menopausal transition. Questioning how best to assess hot flashes – by subjective report or biometric measurement – has practical applications for the comparison of hot-flash frequencies within and between populations. It also has philosophical implications because of the underlying problem: 'what is real?' If a woman reports a hot flash that we do not measure, was it real? Alternatively, if we measure a hot flash that a woman does not report, was it real? When examining the concordance between subjective report and biometric measurement: what is the gold standard? These questions about measurement can be applied to other relatively invisible phenomena, such as pain, stress, memory and sleep quality – conditions that can be both subjectively experienced and objectively measured.

Hot Flashes

Hot flashes during the menopausal transition are experienced as sudden, generally unpleasant, sensations of heat by up to 75% of women in the US (Gold et al., 2006). They are caused by transient episodes of vasodilation and sweating. During a hot flash, a woman's finger temperature can rise as much as 7°C as her blood vessels expand. Sweating can occur in five-minute bursts or in continuous 30-minute waves (Kronenberg and Downey, 1987). Vasodilation and sweating are adaptive heat dissipation responses that evolved to maintain homeostatic body temperatures in hot environments (Sievert, 2007; Sturdee, 2008); however, hot flashes occur

in any ambient temperature. In Puebla, Mexico, a 57-year-old woman described her hot flashes (*bochornos*) in the following way: 'When I have a *bochorno*, I feel a lot of heat until I take off my sweater. I sweat a lot. I sweat in my face, chest, back and stomach' (Sievert, 2006, pp. 128–9). After a hot flash, a woman can feel chilled to the point of shivering (Voda, 1997).

Hot flashes are triggered by the central nervous system around the time of menopause because of an internal thermoregulatory disturbance related to declining levels of circulating estrogen (Freedman, 2005). Low levels of estrogen are associated with a lower temperature threshold for the onset of sweating (Freedman and Blacker, 2002); peri- and post-menopausal women sweat more easily at a lower internal body temperature. Several studies have shown that the main metabolite of the neurotransmitter norepinephrine is increased before and during hot flashes (Freedman, 1998; Freedman et al., 1990); however, the physiology of hot flashes is still not completely understood. Estrogen levels decline among all women, but not all women experience hot flashes (Freeman and Sherif, 2007; Obermeyer, 2000; Sievert, 2006). Variation in hot-flash frequency at midlife has been documented across ethnicities (Gold et al., 2004; Lerner-Geva et al., 2010) and across countries (Obermeyer et al., 2007), suggesting the influence of lifestyle (Gold et al., 2004; Whitcomb et al., 2007), culture (Lock, 1993; Melby et al., 2005), climate (Sievert and Flanagan, 2005) and genetics (Butts et al., 2012) on hot-flash report. Explaining variation in hot-flash experience at midlife is of interest to human biologists and health care practitioners, to the women themselves and to their families.

Measuring Hot Flashes

In order to understand better the experience of hot flashes, numerous surveys have been carried out to assess hot-flash presence/absence and bothersomeness (Melby et al., 2011). Hot flashes have been measured by standardized questionnaires that query hot-flash experience (yes/no) currently, or during the past two weeks, the past four weeks, the past six months, the past year or ever (Melby et al., 2011; Sievert and Flanagan, 2005). In comparable surveys, variation in hot-flash report during the two to four weeks before interview ranges from 12% in Japan (Lock, 1993), to 27% in Thailand (Punyahotra et al., 1997), 32% in Australia (Dennerstein et al., 1993), 50% in Mexico (Sievert and Espinosa-Hernandez, 2003) and 61% in Morocco (Obermeyer et al., 2007).

In addition to presence/absence, investigators have asked about the frequency of hot flashes, e.g. number per week (Thurston et al., 2008), and severity of hot flashes, e.g. mild, moderate, severe (Melby, 2005). Hot flashes have been recorded in daily diaries (Freeman et al., 2011; Sloan et al., 2001). In addition, women have drawn pictures of their hot-flash patterns on diagrams of the female figure (Sievert et al., 2007, 2008; Voda, 1997).

When a woman answers a survey question with 'yes' (she experienced a hot flash) or traces her hot-flash pattern on a female diagram, it can be assumed that (1) she sensed a change in body temperature and/or an increase in sweating, (2) she identified the physical sensation as a particular phenomenon and (3) she was willing to name the experience as a hot flash on a questionnaire for a researcher. When a woman answers 'no,' it has generally been assumed that she did not experience a hot flash; however, this assumption may not be correct. All of the measures of hot flashes listed above – standardized symptom lists, diaries and diagrams – are based on subjective experience filtered through perception and through cultural norms about symptom recognition and report (Crawford, 2007; Melby et al., 2005). Both perception and report are filtered through the context of a particular local world (Csordas, 1994; Lock

and Kaufert, 2001). Culture assigns significance to some conditions or symptoms, and denies significance to others (Lock, 1984; Payer, 1996).

Is it possible to achieve a 'culture-proof' (Draper, 2007) measure of hot-flash experience? Biometrics provides an alternative source of information about symptom experience (Brown et al., 2009). For example, peripheral vasodilation can be measured as increased skin temperature on the fingers, toes, cheeks, forehead, forearm, upper arm, chest, abdomen, back, calf and thigh (Freedman, 2000; Molnar, 1975). Core body temperature can be measured by a small, swallowed transmitter that sends signals to an external antenna (Freedman, 2000). Increases in pulse rates signal a hot flash (Germaine and Freedman, 1984), as do increases in the level of skin conductance (Carpenter et al., 1999, 2004, 2005; de Bakker and Everaerd, 1996; Freedman, 1989; Freedman et al., 1992; Sievert et al., 2002, 2008, 2010; Swartzman et al., 1990; Thurston et al., 2009).

In sternal skin conductance, two electrodes are attached four inches apart to either side of the sternum. A constant voltage current then passes from one electrode to the other. During a hot flash, sweating increases and the level of skin conductance increases because electricity travels more quickly on a moist surface.[1] Figure 1 shows two hot flashes measured by sternal skin conductance. Electrodes have also been placed on the back of the neck (Sievert, 2007; Sievert et al., 2010), but the upper chest is the preferred site for hot-flash measurement. In laboratory settings sternal skin conductance is the method of objective hot-flash measurement that is most highly correlated with subjective hot-flash reports (de Bakker and Everaerd, 1996; Freedman, 2000).

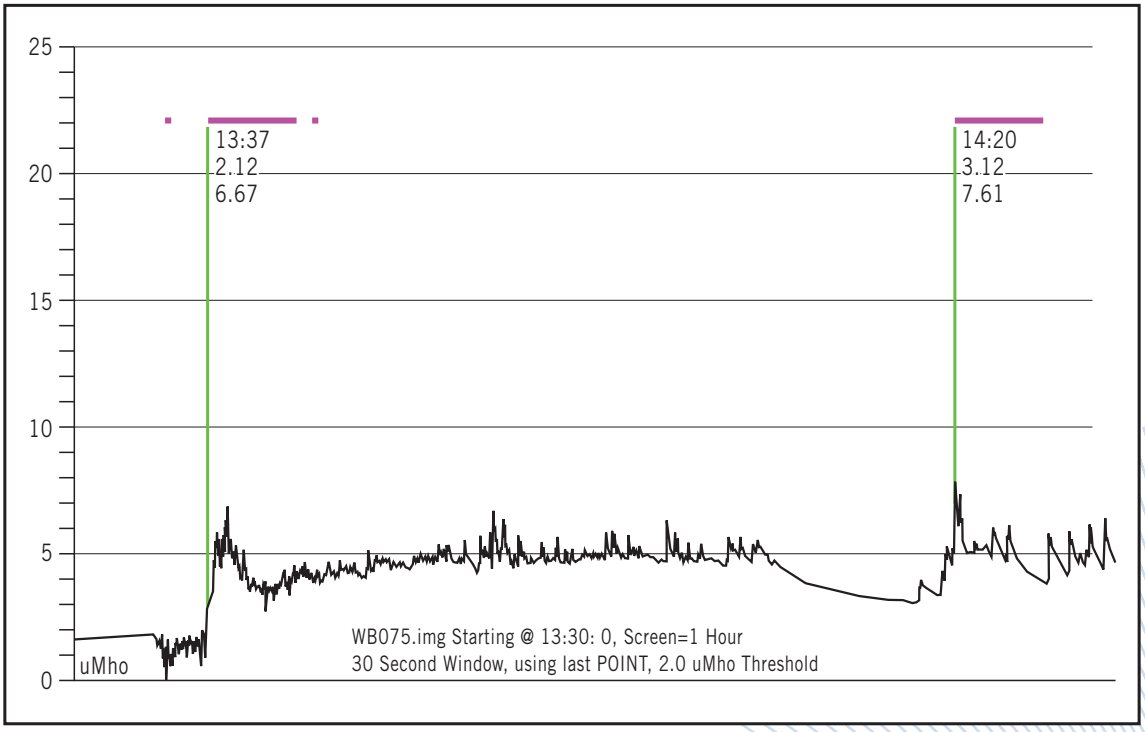

Figure 1: Data from the Biolog ambulatory hot-flash monitor showing two hot flashes.

Concordance between Subjective Report and Objective Measurement

In 1999–2000, the first objective study of hot flashes outside the United States was conducted in Puebla, Mexico, in a laboratory-like setting (Sievert et al., 2002). Of the 67 participants,

seven women reported at least one subjective hot-flash experience but demonstrated no objective hot flashes by sternal skin conductance (Sievert et al., 2002). This finding suggests that, for those seven women, the placement of electrodes on the sternum did not adequately measure the hot flash. This may be because not all women sweat during a hot flash (Sievert et al., 2006). Some women sweat in another part of the body, e.g. the back of the neck, instead of the upper chest (Sievert, 2007). Alternatively, the pattern of sweating may not meet the conventional criteria applied to a change in the sternal skin conductance level needed to identify a hot flash (Thurston et al., 2009, 2011).

In that same study (Sievert et al., 2002), seven women demonstrated at least one hot flash by sternal skin conductance – in other words they sweated on their upper chest and met the hot-flash criteria – but they did not report feeling any hot flashes during the study period. If those women did not experience, identify or label the phenomenon to be a hot flash, then did they experience a hot flash? Which is the true measure of a hot flash – subjective report or a change in the level of sternal skin conductance?

More recent studies of hot flashes have used ambulatory, rather than laboratory, monitors to identify both objective changes in sternal sweating and subjective report. As in laboratory studies, electrodes are used to measure sternal skin conductance levels; however, instead of data going to a polygraph in a lab, the data are saved to a small monitor that is carried in a shoulder bag. When women perceive a hot flash, they press buttons on the monitor.[2]

Ambulatory monitors allow for hot flashes to be measured during the course of normal activities; however, ambulatory measures demonstrate less concordance between objective and subjective hot flashes than do laboratory-based hot-flash monitors (Carpenter et al., 1999, 2004; Carpenter and Rand, 2008; Otte et al., 2009; Sievert et al., 2008; Thurston et al., 2009). For example, a recent study in Hilo, Hawaii, tested a well-known association between Japanese ancestry and low frequency of hot flashes on surveys. In Hilo, we showed that, while Japanese-Americans did indeed report fewer hot flashes on surveys compared to European-Americans (Sievert et al., 2007), they did not demonstrate fewer biometrically measured hot flashes during the 24-hour study period (Brown et al., 2009). This finding has relevance for all comparisons of hot flash across cultures and countries. The association between Japanese ancestry and low frequencies of hot flashes is based on survey research (Lock, 1993; Avis et al., 2001), not biometric documentation. Perhaps Japanese-Americans are less likely to notice hot flashes, or do not name hot flashes, or do not feel that it is appropriate to acknowledge hot flashes, compared with European-American women. A comparison of survey findings is a comparison of perception and report.

When subjective experience matches biometric measurement, this is called a 'true positive.' When a woman reports a hot flash that she did not physiologically demonstrate, this is called a 'false negative' because subjective report is privileged over the biometric measurement. In other words, the monitor gave a 'false' measurement because it did not record the hot flash that a woman said she experienced. When a woman demonstrates a physiological hot flash that she did not identify or report, this is called a 'false positive.' Again, the subjective report is considered to be the gold standard (Carpenter et al., 2004; Sievert, 2007; Sievert et al., 2008, 2010; Thurston et al., 2005). Figure 1 demonstrates two false positive measures because the study participant did not push the buttons on the monitor to indicate that she felt the sensation of heat or sweating. Button pushes would have been recorded on the graph. If self-reported hot-flash frequencies are influenced by personal perceptions and by the cultural significance applied to subjectively perceived phenomenon, then should the subjective experience be the

gold standard? Then, again, if a woman demonstrates but does not perceive a physiological change, did she have a hot flash?

What is Real?

This question about which hot flashes are the real hot flashes – subjectively experienced or objectively measured – is of transdisciplinary interest because the body is both a subject of sensation and experience as well as an object of measurement and management (Csordas, 1994; Shusterman, 2008).

Philosophers and anthropologists apply the perspective of phenomenology when examining the lived experience of the individual body, being-in-the-world (Csordas, 1994; Merleau-Ponty, translation 1962; Scheper-Hughes and Lock, 1987). They seek to understand how human subjectivity is embodied so that the 'body' and the 'subject' are indivisible (Worthman, 1999). From this point of view, perceptions, even corporeal states such as hunger or thirst, cannot be explained by reference to physiological processes of the body alone (Csordas, 1990; Csordas, 1994; Desjarlais, 1992; Fuchs, 2005; Leder, 1990). For example, Fuchs (2002; 2005) describes how the materiality, density and weight of the body are generally unnoticed in everyday performance, but in melancholia the heavy, solid body is felt painfully. In thinking about hot flashes, we are seldom acutely aware of our body temperature during the course of a day; however, hot flashes cause a woman to become very aware of her body. Across Latin America, hot flashes are described as *sofocos* (feeling suffocated), *oleadas de calor* (waves of heat) or *bochornos* (embarrassments or 'shames'). The sudden awareness of body temperature and sweating is an example of a *corporealization* of the lived body (Fuchs, 2002). Unlike melancholia, hot flashes are transient. They come and go quickly, and, perhaps for this reason, the report of the bothersomeness of hot flashes varies across individuals and cultures (Crawford, 2007).

Just as the physiology of hot flashes is not clearly understood by investigators, the inner workings of the body are also hidden from the subject's point of view so that perceptions can be vague or ambiguous. Merleau-Ponty differentiated between conscious perception without and with explicit awareness. Regarding the first state, Shusterman (2008) explains that it is possible to be conscious and to perceive something (e.g. a hot flash) but not to recognize it as a specific object of consciousness. 'My awareness of it is at most a marginal or recessive awareness' (p. 54). One can imagine a lack of concordance between this 'unreflective lived body' and the 'conceptual representations of scientific explanations' (p. 63) as demonstrated by the false positive measures described above. Shusterman (p. 70) goes on to say that 'somatic self-consciousness involves a reflective awareness that one's self is experiencing the sensations on which one's attention is focused.' This 'somatic self-consciousness' would result in true positive measures of hot flashes.

Reflective thinking does not necessarily capture unreflective experience, because reflectivity changes 'our basic experience by introducing categories and conceptual distinctions that were not originally given' (Shusterman, 2008, p. 65). In Campeche, Mexico, women attributed episodes of heat ('*calores*') to the hot climate, to eating *chiles*, emotional stress, high blood pressure, *nervios* and physical exertion (Sievert et al., in press). Women answered 'yes' when asked if they experienced *calores*. It was not until we asked 'why?' that we learned that women attributed these episodes of heat to factors other than menopause. Is sudden sweating attributed to emotional stress a hot flash? Rethinking episodes of heat or sweating as due to menopausal hot flashes changes the experience.

Objectivity has conventionally been understood to mean the rational and dispassionate search for truth and certitude (Weber, 1995). An objective measure positions the hot flash as an object that is external, a phenomenon apart from self-consciousness (Weber, 1995, p. 36) because the objective measure is perceptible to persons other than the woman who is experiencing the hot flash. The conventional method of asking a woman, by structured questionnaire, if she has experienced a hot flash in the past two weeks seems to be objective, and cross-cultural comparisons treat the answers to standardized symptom lists as equivalent objects that can be evaluated side by side (e.g. Anderson et al., 2004; Lerner-Geva et al., 2010; Obermeyer et al., 2007). However, the standard symptom list does not elicit the report of hot flashes that occur in 'marginal or recessive awareness.' The standardized questionnaire will always be limited by the filters of perception and cultural context.

Objective measures allow for agreement about a certain reality to provide an 'intersubjectively acceptable representation of the world' (Schatzki, 1995, p. 137). As Rescher (1997, p. 91) expands, our concept of a real thing 'provides a fixed point, a stable center around which communication revolves.' Hence, objective hot-flash measures have been used to assess the efficacy of pharmaceutical and behavioral treatments for hot flashes (Carpenter et al., 2007; Elavsky et al., 2012; Freedman and Woodward, 1992). The objective hot flash is not, however, fully independent of the physical characteristics of the subject, e.g. body mass index (Thurston et al., 2011) or sweating patterns (Sievert, 2007), that may alter objective measurement and comparison.

Objective criteria can allow for conflict resolution, as long as the dispute can be measured 'by an object that is clearly separable from all subjectivity' (Weber, 1995, p. 37). Hot flashes can be measured and, despite critiques of conventional hot-flash criteria (Thurston et al., 2011), objective measures of hot flashes can be evaluated to compare, for example, diurnal patterns across populations (Carpenter et al., 2001; Freedman et al., 1995; Sievert et al., 2010). As Rescher (1997) points out, scientific consensus is not stable over time, e.g. hot-flash measurement will improve with advances in technology. In the meantime, hot flashes are measurable, temporally bounded entities that can be documented and separated from the vagaries of perception, awareness and cognitive labeling. The question remains whether or not a biometrically documented hot flash, measured but not consciously noted or identified, is 'real.'

Different Methods of Measurement: Different Information

The questions posed here are not about the rightness or wrongness of biometric measures and subjective report. Knowledge can be attained subjectively or objectively. The question of which hot flash – subjectively reported or biometrically documented – is 'real,' and which hot flash should be privileged as the gold standard in measures of concordance, should be of interest to those who study pain (Good et al., 1992; Jackson, 1994; Leder, 1984), memory (Weber et al., 2012), stress (Brown et al., 2006) and other human conditions (Kaufman, 1988; Lowe, 1985). In the case of hot flashes, subjective report and polygraph output portray different phenomena.

Subjective reactions 'are just as quantifiable as their physical dimensions' (Rescher, 1997, p. 76), as illustrated by the use of surveys in menopausal research. Variation across populations in symptom report prompts an analysis of cultural context to identify how symptoms are perceived, identified, labeled and reported (Crawford, 2007; Melby et al., 2005). Similarly, variation across populations in rates of concordance between subjective and objective measures prompt studies of sweating patterns and acclimatization (Sievert, 2007). As for which measure should

be privileged, this dilemma is solved by asking about clinical significance and quality of life. Hot flashes are among the most common reasons given for starting, continuing or reinitiating hormone therapy (Ness et al., 2005; Newton et al., 2008). The hot flashes that matter are those that are bothersome. From that perspective, biometric measures of physiological change have little impact.

Notes

[1]It is possible to differentiate a hot flash from sweating during exercise, or with cooking or some other ambient source of heat, by the pattern of change in the level of sweating. The sweating associated with hot flashes occurs quickly and drops slowly. A generally applied criteria is an increase of two micro mhos within 30 seconds.

[2]Women are generally asked to keep a diary as well.

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