We have developed a pragmatic approach to menopausal status classification of clinical research study participants that allows for women who have gynaecological circumstances that mask their natural menstrual pattern. In order to evaluate menopausal status we looked first at the classifications for the transition through the menopause to assist researchers and clinicians in this field that have been developed by others. The Stages of Reproductive Aging Workshop (STRAW) classification provides menopausal transitional stages that are based on menstrual cycle pattern changes combined with serum FSH levels. More recently the endocrine features of the STRAW stages have been described in detail. However, to utilize these staging criteria one needs a detailed description of each woman’s natural menstrual pattern and ideally hormonal measures. In the Study of Women’s Health Across the Nation (SWAN), menopausal staging was based on information about each woman’s bleeding collected by questionnaire. However, in the SWAN study, the menopausal staging categories employed did not allow for the classification of women who had a prior hysterectomy such that these women were excluded from several analyses. In contrast the Women’s Ischemia Syndrome Evaluation (WISE) study employed an algorithm that enabled the categorization of hysterectomized women. However, this algorithm also included the use of serum hormone measures such that the application of the algorithm requires collection of blood from study participants.

Thus we have developed a system of classification of menopausal status that enabled the best estimate classification of women who could not provide a description of their natural menstrual cycle, taking into account that a study may not include blood collection for the measurement of gonadotropins and ovarian hormones.

We made the following decisions to develop this algorithm:

- All women who reported a bilateral oophorectomy were classified as postmenopausal as were all women >58 years of age. The latter was based on the limited published data that provides a median age for natural menopause of 51 years, tempered by our the clinical experience of managing women still menstruating up until the age of 57 years. This is more conservative than the upper limit of 55 years which we and other have applied in the past.

- Further classification was determined by whether or not women could describe their natural cycles.
  - Women with an intact uterus who report being more than twelve months beyond their last menstrual period were classified as postmenopausal.
  - Women not reporting any hormonal treatment and who reported regular menstrual cycles and being free of vasomotor symptoms were classified as premenopausal.
  - For women unable to describe their natural menstrual cycle because of hysterectomy or use of contraception, we followed a series of questions based on presence or absence of vasomotor symptoms.
  - As it was not possible to have blood collected at the time of diagnosis for measurement of gonadotrophins we used the presence of vasomotor symptoms as a surrogate for increased FSH and applied this as FSH is applied in STRAW and has been used in the WISE study.

References
