



Medical School  
Department of  
Obstetrics, Gynecology and  
Reproductive Sciences

August 11, 1997

Lillian Yin, Ph.D.  
Food and Drug Administration  
Center for Devices and Radiological Health - HIFZ170  
9200 Corporate Blvd  
Rockville MD 20850

RE: Home Uterine Activity Monitoring (HUAM) Devices

Dear Dr. Yin:

As Chairman of the Committee on Obstetric Practice of the American College of Obstetricians and Gynecologists, it has come to my attention that the FDA Devices Section is considering approval of additional home uterine activity monitoring devices. The Committee on Obstetric Practice would hope that the panel on Ob/Gyn Devices of the FDA would reassess their initial approval of home uterine activity monitoring devices.

Based upon a "meta-analysis-like" review of the subject, our committee concluded that data are insufficient to support a benefit from HUAM. Recent data published by Dyson and colleagues concluded that daily nursing contact alone, or with HUAM, did not improve outcome (see recent Committee Opinion No. 172, May 1996 Home Uterine Activity Monitoring). However, daily nursing contact, especially with HUAM, did lead to an increase of unscheduled visits which resulted in the increased "non-beneficial" use of tocolytes. The abstract of this study was published in the American Journal of Obstetrics and Gynecology, Vol. 176, No. 1, part 2 (Society of Perinatal Obstetricians' Annual Meeting).

It is our opinion that before such devices are approved, they should have proven benefits without adverse effects. Before other such devices are approved, it is hoped that randomized, prospective studies will be conducted.

Thank you for your attention to this matter.

Sincerely,

A handwritten signature in black ink, appearing to read 'Larry C. Gilstrap, III, M.D.'.

Larry C. Gilstrap, III, M.D.  
Chair, Committee on Obstetric Practice  
The American College of Obstetricians and Gynecologists

LCG:cd

cc: Stanley Zinberg, M.D.

97P-0300

CB

# Committee Opinion



Number 172, May 1996 (Replaces Number 115, September 1992)

## Home Uterine Activity Monitoring

Of all neonates born alive in the United States in 1993, 7.2% weighed less than 2,500 g (1). This figure represents the highest incidence of low birth weight since 1976. The incidence of very low birth weight (births of less than 1,500 g) has also remained unchanged since 1991 with an incidence of 1.3% (1). Over the past 30 years, the incidence of neonates weighing less than 2,500 g has declined only slightly and the rate of neonates weighing less than 1,500 g has not changed substantially (2, 3).

In 1992, more than 34,000 children in the United States died in their first year of life. These deaths result in an infant mortality rate of 8.5 deaths per 1,000 live births (4). Diseases related to prematurity are a major cause. Although this is the lowest rate ever recorded in the United States, it compares unfavorably with most other Western industrialized countries. A variety of primary and secondary preventive strategies have been suggested to reduce the incidence of preterm delivery. In spite of these efforts, overall reduction in the incidence of preterm births over time has been slight.

### Overview

Home uterine activity monitoring (HUAM) is a system of care to detect preterm labor. It uses a combination of the recording of uterine contractions with a tocodynamometer and daily telephone calls from a health care provider to offer patient support and advice. A recording of uterine contractions is transferred by telephone to the health care provider for rapid evaluation. The premise of HUAM is that women will have an identifiable increase in uterine contractions before the onset of preterm labor and that these prodromal uterine contractions otherwise may not be recognized by the patient. Advocates of the system propose that early identification of preterm uterine contractions will permit earlier administration of tocolytic therapy that, in turn, may be more effective than later therapy in preventing preterm births.

The ability to identify women at risk for preterm birth based on their history or risk factors is poor (5). Because many risk-scoring systems depend heavily on a history of preterm birth, the positive predictive value of risk scoring for nulliparous women is even lower than that for multiparous women. Thus, with widespread availability, HUAM may be used for many women who will not have premature labor, and some women who experience preterm labor will not receive HUAM. Wide-

appropriate endpoint for the approval of this technology. It did not require proof that the device prevents premature birth and the associated neonatal morbidity and mortality, which are the most important outcomes for clinicians and patients (25). Some might argue that cervical dilatation and effacement is a subjective endpoint.

#### ***Success of Treatment of Preterm Labor***

Investigators have attempted to determine the benefit of HUAM by studying its impact on the success of treatment for preterm labor. The hypothesis is that an improvement in success of treatment might be based on earlier initiation of treatment when cervical dilatation is less or before preterm labor becomes refractory to drug therapy. This approach is also limited to subgroup analysis of patients and controls with a diagnosis of preterm labor, rather than the entire study population.

Data from several of these studies suggest that treatment of preterm labor is more successful with the use of HUAM. Examining the subgroup of patients who experienced preterm labor, Morrison found that the percentage of monitored women in whom tocolysis was not effective was lower than that of women not monitored, although no statistical analysis was provided (18). Hill found a significant benefit of HUAM in preventing delivery within 48 hours in women who presented in preterm labor (19). Knuppel and Hill observed that significantly more controls failed tocolysis and delivered compared with those women who were monitored and experienced preterm labor (19, 20). In Watson's study, all of the women had preterm labor in the index pregnancy (26). In the subgroup of women who experienced recurrent preterm labor, significantly more of the controls delivered despite tocolytic treatment. Dyson also found this benefit in preterm labor with twins, although not with singleton pregnancies (21). As previously noted, the use of infants rather than pregnancies as the unit of analysis artificially increases the statistical power for the twin result. Wapner found a significant prolongation in the duration of pregnancy following treatment of preterm labor in monitored patients, and delivery was delayed by more than 48 hours in a significantly greater number of patients (24). In contrast, Iams examined the subgroup of patients who experienced preterm labor (7). He found no difference between those who were monitored and those who were not with regard to their suitability for tocolysis or the percentage of women who failed treatment.

#### ***Prevention of Preterm Delivery***

A number of studies using different patient risk

factors and different definitions of preterm delivery demonstrate a benefit in reducing preterm delivery but only in monitored women who had preterm labor compared with controls who had preterm labor and were not monitored (19–22, 24, 26). Reanalysis of the data from one study (19) found no significant difference in the incidence of preterm delivery when all enrolled patients are analyzed (13, 26). When the entire study population was analyzed, Wapner's study did not show a statistically significant improvement in pregnancy outcome as measured by gestational age, weight at delivery, and delivery of neonates weighing less than 2,000 g (24).

Only one of the studies that support the use of HUAM in preventing premature delivery does not depend on the analysis of subgroups of patients. In a study comparing HUAM to education and nursing contact, Morrison reported that the monitored women had a lower incidence of delivery before 37 weeks of gestation (18). Morrison also found significantly greater time elapsed from diagnosis of preterm labor to delivery in the monitored group than in controls ( $8.2 \pm 2.7$  weeks versus  $4.2 \pm 2.9$  weeks). This study was not blinded and provided limited nursing contact to the control group.

In contrast, several investigators found no difference in the incidence of preterm delivery or gestational age at delivery between monitored and unmonitored women (7, 23, 27). These investigators, who did not show a benefit of HUAM, tended to analyze all women who had been randomized rather than only the subgroup of women who experienced preterm labor.

Other neonatal outcomes have been examined, such as respiratory distress syndrome, neonatal intensive care unit admissions, total length of neonatal intensive care, and total nursery days. The results regarding these other endpoints also are not consistent.

Some investigators have attempted to isolate the benefit of the components of HUAM as a system of care, specifically the health provider contact and the tocodynamometer. Because of limitations and differences in design, consistent conclusions regarding these components cannot be made. The following conclusions can be made, however:

- From a clinical point of view, use of an intermediate endpoint, such as cervical dilatation, is not justified when the endpoint—prevention of preterm delivery—can be measured.
- The available data do not support the effectiveness of HUAM for the prevention of preterm birth.

**Table 1. Summary of Randomized Clinical Trials (Reference No.) of Human Uterine Activity Monitoring\* (continued)**

	Morrison (18)	Iams (6,7)	Watson (26)	Knuppel (20)	Hill (19)	Dyson (21)		Mou (22)	Blondel (27)	Nagey (23)	Wapner (24)
						Singletons	Twins				
Birth weight		ND				ND	HUAM benefit†	HUAM benefit for singletons†			ND
Tocolytic failure			HUAM benefit†	HUAM benefit†	HUAM benefit†						
Incidence of LBW						ND			ND‡		ND
Incidence of VLBW		ND				ND	HUAM benefit§				
Incidence of RDS						ND					
Rate of ICN admission						ND	HUAM benefit§	HUAM benefit†			ND
Infant length of stay						ND	HUAM benefit§				ND
% requiring O <sub>2</sub>								HUAM benefit†			
% requiring mechanical ventilation							HUAM benefit†				

\*PML indicates premature labor; HUAM, home uterine activity monitoring; PTD, preterm delivery; ND, no difference; LBW, low birth weight; VLBW, very low birth weight; RDS, respiratory distress syndrome; ICN, intensive care nursery.

†Benefit was found only for the subgroup with preterm labor.

§Statistical significance may be invalidated due to counting newborns rather than deliveries in multiple gestations.

‡Power was inadequate.

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