## Determining the accuracy of gestational dating among women presenting for an abortion: Results from Greater Accra and Eastern Region in Ghana

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Introduction: In Ghana, despite having a relatively liberal abortion law, evidence shows that women's selfadministration of misoprostol for induced abortion outside of a clinical setting is common practice. 12,3 Misoprostol alone, when taken according to the World Health Organization's (WHO) recommended regimen, is effective for medical abortion with a success rate of 85% for gestations up to 9 weeks.<sup>4</sup> Although there is scant evidence of effectiveness for gestations between nine and 13 weeks, the WHO endorses using the evidence based regimen for below nine weeks for gestations between nine and 13 weeks.<sup>5</sup> Given its safety and simple administration, some have argued against the need for clinical oversight in the use of misoprostol, except in the case of treatment failure or complications. <sup>6</sup> The correct use of misoprostol depends on women's ability to accurately assess the duration of their gestation to determine whether it is early enough to abort safely and effectively with this method. In Ghana, many women self-administer misoprostol without any clinical consultations, believing that they know the correct gestational period in which the drug must be utilized and how far along they are in their pregnancy. Given the estimated prevalence of misoprostol use outside of medical supervision in Ghana, a better understanding of women's ability to date their gestations is critical for informing programmatic and policy efforts to increase women's access to medical abortion (MA) outside of health facilities. The option of using MA outside of a clinical context could potentially increase women's access to safe abortion and, thus, contribute directly to a decrease in maternal morbidity and mortality.

The primary objective of this study was to determine the proportion of women, presenting for an induced abortion within clinical facilities in Ghana, who could accurately determine whether their pregnancy was <13 or  $\ge13$  weeks gestation using a gestational wheel, a tool for calculating gestational age from last menstrual period (LMP). This cutoff was chosen to align with the WHO recommended regimen for misoprostol alone in the first trimester. An additional aim was to examine the association between women who fall into a "risky disagreement group" (i.e., a woman dates her pregnancy as <13 weeks vs. the provider dating the pregnancy as  $\ge13$  weeks) and potential correlates (e.g., age, educational attainment, literacy level, marital status, religion, gravidity, parity, pregnancy symptoms, menstrual regularity, and perceived certainty of LMP).

## **Research Design and Methods**

Study design and eligibility criteria: We conducted a cross-sectional, observational study with women attending two public and two private health facilities in Eastern and Greater Accra regions. Two ethical review boards, Ghana Health Service Ethical Review Board and Allendale IRB in the US, approved the protocol before study initiation. Women attending the facilities between February and July 2014, were recruited for participation. Women must have met the following criteria to be eligible for study inclusion: 1) attend a study site for an induced abortion during the study period; 2) be ≥18 years of age; 3) have completed primary school (a proxy measure for functional literacy); 4) not have previously been told by a health care provider how far along they are in the current pregnancy; and 5) be able and willing to provide consent for study participation.

**Study procedures:** On-site, full time, trained study interviewers (not facility staff) screened consecutive, potentially-eligible women at the study facilities and consented women interested in participating in the study. Study interviewers orally administered the participant questionnaire to collect data on participant demographics, reproductive history (RH), and self-assessed gestational duration using the Gestational Wheel (based on the self-reported date of their LMP). First, the interviewer collected demographics and pertinent history, including the date of a woman's last menses; second, they asked the participant to determine their gestational age using the wheel — at this stage of the interview, the participant did not receive any instruction on how to use the wheel; lastly, if a woman was unable to use the wheel without instruction, interviewers provided women with an overview of how to use the gestational wheel and then asked them to use it to determine their gestational age. Women were also asked about the perceived ease of use of the wheel.

After the interview by study staff, women were seen by a study provider (doctor or nurse midwife) who assessed gestational age independently. Standard of care for gestational dating in Ghana is bimanual examination (BME) although some women received ultrasounds or dating via abdominal palpation. Providers documented gestational age and select patient characteristics, such as detected fibroids or multiple gestations, in a provider questionnaire, which they immediate gave to the on-site interviewer. To reduce the potential for bias, study providers were blinded to the study interviewer's gestational age assessment. To standardize gestational dating across study providers and sites, providers received refresher training on bimanual examination from an Ipas Global Master Trainer and were periodically observed during the study period by a hired clinical consultant.

**Data Management and Analysis:** A study field coordinator collected the completed participant files on a routine basis from the sites. Data was entered into EpiData and converted into Stata 11.2 for analysis. Descriptive statistics were computed – including frequencies and associated percentages for categorical data, and means and standard deviations for continuous data. The analysis population consists of all eligible women with non-missing data for the outcomes of interest. Women who were reported to have uterine fibroids or multiple gestations (both of which could affect the provider's assessment of gestational age) have been excluded from the analyses.

For the primary study objective, we calculated the proportion of participants who accurately determined that their pregnancy was <13 or ≥13 weeks using a gestational wheel (based on self-reported LMP). We used a provider's clinical dating as the reference standard. Given that BME is the standard of care in Ghana, we used BME whenever available and then ultrasound and then abdominal palpation; we named this variable "provider's best estimate." We present contingency tables detailing the percent agreement between women and providers with regards to gestational dating, and the distribution of provider determined gestational ages for women in the "risky disagreement group." This group is defined as women who assess their gestational age as <13 weeks when the provider dates their pregnancy as ≥13. At this time we have not investigated the association between being in the "risky disagreement group" and a woman's personal characteristics but these analyses will be completed in the coming moments and included in our final paper. The characteristics to be explored are: age, educational attainment, functional literacy, relationship status, religious affiliation, experienced pregnancy symptoms, regularity of menstrual cycle, certainty of LMP, contraceptive use at time of conception, parity and gravidity. Tests of association will include t-test for age, Wilcoxon rank sum for parity and gravidity, and chi-square (or fisher's exact for small cell numbers) for all other variables. Adjusted analyses are not possible given the small sample size for our outcome of interest.

**Preliminary Findings:** Study staff screened 1,282 women for participation in the study and 415 were deemed ineligible. Thirty-five percent of ineligible women already knew the estimated gestational age of their pregnancy and the remainder was ineligible due to no formal education or being younger than 18 years of age. Overall, 867 women were eligible for participation although 19 women declined to participate. Eight hundred and forty-eight women consented to participate and provided data, but five women were ultimately excluded from analyses due to provider reported multiple gestations or fibroids/uterine masses. Our final sample size for analysis was 843 women with a participation rate of 98% (848/867).

Almost two-thirds of study participants reported being 24 years of age or older. Over half (57%) had completed secondary school or higher and 61% reported being able to easily read a newspaper in English. A majority of women were partnered but not married (71%), with only 3% of women reporting no steady romantic partner. Consistent with the predominant religious affiliation in Ghana, 90% of women reported being Christian. Statistically significant differences in non-eligibility related demographic characteristics between participants and non-participants were found for ability to read a newspaper and relationship status.

Eighty-seven percent of women provided an exact date for the first day of their last menstrual period (LMP). Another 12% were able to recall their last menses being in the first, middle or last half of a recalled month, and 1% couldn't recall a date at all. Over half of participants (53%) reported having somewhat regular periods, while 41% said they were very regular and 5% said their periods were irregular. Overall, 95% of women said that they were either very certain or fairly certain (76% and 19% respectively) of their recalled LMP.

With regards to using the gestational wheel, 28% were able to use the wheel without any verbal instruction from the data collector. The other 72% were provided with verbal step-by-step instructions after initially trying to complete the task on their own. We detected no significant difference between women who required explanation vs. those who did not with regard to age group; significantly more women who did not require instructions had attended university (38% vs. 8% respectively). The 1% of women who could not recall the date of their LMP (n=9) were not asked to participate in the gestational wheel portion of the interview since the calculation relies on recalled LMP. More than half of participants (60%) said the wheel was easy to use, 29% said somewhat easy and 10% said not easy at all.

A majority of providers dated a woman's pregnancy via BME resulting in 92% of participants having a provider estimate based on BME. The other 8% of women had their pregnancies dated by ultrasound (n=1) or abdominal palpation (n=63). Agreement between a woman's estimate of gestational age (based on her use of the wheel) and a provider's estimate was quite high. Table 1 displays the results for the four possible outcomes of agreement. Overall agreement for gestational age between women and providers was 94%. That is to say that 92% of women estimated their gestational age as <13 weeks and so did the provider and 2% of women estimated their gestational age as ≥13 weeks and so did the provider. An additional 1% fall into a "low risk disagreement group" meaning that a woman is dating her pregnancy as more advanced than the clinician. Five percent of women fall into a "risky disagreement group" meaning that a woman dating her pregnancy as <13 weeks but the provider dated it at ≥13 weeks. In Table 2 below we present the gestational age distribution for the 39 women in the risky disagreement group. Almost 60% of women in this group were dated at 13 or 14 weeks gestation and the remainder between 16 and 22 weeks. One woman in the risky disagreement group was estimated to be 28 weeks pregnant.

Table 1. Comparison between Women and Providers for Gestational Age <13 vs. ≥13 Weeks (n=828)						
		Provider Estimate				
		<13		≥13		
		n	%	N	%	
Woman's Estimate						
	<13	760	92%	39	5%	
	≥13	12	1%	17	2%	
	Total	772		56		

Table 2. Distribution of provider estimated gestational age for risky disagreement in 13 week group						
Weeks	n	% of risk group	% of study sample			
13	1	3%	0%			
14	22	56%	3%			
16	8	21%	1%			
18	5	13%	1%			
22	2	5%	0%			
28	1	3%	0%			
Total	39					

Discussion: Our results indicate that most women seeking an abortion in Ghana can accurately recall their LMP. These results are consistent with previous research in other countries. <sup>7</sup> Unfortunately, simply knowing one's LMP does not necessarily translate into a woman accurately (and independently) estimating the gestational age of her pregnancy. This study tested women's ability to use a gestational wheel to date their pregnancy, an important step in using misoprostol safely outside of a healthcare facility. With simple step-by-step instructions, almost all women were able to use the wheel and a majority found it easy. Empirical and anecdotal evidence indicate that women in Ghana are actively seeking MA outside of the health system - educating women and community members on using a gestational wheel is therefore a promising strategy for improving safety of MA use outside the health system. A majority of our study population accurately dated their pregnancy as being <13 weeks gestation which would have put them at low risk for complications if they had chosen to use MA outside of the health facility. Even for women who may misestimate their gestational age (such as those women in the risky disagreement group), the result would likely not be clinically significant because any reduction in effectiveness of MA regimens as gestational age advances is gradual, not sudden.8 Ultimately, community based activities that include increasing women's knowledge of MA eligibility and dosing, as well as the ability to accurately date their pregnancies, have the potential to increase women's access to safe abortion at the community level, further advancing the goal of improved maternal health in Ghana.

## References

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