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Measuring health utility in varying pregnancy contexts among a diverse cohort of pregnant women

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23**ABSTRACT**

24

25Objective: To contribute to decision analysis by estimating utility, defined as an individual's

26valuation of specific health states, for different pregnancy contexts.

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28Study design: Cross-sectional analysis of data from pregnant women recruited at pregnancy

29testing clinics during June 2014-June 2015. Utility was measured using the visual analog scale

30(VAS), PROMIS GSF-derived utility, standard gamble (SG), and time-trade-off (TTO)

31approaches. Six dimensions of pregnancy context were assessed including: intention, desirability,

32planning, timing, wantedness, and happiness. Multivariable regression modeling was used to

33examine the associations between pregnancy context and utility while controlling for women's

34sociodemographic and health characteristics.

35

36Results: Among 123 participants with diverse characteristics, aged 27±6 years, with mean

37gestation of 7.5±3 weeks, few reported optimal pregnancy contexts. Mean utility of the

38pregnancy state varied across contexts, whether measured with VAS (0.28-0.91), PROMIS GSF-

39derived utility (0.66-0.75), SG (0.985-1.00) or TTO (0.9990-0.99999). The VAS-derived mean

40utility score for unintended pregnancy was 0.68 (95% CI 0.59, 0.77). Multivariable regression

41analysis demonstrated significant disutility of unintended pregnancy, as well as all other

42unfavorable pregnancy contexts, when measured by VAS. In contrast, PROMIS GSF-derived

43utility only detected a significant reduction in utility among ambivalent compared to wanted

44pregnancy, while SG and TTO did not show meaningful differences in utility across pregnancy

45contexts.

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46 <u>Conclusions</u>: Unintended pregnancy is associated with significant patient-reported disutility, as

47 is pregnancy occurring in other unfavorable contexts. VAS-based measurements provide the

48 most nuanced measures of the utility for pregnancy in varying contexts.

49 <u>Implications</u>: Decision analyses, including assessments of the cost-effectiveness of pregnancy

50 related interventions, should incorporate measures of the utility of pregnancy in various contexts.

51

52 <u>Keywords:</u> London Measure of Unplanned Pregnancy, unintended pregnancy, utility, visual

53 analog scale

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58INTRODUCTION

59   Approximately half (45%) of all U.S. pregnancies are unintended [1], resulting in an

60estimated $4.5 billion in annual direct medical costs [2] and $21 billion in 2010 Federal and state

61public expenditures [3]. With increased focus on reducing unintended pregnancy [4], cost-

62effectiveness analyses are a useful tool to inform decisions regarding efforts to reduce

63unintended pregnancies and improve reproductive health outcomes by evaluating expected

64economic and quality of life impact of various interventions [5]. Yet cost effectiveness research

65related to reproduction, including assessment of utility related to pregnancy, is currently

66understudied [5, 6]. Further, reliable and valid utility measure estimates are necessary for cost-

67effectiveness analyses regarding unintended pregnancy. To date, the quality of these studies has

68been limited by lack of objective measures that reflect differences in health utility by pregnancy

69context.

70   "Utility" is one way of evaluating health-related quality of life (HRQoL) for specific

71health states [7].   Existing research on the utility of pregnancy is limited by using utility

72estimates derived from hypothetical health scenarios among non-pregnant participants [8, 9]. As

73perspectives on hypothetical health states differ from individuals' actual experiences [10],

74research is needed to better characterize the utility of pregnancy in unfavorable pregnancy

75contexts using more relevant study populations.   Furthermore, recent literature has called for

76awareness of the limitations of considering only whether a pregnancy was intended or planned

77when evaluating the effects of the pregnancy on a woman's life and health [11, 12].

78Multidimensional pregnancy perspectives may be relevant to women's perceived utility of

79pregnancy as well.

80   To fill this gap, our study aimed to evaluate health utility of pregnancy occurring in a

81 variety of "contexts" measured as intention, wantedness, planning, timing, desirability, and

82 happiness [13] among a cohort of pregnant women. Specifically, we aimed to calculate utility

83 estimates for varied contexts of pregnancy that can be used in future cost-effectiveness analyses.

84 We also compared utilities elicited using the visual analog scale (VAS) approach [9, 14], which

85 has demonstrated validity in previous studies examining valuation of pregnancy outcomes [15,

86 16], with those derived from other approaches, including standard gamble [7, 17], time-trade-off

87 [18], and the Patient Reported Outcome Measurement Information System (PROMIS) Global

88 Short Form (GSF)-derived utility [19].

89

90 METHODS

91 *Study setting and design*

92   Data for this analysis came from a sample of women presenting for pregnancy testing

93 services at two clinical sites in New Haven, CT, during the period of June 2014 to June 2015.

94 While the original study included women recruited at various clinical settings including abortion

95 care sites, the current analysis is restricted to women with a recent pregnancy diagnosis from

96 pregnancy testing sites only in order to best assess the relationship between pregnancy context

97 and utility. Women were eligible if they had a positive pregnancy test on the day of recruitment,

98 were English or Spanish speaking, had completed <24 weeks of gestation, were 15-44 years of

99 age, and completed study enrollment within 1 week of their clinical pregnancy test. Participants

100 could complete the study in English or Spanish. Overall, research staff approached 225 women

101with a positive pregnancy test regarding study participation. Of those, 123 women were eligible

102and completed the enrollment questionnaire.

103   The enrollment questionnaire was self-administered, and ascertained each participant's

104sociodemographic characteristics, medical history, reproductive history, HRQoL, and

105assessments of the utility of their current pregnancy. The study protocol was reviewed and

106approved by the Yale University Human Research Protection Program. Written consent was

107obtained from study participants prior to enrollment.

108*Measures of pregnancy context*

109   As previously described [13], there are six measures of pregnancy context (Appendix A),

110and assessment of utility scores associated with these pregnancy contexts can enable a more

111comprehensive understanding of patients' perceptions about their pregnancy-related health state.

112These context measures included 3 "*pre-pregnancy perspectives,*" including intention,

113wantedness, and planning, and 3 "*post-conception perspectives,*" including timing, desirability,

114and happiness. Each of the pregnancy context measures was evaluated as a 3-level categorical

115variable reflecting a (1) favorable, (2) ambivalent/neutral, or (3) unfavorable pregnancy context.

116For example, pregnancy intention was categorized as: "intended", "intentions changing", or

117"unintended." Pregnancy intention, wantedness, and timing were measured using elements from

118the London Measures of Unplanned Pregnancy (LMUP) construct [20].

119*Measures of Utility*

120   Utility is a metric quantifying the "relative value placed on a specific health status or an

121improvement in health status" [21]. Utility values range from 0 to 1, with 0 representing death

122and 1 representing perfect health state [22], while disutility is defined as the corresponding

123decrease or measured decrement in overall utility. We measured utility using four different

124approaches detailed below.

125Visual Analog Scale

126   Visual analog scale (VAS) measures utility of health states [9, 14] by asking participants

127to indicate how they felt after learning they were pregnant by placing a mark on a 10-cm line that

128ranged from 0 ("As if I was dying') to 10 ("In perfect health")[9]. Values from the 10-cm scale

129were then calibrated to a 0-1.0 scale.

130PROMIS Global Short Form derived utility

131   We administered the National Institutes of Health (NIH) Patient Reported Outcome

132Measurement Information System (PROMIS) Global Short Form (GSF) [23, 24] to assess

133HRQoL [13]. Participants' responses to the GSF were converted to utility scores based on a

134previously validated algorithm mapping GSF responses to the EuroQol (EQ-5D) utility score

135[19].

136Standard Gamble

137   The standard gamble [7] elicitation approach used questions previously employed to

138assess utility of a hypothetical unintended pregnancy [9] (see Appendix B). The accepted risk of

139death was then converted to a utility score as (1-accepted risk of death). SG is a well-established

140method grounded in traditional economic theories to elicit individual's preferences about a given

141health state under specific conditions of uncertainty [22]. In this method, respondents are given

142choices regarding willingness to accept a risk of death in order to avoid a specified health

143 outcome; specific to this study, participants' willingness to accept a risk of death to avoid the

144 current pregnancy.

145 <u>Time Trade-Off (TTO)</u>

146 Utility assessed using TTO is based upon willingness to trade time at the end of life to

147 avoid a specific disease or health state [22]. In the TTO approach (see Appendix B), disutility

148 was calculated as the time that a woman reported being willing to give up to avoid being

149 pregnant divided by her life expectancy (life expectancy based on U.S. life tables [25]). Her

150 utility score is then calculated as (1-disutility). For women who selected the upper bound

151 category of time willing to give up (i.e., ≥3 months), our primary analysis calculated their utility

152 score assumed 3 months as the maximum time they were willing to give up. We also performed a

153 sensitivity analysis by using 10 years as the maximum time willing to give up for women in this

154 upper bound category [9].

155 *Patient characteristics*

156 Measures of potential confounding factors in the association between pregnancy context

157 and utility included sociodemographic characteristics (i.e., age, race, ethnicity, level of

158 education, employment, and relationship status), reproductive history (i.e., parity, previous

159 miscarriage, and previous abortion), presence of chronic medical condition (e.g. asthma,

160 diabetes, thyroid problem), depression, anxiety, and substance use during the previous 3 months

161 (smoking and tobacco use, marijuana use and alcohol consumption). Gestational age was

162 measured based on reported last menstrual period at time of enrollment.

163 *Statistical analysis*

164	Descriptive statistics were estimated to summarize patient characteristics. Bivariate

165associations between pregnancy contexts and measures of utility were assessed using analysis of

166variance (ANOVA) or Kruskall Wallis tests for continuous measures depending on whether the

167utility score was normally distributed. We also estimated linear regression models for VAS and

168GSF-derived utility scores with and without adjusting for other covariates to examine the

169magnitude of difference in utility between different pregnancy contexts. Each pregnancy context

170was assessed in a separate model, using favorable pregnancy context as the referent group (e.g.

171intended pregnancy). Pregnancy context was forced into the model and patient characteristics

172that were significant at $p < 0.20$ level in bivariate analysis were included as covariates in the

173regression model. Such regression analysis was not performed for SG and TTO-derived utility

174scores because there was very limited variation in the scores.

175	Twenty-eight women had missing observations for VAS measurement. We assessed their

176potential impact on interpretation of findings by comparing patient characteristics

177(sociodemographics, pregnancy context, and utility scores) between women who completed the

178VAS versus those with incomplete VAS information. Statistical analysis was performed using

179SAS 9.4 (SAS Institute, Cary, NC).

180

181RESULTS

182*Patient Characteristics and Pregnancy Context*

183	Among the 123 participants, mean age was 26.7(±6.3) years and average gestational age

184at enrollment was 7.5(±3.0) weeks (Table 1). Most participants were non-Hispanic Black

185(36.9%) or Hispanic (45.9%). Few (14.8%) were married or had at least some college education

186(36.0%). Most women were parous (72.9%), and previous miscarriage was reported by 38.8%

187and previous abortion by 37.9%.

188	Fifty percent of participants reported that they did not intend to become pregnant, 25.2%

189that they did not want a baby, 17.9% that pregnancy was unplanned, and 19.5% that the

190pregnancy occurred at the wrong time (Table 2). However, most women reported that they were

191happy about the pregnancy news (72.4%) and that the pregnancy was desired (60.1%).

192

193*Association of Pregnancy Context with Utility*

194	Overall, VAS scores among the sample ranged from 0.04-1.00 with average score of

1950.79(±0.27). Mean VAS score varied substantially across different pregnancy context (Figure

1961A, Table 3), with VAS-derived mean utility score for unintended pregnancy of 0.68 (95% CI

1970.59, 0.77). Wide variation is observed for context measure of happiness with pregnancy news,

198ranging from 0.28 among those unhappy, 0.67 for neither happy or unhappy, and 0.88 among

199women happy with pregnancy news. Similar patterns are observed for other context measures,

200with highest VAS scores among those reporting favorable pregnancy contexts, lower for

201ambivalent categories and the lowest scores among those with unfavorable pregnancy contexts

202(e.g. unwanted, unintended, unplanned pregnancy). For each of the six measures of pregnancy

203context, the VAS score differed significantly across the favorable, ambivalent/neutral, and

204unfavorable perception categories (p<0.001 for all).

205	Range of PROMIS GSF-derived utility scores was 0.46-0.88, averaging 0.71(±0.10) for

206the sample. PROMIS GSF-derived utility scores demonstrated a similar pattern across pregnancy

207context, but with somewhat less variation than VAS-derived scores. Mean utility scores

208 demonstrated less variation in range across favorable, ambivalent, and unfavorable contexts,

209 particularly for pregnancy intention, ranging from 0.70-0.73. Additionally, lowest mean utility

210 scores for wantedness were observed among those who reported mixed feelings (0.68), while

211 utility among wanted and unwanted pregnancies was 0.74 and 0.71, respectively. GSF-derived

212 utility scores differed significantly across favorable, ambivalent/neutral, and unfavorable

213 perception categories for four pregnancy contexts (i.e., wantedness, timing, desirability, and

214 happiness).

215   In contrast, SG and TTO-based utility scores showed very limited variability across the

216 different pregnancy contexts and were clustered around 1.0, with overall scores ranging 0.90-1.0

217 for SG and 0.994-1.00 for TTO; mean values were 0.996($\pm$0.017) for SG and 0.9997($\pm$0.001) for

218 TTO, respectively.   The mean SG-based utility varied slightly from 0.985 in unhappy pregnancy

219 to 1.00 in women who had changing intention or mixed wantedness about pregnancy, while the

220 mean TTO-based utility score varied subtly from 0.9990 in unhappy pregnancy to 0.99999 in

221 intended pregnancy. Although SG and TTO-based utility scores differed statistically across the

222 favorable, ambivalent/neutral, and unfavorable perception categories for three and six of the

223 measures of pregnancy context, respectively, the magnitude of the difference was minimal. Our

224 sensitivity analysis using an upper bound of 10 years for calculation of TTO-based utility score

225 showed no material difference in results.

226   Unadjusted and adjusted regression analyses for the association of pregnancy context

227 with VAS utility are presented in Figure 1B and Table 4. After adjusting for patient

228 characteristics, greater disutility was observed among those who did not intend to get pregnant,

229 did not want to have a baby, or were ambivalent or reported unplanned pregnancy (mean

230 adjusted difference ranging from -0.13 to -0.28, p<0.03 for these contexts), compared to women

231reporting their pregnancy was intended, they wanted to have a baby, or pregnancy was planned,

232respectively. Likewise, women who indicated it was the wrong time to become pregnant, were

233not sure or not desiring the pregnancy, or were unhappy about the pregnancy news, demonstrated

234greater disutility measured by VAS compared to those reporting pregnancies that occurred at the

235right time, were desired, or produced feelings of happiness with the pregnancy news (mean

236adjusted difference ranging from -0.29 to -0.54, p<0.01 for these contexts).

237   Table 4 also reported unadjusted and adjusted regression analyses for the association of

238pregnancy context with PROMIS GSF-derived utility score. After adjusting for patient

239sociodemographic and health characteristics, PROMIS GSF-derived utility score only differed

240significantly between women who had ambivalent feelings and those wanting to have a baby

241(mean adjusted difference = -0.05, p=0.01). There was no significant difference in other

242dimensions of pregnancy context.

243   Comparison of participants who had complete VAS data versus those with missing data

244on VAS suggested no statistically significant differences in participant characteristics, pregnancy

245context, and utility measures (all p values >0.05; data not shown in tables).

246

247DISCUSSION

248   Among women with a recent pregnancy diagnosis, pregnancies that were reported to

249have occurred at the wrong time, were unintended, unwanted, not desired, unplanned, or met

250with unhappiness, are associated with disutility as measured by the visual analog scale (VAS).

251The value and range in variability of utility score for these pregnancy contexts differed by

252measurement approach with the VAS-based approach demonstrating more discriminatory ability

253across pregnancy context than other measurement methods. This analysis provides utility

254estimates for "unintended pregnancy", as well as other pregnancy contexts, that can be used in

255future cost-effectiveness analyses.

256   A previous study evaluating the utility of unintended pregnancy among 192 non-pregnant

257women reported a VAS-based score of 0.49 [9]. In contrast, we found a higher VAS-based utility

258score of 0.68 among women currently experiencing an unintended pregnancy. This is consistent

259with previous literature suggesting higher utility/lower disutility among individuals experiencing

260actual health states compared to hypothetical health states [10], highlighting the importance of

261assessing utility in actual patient populations.

262   Our study improves upon and extends the literature in several important ways. First,

263research examining utility regarding pregnancy among currently pregnant women has been

264sparse [26, 27] and previous cost-effectiveness analyses have relied on published utility metrics

265derived from non-pregnant samples [8, 9, 28, 29]. Earlier studies have often focused on

266hypothetical scenarios of pregnancy [15, 16, 30], and therefore may not accurately reflect the

267experiences of pregnant women, including pregnant women's experiences of different pregnancy

268contexts. In contrast, we assessed utility among currently pregnant women close to the time of

269pregnancy diagnosis, and controlled for potential confounders in multivariable analysis. Further,

270use of multidimensional context measures beyond traditional measures of planning and intention

271are integral to improving our understanding of individual pregnancy perspectives and essential

272for evaluating impact of various strategies for addressing women's reproductive healthcare needs

273[11, 12]. However, there has been a lack of data on utility with respect to different pregnancy

274contexts in the literature. In this regard, our study extends analysis of multidimensional

275pregnancy perspectives, including pregnancy timing, wantedness, desirability, and happiness

276with pregnancy. Additionally, we evaluated ambivalence as a separate category, which has been

277largely overlooked in previous research, and demonstrated significant disutility within this

278context category (e.g. mixed feelings about wanting to be pregnant). This highlights the

279importance of more attention to this unique group in future research and clinical care.

280　　　　Based on our findings, VAS captures the variability of utility across various pregnancy

281contexts and may be the most appropriate metric for use in assessing health utility among

282pregnant women. Previous research has demonstrated the validity of VAS in evaluating health

283states related to pregnancy and birth outcomes, reporting high test-retest reliability among a

284community-based sample [15] and within group validity among patient, layperson, and

285professional participant groups [16]. Moreover, VAS measures adequately captured significant

286differences within specific gynecological conditions including urinary incontinence measures

287[31] and pelvic inflammatory disease health states [32]. In our analysis, we also found expected

288differences in VAS-based utility across various pregnancy contexts and significant disutility for

289ambivalent/unfavorable contexts. On the contrary, GSF-derived utility score only captured

290variability in selected pregnancy contexts, and SG and TTO-derived utility measures varied

291minimally across levels of pregnancy context. It is likely that these elicitation methods may not

292be sensitive enough to detect differences in women's perceptions about the various pregnancy

293contexts. In addition, methods based on responses to risk of death (SG) or trading time at the end

294of life (TTO) were designed to evaluate chronic or terminal disease health states and may not be

295suitable for assessing utility of pregnancy-related health states which are generally not life-

296threatening conditions.

297　　　　An important consideration is that utility measured during pregnancy reflects a short-

298term, transient health state. While we demonstrate that unfavorable and ambivalent pregnancy

299contexts are associated with significant disutility, further research is necessary to quantify

300potential changes in women's perception about pregnancy over time, i.e. whether their reported

301utility scores may differ as pregnancy progresses and after pregnancy ends (post-abortal or

302postpartum). Additionally, we demonstrate those with favorable pregnancy contexts have higher

303utility (e.g. mean VAS for all favorable contexts between 0.88-0.91). Understanding the duration

304of disutility associated with unfavorable pregnancy contexts will further inform future cost-

305effectiveness analyses. With over 6 million women experiencing pregnancy annually in the U.S.

306[33], these additional data will be particularly important to help enhance overall population

307health.

308   There are several limitations to the current study. Our cohort included women recruited

309from urban clinics and therefore may not be representative of the general population of pregnant

310women. However, the geographic area of our study recruitment is similar in demographic

311characteristics to the overall U.S. population [34] and study participants also demonstrated

312substantial diversity in sociodemographic characteristics, reproductive history, utility scores, and

313pregnancy context. Additionally, our sample size was relatively small; however, we observed

314statistically significant differences in utility scores across levels of pregnancy context, suggesting

315this is not a material concern. Future studies with a larger sample size could permit further

316informative analyses, such as sub-analyses to identify specific patient characteristics associated

317with lower or higher utility among women with the same pregnancy context. For SG and TTO,

318we were not able to perform multivariable analysis due to the limited variability in overall scores

319skewed towards 1.0. Additional research would be helpful to confirm whether such limited

320variation in utility exists amongst a population of pregnant women using these traditional

321elicitation methods. We also observed missing values for VAS among 28 participants in our

322analytic sample, which may be due in part to the self-administered format of the questionnaire

323and the VAS element inadvertently skipped by respondents. Our sensitivity analysis

324demonstrated no significant differences between those with VAS measures and those without.

325Further, while VAS may be most appropriate for use among a pregnancy population with varied

326pregnancy contexts, its strengths and limitations in measuring health utility has been debated.

327Compared to choice-based elicitation methods such as SG and TTO, the VAS approach has been

328criticized for being theoretically limited [35] as a single-scale construct that is not choice-based.

329Yet others have argued it is theoretically grounded and does incorporate an element of choice

330that is scaled-based using the VAS line, rather than a choice between two options [36]. Further

331research validating our findings in other samples, including among women seeking abortion, will

332provide additional insights regarding the most appropriate measurement of utility for different

333pregnancy contexts.

334

335CONCLUSION

336Among a diverse cohort of women with a recent diagnosis of pregnancy, health utility varied by

337pregnancy context. Unwanted, unintended, unplanned, not desired, poorly timed or unhappy

338pregnancies were significantly associated with significant disutility. In addition, women with

339ambivalent pregnancy contexts also reported considerable disutility. These data provided robust

340utility scores for specific pregnancy contexts to inform future cost-effectiveness evaluations

341related to pregnancy. Further research examining potential changes in pregnancy-related utility

342metrics over time is warranted.

343

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