Final Progress Report for Research Projects Funded by Health Research Grants

Instructions: Please complete all of the items as instructed. Do not delete instructions. Do not leave any items blank; responses must be provided for all items. If your response to an item is "None", please specify "None" as your response. "Not applicable" is not an acceptable response for any of the items. There is no limit to the length of your response to any question. Responses should be single-spaced, no smaller than 12-point type. The report **must be completed using MS Word**. Submitted reports must be Word documents; they should not be converted to pdf format. Questions? Contact Health Research Program staff at 717-783-2548.

1. **Grantee Institution:** Lehigh University

2. **Reporting Period (start and end date of grant award period):** 1/1/2012 – 6/30/2014

3. **Grant Contact Person (First Name, M.I., Last Name, Degrees):** Nicole M. Corali, MBA, CRA

4. **Grant Contact Person's Telephone Number:** 610-758-4585

5. **Grant SAP Number:** 4100057665

6. **Project Number and Title of Research Project:** 2 – Cortisol, Estradiol, and Psychosocial Stress as Predictors of Postpartum Depressive Symptoms

7. **Start and End Date of Research Project:** 1/1/2012 – 6/30/2014

8. **Name of Principal Investigator for the Research Project:** Christopher T. Burke, Ph.D.

9. **Research Project Expenses**.

   9(A) Please provide the total amount of health research grant funds spent on this project for the entire duration of the grant, including indirect costs and any interest earned that was spent:

   $ 40,250

   9(B) Provide the last names (include first initial if multiple individuals with the same last name are listed) of **all** persons who worked on this research project and were supported with health research funds. Include position titles (Principal Investigator, Graduate Assistant, Post-doctoral Fellow, etc.), percent of effort on project and total health research funds expended for the position. For multiple year projects, if percent of effort varied from year to year, report in the % of Effort column the effort by year 1, 2, 3, etc. of the project (x% Yr 1; z% Yr 2-3).

Last Name, First Name	Position Title	% of Effort on Project	Cost
None			

9(C) Provide the names of **all** persons who worked on this research project, but who *were not* supported with health research funds. Include position titles (Research Assistant, Administrative Assistant, etc.) and percent of effort on project. For multiple year projects, if percent of effort varied from year to year, report in the % of Effort column the effort by year 1, 2, 3, etc. of the project (x% Yr 1; z% Yr 2-3).

Last Name, First Name	Position Title	% of Effort on Project
Burke, Christopher T.	Principal Investigator	5%
Perndorfer, Christine	Graduate Research Assistant	5%

9(D) Provide a list of **all** scientific equipment purchased as part of this research grant, a short description of the value (benefit) derived by the institution from this equipment, and the cost of the equipment.

Type of Scientific Equipment	Value Derived	Cost
Locking clinical freezer	Keeps saliva samples frozen at -30ºC (necessary to ensure the stability of certain components in saliva) between the time of collection and shipment to the testing services company. The locking feature prevents unauthorized individuals from accessing the samples.	$809.14

10. Co-funding of Research Project during Health Research Grant Award Period. Did this research project receive funding from any other source during the project period when it was supported by the health research grant?

Yes_____ No____X____

If yes, please indicate the source and amount of other funds:

11. Leveraging of Additional Funds

11(A) As a result of the health research funds provided for this research project, were you able to apply for and/or obtain funding from other sources to continue or expand the research?

Yes_____ No____X_____

If yes, please list the applications submitted (column A), the funding agency (National Institutes of Health—NIH, or other source in column B), the month and year when the application was submitted (column C), and the amount of funds requested (column D). If you have received a notice that the grant will be funded, please indicate the amount of funds to be awarded (column E). If the grant was not funded, insert "not funded" in column E.

Do not include funding from your own institution or from CURE (tobacco settlement funds). Do not include grants submitted prior to the start date of the grant as shown in Question 2. If you list grants submitted within 1-6 months of the start date of this grant, add a statement below the table indicating how the data/results from this project were used to secure that grant.

A. Title of research project on grant application	B. Funding agency (check those that apply)	C. Month and Year Submitted	D. Amount of funds requested:	E. Amount of funds to be awarded:
	☐NIH ☐ Other federal (specify:_____ _____) ☐ Nonfederal source (specify: _____)		$	$
	☐NIH ☐ Other federal (specify:_____ _____) ☐ Nonfederal source (specify: _____)		$	$

	☐NIH ☐ Other federal (specify:_____ _____) ☐ Nonfederal source (specify: _____)		$	$

11(B) Are you planning to apply for additional funding in the future to continue or expand the research?

Yes____X____ No_____

If yes, please describe your plans:

The size of the CURE award allowed me to collect data from approximately 40 women, which represents a reasonable pilot/feasibility study. As reported below, the results of this study are promising, so my plan is to apply for a larger grant from NIH to investigate the phenomenon in a larger sample. One grant program in particular (PA-12-216, "Women's Mental Health During Pregnancy and the Postpartum Period") seems to be a particularly good fit. In addition to simply exploring the effect in a larger sample, this submission would also aim to investigate how the phenomenon operates across a more diverse sample (both socioeconomically and demographically), as one of the limitations of the present study is its relatively homogenous sample.

12. Future of Research Project. What are the future plans for this research project?

As described below, I plan to continue analyzing the data collected from this project, as I have only been able to complete preliminary analyses in the short time since data collection was completed. After completing data analysis, I plan to write up the finalized results for publication in a journal with a health psychology focus. I also plan to submit these results for presentation at a national conference. Finally, as stated above, I plan to use these data as pilot data for a larger grant submission to NIH.

13. New Investigator Training and Development. Did students participate in project supported internships or graduate or post-graduate training for at least one semester or one summer?

Yes____X____ No_____

If yes, how many students? Please specify in the tables below:

	Undergraduate	Masters	Pre-doc	Post-doc
Male	0	0	0	0
Female	1	1	0	0
Unknown	0	0	0	0
Total	**1**	**1**	**0**	**0**

	Undergraduate	Masters	Pre-doc	Post-doc
Hispanic	0	0	0	0
Non-Hispanic	1	1	0	0
Unknown	0	0	0	0
Total	**1**	**1**	**0**	**0**

	Undergraduate	Masters	Pre-doc	Post-doc
White	1	1	0	0
Black	0	0	0	0
Asian	0	0	0	0
Other	0	0	0	0
Unknown	0	0	0	0
Total	**1**	**1**	**0**	**0**

14. Recruitment of Out-of–State Researchers. Did you bring researchers into Pennsylvania to carry out this research project?

Yes_____ No____X_____

If yes, please list the name and degree of each researcher and his/her previous affiliation:

15. Impact on Research Capacity and Quality. Did the health research project enhance the quality and/or capacity of research at your institution?

Yes_____ No____X_____

If yes, describe how improvements in infrastructure, the addition of new investigators, and other resources have led to more and better research.

16. Collaboration, business and community involvement.

16(A) Did the health research funds lead to collaboration with research partners outside of your institution (e.g., entire university, entire hospital system)?

Yes_____ No_____X_____

If yes, please describe the collaborations:

16(B) Did the research project result in commercial development of any research products?

Yes_____ No____X_____

If yes, please describe commercial development activities that resulted from the research project:

16(C) Did the research lead to new involvement with the community?

Yes_____ No____X_____

If yes, please describe involvement with community groups that resulted from the research project:

17. Progress in Achieving Research Goals, Objectives and Aims.

List the project goals, objectives and specific aims (as contained in the grant agreement). Summarize the progress made in achieving these goals, objectives and aims for the period that the project was funded (i.e., from project start date through end date). Indicate whether or not each goal/objective/aim was achieved; if something was not achieved, note the reasons why. Describe the methods used. If changes were made to the research goals/objectives/aims, methods, design or timeline since the original grant application was submitted, please describe the changes. Provide detailed results of the project. Include evidence of the data that was generated and analyzed, and provide tables, graphs, and figures of the data. List published abstracts, poster presentations and scientific meeting presentations at the end of the summary of progress; peer-reviewed publications should be listed under item 20.

This response should be a DETAILED report of the methods and findings. It is not sufficient to state that the work was completed. Insufficient information may result in an unfavorable performance review, which may jeopardize future funding. If research findings are pending publication you must still include enough detail for the expert peer reviewers to evaluate the progress during the course of the project.

Health research grants funded under the Tobacco Settlement Act will be evaluated via a performance review by an expert panel of researchers and clinicians who will assess project work using this Final Progress Report, all project Annual Reports and the project's strategic plan. After the final performance review of each project is complete, approximately 12-16 months after the end of the grant, this Final Progress Report, as well as the Final Performance Review Report containing the comments of the expert review panel, and the grantee's written response to the Final Performance Review Report, will be posted on the CURE Web site.

There is no limit to the length of your response. Responses must be single-spaced below, no smaller than 12-point type. If you cut and paste text from a publication, be sure

symbols print properly, e.g., the Greek symbol for alpha (α) and beta (ß) should not print as boxes (□) and include the appropriate citation(s). DO NOT DELETE THESE INSTRUCTIONS.

Specific Aims and Hypotheses

This project was aimed at understanding the links between day-to-day stress processes during pregnancy and risk for postpartum depression. Research suggests that stress experienced during pregnancy is associated with an increased risk for postpartum depression, although the specific mechanisms are not clearly understood. Animal models suggested that estradiol (E2) might hinder the ability of cortisol (CORT) to regulate the body's stress response, potentially extending or intensifying the stress response. Because changes in CORT and E2 are also integral parts of pregnancy, I hypothesized that they would play a role in the link between prenatal stress and postpartum depression. In particular, I suggested that there would be bidirectional links between the experience of stress and changes in these hormones, such that daily stress would lead to increased CORT, perhaps particularly when E2 was high; that CORT and E2 would interact to predict sleep quality and morning mood; and that poor sleep and worse morning mood would predict greater stress later in the day, particularly when E2 was also elevated in the morning. Connecting this process to risk for postpartum depression, I suggested that the intercepts and slopes of growth curves of these daily processes (distress, CORT, E2) would predict increased depressive symptoms postpartum, adjusting for prenatal depressive symptoms. The Specific Aims, excerpted from the grant agreement, were as follows:

1) Examine the day-to-day links between CORT, E2, and stress during pregnancy. Namely, (a) daily stress should increase evening CORT, particularly when E2 is also elevated; (b) elevated evening CORT should predict poor sleep and physical symptoms on waking; and (c) poor sleep and physical symptoms on waking should increase susceptibility to stress later in the day.

2) Probe the associations between this daily process and PPD risk. Higher levels of (and greater increases in) CORT indicate higher levels of stress, which should predict depressive symptoms in the postpartum (adjusting for risk factors like history of depression). This link may be especially strong for women with higher levels of (or more rapidly increasing) levels of E2.

Participant Recruitment and Characteristics

We used two primary methods for recruiting participants into the study. The first (and predominant) was to purchase ad space on paper placemats used in local diners and family restaurants. This method of advertisement provided very broad exposure to the local population in a very cost-effective way. The second method was to advertise on the Lehigh University daily email announcements for faculty and staff. Both methods were successful in directly reaching eligible women, as well as indirectly via family and friends (e.g., many women reported that a parent saw the ad on a placemat). All told, 106 women contacted us inquiring about the study, of whom 42 were eligible and enrolled in the study. The two

primary reasons for ineligibility were being too far advanced in the pregnancy and living too far from Lehigh University (proximity was important because researchers needed to collect completed saliva samples from participants' homes and keep them frozen en route to the laboratory freezer).

The women who enrolled in the study were 30.8 years old on average (range: 19.3-38.5). All but two women identified exclusively as White, with the other two identifying as mixed ethnicity. Ninety percent reported being married to the father of the child they were carrying, and 10% reported being committed, but not married (all reported currently living with this partner). The length of the romantic relationship was 6.9 years at the time of enrollment on average, with a range of 1.08 to 18.0 years. Eighty-five percent reported working outside of the home at enrollment, for an average of 36.7 hours per week (range: 8-50 hours). Those women who worked reported providing an average of 44.8% of the family's income, with a range of 0-100%. Finally, 76% of the women had a bachelor's degree or higher. Thus, the sample generally consisted of well-educated, White women in intact romantic relationships and dual-income households. Clearly, these sample characteristics limit the generalizability of the results reported below.

Study Design and Procedure

After agreeing to participate, a researcher scheduled a face-to-face meeting with each prospective participant to discuss the study procedures in more detail, answer any questions, obtain informed consent, and provide training on the saliva collection and handling procedures. The researcher also confirmed that the participant was comfortable completing the surveys online (all were). Following this meeting, participants were assigned an identification number and emailed detailed information about the timing of the different phases of the study and links to the different surveys.

As described in the grant agreement, the study contained three distinct phases, which occurred at different points in time relative to the birth of the child. The surveys in each phase were administered online via the Qualtrics survey website (www.qualtrics.com). The researchers confirmed during a pre-enrollment meeting. The first phase consisted of a survey (approximately 30 minutes in length) completed by participants in the 27th week of gestation. This survey contained a variety of demographic and background questions (e.g., household composition, participation in work/school outside of the home), baseline measures of stress (measured with Cohen, Kamarck, and Mermelstein's (1983) Perceived Stress Scale) and depressive symptoms (measured with Cox, Holden, & Sagovsky's (1987) Edinburgh Postnatal Depression Scale), as well as measures of several other potentially relevant constructs (e.g., self-esteem, attachment orientation, parenting beliefs and confidence, history of depression and anxiety, perceived social support). These additional measures were included to allow testing for potential alternative explanations for observed findings. The measures selected have been widely used in past research, including in the context of pregnancy, with good evidence of their reliability and validity.

Approximately one week later, participants began Phase 2 – a one-week period in which they completed two short surveys and provided two saliva samples each day (once in the morning

within an hour of waking, and once in the evening within an hour of going to bed). These surveys were modeled on ones used in previous work on daily stress processes (e.g., Gleason, Iida, Shrout, & Bolger, 2008). Each included an assessment of current mood using an adaptation of the Profile of Mood States scale (McNair, Lorr, & Droppleman, 1971). In the analyses presented here, I created a distress subscale, which included ratings of currently experiencing seven emotional adjectives: anxious, on edge, uneasy, blue, sad, discouraged, and hopeless. In addition to mood, the morning survey included questions about the amount and quality of sleep, how the participant felt physically upon waking, and the number of times waking in the night. The evening survey, which was somewhat longer, included questions about the events and social interactions of the day. Of particular in interest for the present analyses, were three measures of daily stress. First, we asked women to rate how difficult or demanding the day was overall on a five-point scale from "not at all" to "extremely". Second, we asked them to write a brief description of the most difficult or demanding aspect of the day and to rate it on the same scale. Third, we provided a checklist of fifteen potential stressful events of the day (ranging from extra work to financial problems to physical symptoms) and asked participants to indicate which occurred that day. The total number of events they selected represented a third indicator of daily stress.

After this week was finished, a member of the research team contacted the participant to arrange pickup of the saliva samples, which participants were keeping frozen in their home freezers. Following the sample pickup, participants were emailed a $20 gift card to Babies R Us as compensation for their efforts to that point.

Women were instructed to contact the researchers following childbirth to plan for the postpartum survey. If we did not hear from them sooner, a researcher reached out by email approximately 1-2 weeks after the estimated date of delivery with a reminder to contact us after childbirth. Participants were instructed to complete the postpartum survey between 4 and 5 weeks postpartum (Phase 3). The content of the postpartum survey was essentially the same as the prenatal survey, excluding basic demographic information that was unnecessary to ask again (e.g., date of birth, race). Upon completion of the postpartum survey, women were emailed a second $20 gift card and thanked for their participation. See Table 1 for sample sizes at each phase of the study.

Results

Prior to commencing data analysis, I compiled the data sets from the various sources, and cleaned the data as necessary. Data cleaning primarily involved verifying that date/time stamps on online surveys fell within an acceptable window of time and checking for incorrect or out of range responses. For instance, in one case a participant entered the wrong identification number, which was corrected. Out of range responses that could not be reconciled were recoded as missing. In terms of identifying an "acceptable window of time" for completing surveys and saliva samples, participants were instructed to complete the morning and evening surveys and saliva samples within 60 minutes of getting out of bed and within 60 minutes of going to bed, respectively. As a first pass, I excluded morning responses completed more than two hours after their self-reported waking time, and for the evening survey I excluded responses completed outside of the window 6:00pm-6:00am. However,

given the presence of diurnal cycles in the hormones of interest, I wanted to ensure that any surveys/samples completed outside of the appropriate times in the daily sleep-wake cycle were removed from the data. With the remaining cases, I sorted the data by completion time, identified extreme values, and cross-checked each with the time stamps for (a) the corresponding survey (i.e., morning or evening) on different days and (b) the previous and subsequent surveys for that subject. Responses were excluded if completion times were inconsistent with the subject's general pattern of responding and if the survey was completed close in time to an adjacent survey, indicating that subjects did not complete them at the appropriate time in their daily sleep-wake cycle. Finally, I eliminated the data from one subject who reported that she sometimes worked a night shift, as it became unclear which surveys/samples to treat as "morning" and which to treat as "evening". Below, I report the preliminary results of statistical analyses designed to test the Specific Aims of the project.

Specific Aim 1

For clarity of presentation, I will report the results for Specific Aim 1 in a slightly different order than listed above. Specifically, I first tested how evening CORT, E2, and distress predict sleep quality, physical symptoms, and distress the following morning. I then tested how these morning factors predicted stress experiences later in the day, and whether these effects were modified by morning CORT and E2. Third, I report analyses testing how daily stress impacts evening distress, CORT and E2, and whether these effects were modified by morning distress, CORT, and E2.

I used mixed (or multilevel) model analyses to test each of these questions due to the nested structure of the data (observations nested within person). All within-subjects (i.e., daily) predictors were person-centered, such that fixed effect estimates can be interpreted as the expected change in the outcome for each unit deviation from the individual's mean on the predictor. To ensure that individual differences in predictors were not lost, the between-person means were included in the models as well (after being centered at their respective grand means), in line with best practices in the field (e.g., Raudenbush & Bryk, 2002).

Do evening CORT, E2, and distress predict sleep quality, morning physical symptoms, and morning distress?

Throughout the analyses, sleep quality, morning physical symptoms, and number of night wakings exhibited a very similar pattern, and they showed moderate positive correlations with each other (rs ranged from 0.42 to 0.66). Therefore, for simplicity of presentation, I standardized each and averaged these standardized scores to form an index of sleep quality, which had a reliability of approximately 0.72. This first analysis revealed, contrary to expectations, that evening CORT, E2, and distress did not predict the sleep quality index (ts < 0.88, ps $> .378$). However, effects did emerge in the analysis predicting morning levels of distress. In particular, there was a significant two-way interaction between evening CORT and evening E2 predicting morning distress ($t(114) = 2.23$, $p = .028$; see Figure 1). A simple slopes analysis revealed that when evening E2 was 1 standard deviation (SD) higher than average, there was no association between evening CORT and morning distress ($t(114) = 1.00$, $p = .319$). When evening E2 was 1 SD below average, there was a significant negative

association between evening CORT and morning distress, $t(114) = 2.08$, $p = .040$. As seen in Figure 1, this pattern suggests that when E2 is high in the evening, morning distress is equally high regardless of evening CORT. However, when E2 is low in the evening, higher evening CORT actually predicts less distress in the evening. This analysis also revealed that individuals with higher evening CORT on average reported significantly higher morning distress, $t(114) = 2.51$, $p = .014$. Thus, although the predicted effects were not apparent for the sleep-related variables, this analysis provides some support that elevated evening CORT and E2 carry forward to morning distress.

Do sleep quality and morning mood predict higher levels of stress later in the day, and do these effects depend on morning CORT and E2?

The next step in the analysis was to examine whether sleep quality and distress would in turn influence the experience of stress later in the day. As described above, there were three ways in which daily stress was assessed in the evening survey (i.e., a rating of the overall stressfulness of the day, a rating of the stressfulness of the most difficult or demanding event of the day, and a count of troublesome events encountered). These measures were substantially positively correlated (*r*s ranged from .36 to .70). Considering them as a set, they had a reliability of approximately 0.70. Given this result, for simplicity of presentation, I standardized each of the variables and averaged them together to create a daily stress index. The results reported below use this index as the outcome variable.

Paralleling the findings from the previous set of analyses, the sleep quality index did not predict daily stress, either alone or interacting with morning CORT and E2. Once again, the analysis using morning distress in place of the sleep quality index provided results more in line with the hypotheses. There was a significant main effect of morning distress on reports of stress ($t(130) = 2.73$, $p = .007$), such that higher morning distress predicted having a more stressful day. This effect was qualified by a significant interaction between morning distress and morning CORT, $t(130) = 3.09$, $p = .002$. There was a significant main effect of morning E2 ($t(130) = 2.23$, $p = .027$), such that higher morning E2 predicted greater stress experienced during the day. This effect of E2 was significantly stronger to the extent that morning CORT was also elevated, $t(130) = 3.18$, $p = .002$. Finally, there was a significant three-way interaction between morning distress, E2, and CORT predicting daily stress, $t(130) = 1.92$, $p = .058$. As seen in Figure 2, there was only a significant positive association between morning distress and stress experienced later in the day when both CORT and E2 were higher than average in the morning, $t(130) = 2.34$, $p = .021$. The link between morning stress and daily stress was nonsignificant when morning E2 was low and CORT was high ($t(130) = 1.35$, $p = .181$) and when CORT was low and E2 was high ($t(130) = 1.38$, $p = .169$). When both morning E2 and morning CORT were below average, there was a marginal positive association between morning distress and later reports of stress, $t(130) = 1.92$, $p = .057$. Thus, this analysis generally supported the prediction that higher morning distress would predict experiencing more stress later in the day, particularly when CORT and E2 were also elevated.

How does stress experienced during the day relate to evening distress, CORT, and E2, and do these effects depend on morning distress, CORT, and E2?

The final set of analyses for Specific Aim 1 examined how morning distress, CORT, and E2 modified the impact of daily stress on evening distress, CORT, and E2. Once again, I used the composite index of daily stress. The stress composite variable did not predict evening CORT or E2, either directly or interacting with morning CORT and E2 (ts < 1.53, ps > .130). The stress composite did, however, predict an increase in evening distress, $t(130) = 5.66$, $p < .001$. This effect was somewhat weaker to the extent that morning distress was elevated ($t(130) = 2.09$, $p = .039$), perhaps because morning anxiety was elevated in anticipation of daily stressors. There was a significant two-way interaction between morning distress and morning E2 ($t(130) = 2.96$, $p = .004$), which was qualified by a three-way interaction between morning distress, E2, and daily stress, $t(130) = 5.10$, $p < .001$. The pattern of this effect (see Figure 3) somewhat paralleled the pattern in Figure 2: When both morning distress and morning E2 were high, there was a significant positive association between daily stress and evening distress, $t(130) = 4.78$, $p < .001$. A similar effect emerged when both morning distress and E2 were low, $t(130) = 6.16$, $p < .001$. When morning distress was high and E2 low (and vice versa), the effect of daily stress on evening distress did not reach significance, ts < 1.70, ps > .093.

Thus, the set of analyses associated with Specific Aim 1 provided some evidence of the hypothesized process. Namely, evening levels of CORT and E2 predicted elevated distress in the morning, which in turn predicted the degree of stress experienced by the individual later in the day. The carrying forward of morning distress was most pronounced when both CORT and E2 were also elevated in the morning. Finally, daily stress predicted the highest level of evening distress when both morning distress and E2 were higher than average. This elevated evening distress should then carry forward to the next morning, continuing the cycle.

Specific Aim 2

To test the second specific aim, I began by conducting a series of linear growth curve analyses with the Phase 2 data in which each variable (morning and evening distress, CORT, and E2) was predicted by study day, adjusting for day of the week (because each might vary systematically between, for instance, workweek and weekend). I allowed for between-subject variability in both the intercept and slope and saved these individual differences to a new data set containing postpartum (i.e., Phase 3) depressive symptoms and prenatal (i.e., Phase 1) depressive symptoms. I then predicted postpartum depressive symptoms from this intercept and slope. In these analyses, I adjusted for prenatal depressive symptoms to rule out the possibility that it was pre-existing depression rather than these daily experiences variables that were driving the elevated postpartum depressive symptoms. Only one of these analyses resulted in a positive finding, so I report only that one. I found that there was significant variability in the intercept of morning distress (SD = 0.31 on the 1-5 scale of morning distress). Because the slope of morning distress was not significant, this intercept variability can be thought of as a basic individual difference in morning distress. This variability in morning distress, in turn, predicted higher levels of depressive symptoms postpartum, adjusting for prenatal depressive symptoms, $t(30) = 3.28$, $p = .003$. Each standard deviation increase in morning distress was associated with a 2.8-point (or 0.68-SD) increase in postpartum depressive symptoms. Although I was hoping to find links between the slopes

and postpartum depressive symptoms, this analysis provides some preliminary support for the connection between the daily stress process during pregnancy and postpartum depressive symptoms.

Future Analyses

I consider the results presented here as preliminary, as the full data set (since the final participant completed the postpartum survey) has only been available for a short time. For the growth curve analyses associated with Specific Aim 2, although I have begun exploring links between Phase 2 trajectories and Phase 3 depressive symptoms. I have not yet considered interactions between the trajectories of CORT and E2 predicting postpartum depressive symptoms, which is what I had originally predicted. These analyses will be facilitated by the Mplus software and state-of-the-art statistical methods books that I was able to purchase. I have also not begun to investigate the role of the other variables (such as self-esteem and perceived stress) incorporated into the prenatal and postpartum surveys. I am fortunate to have collected such a rich data set that will not only enable me to pursue external funding, but also to potentially perform additional analyses beyond the scope of the current project.

Table 1. Recruitment and data collection overall and during the period 7/1/2013-6/30/2014

	Overall	Reporting period 7/1/2013-6/30/2014
Initial contact	106	15
Agreement to participate	42	7
Commence prenatal phase	42	16
Complete prenatal phase	39	16
Commence postpartum phase	35	23
Complete postpartum phase	35	23
Saliva samples collected	39	18
Saliva samples processed	39	27

Figure 1. Interaction of last evening's CORT and E2 predicting morning distress

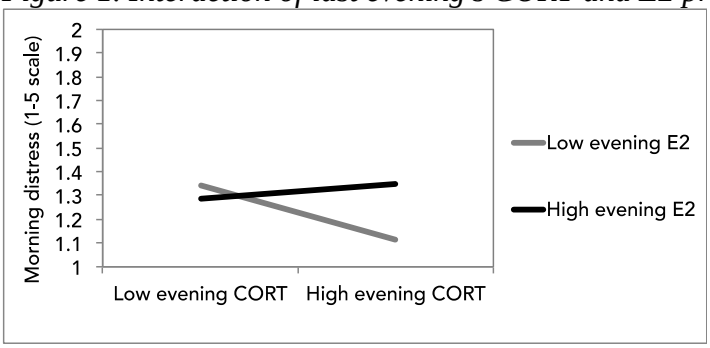


Figure 2. Interaction of morning distress, CORT, and E2 predicting stress composite index

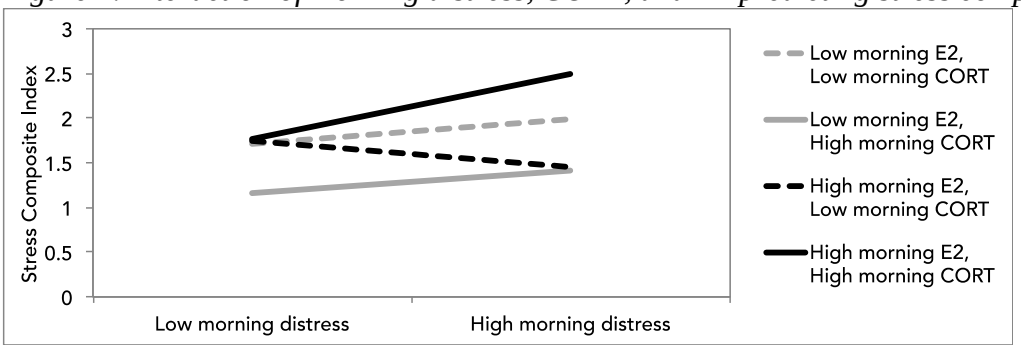
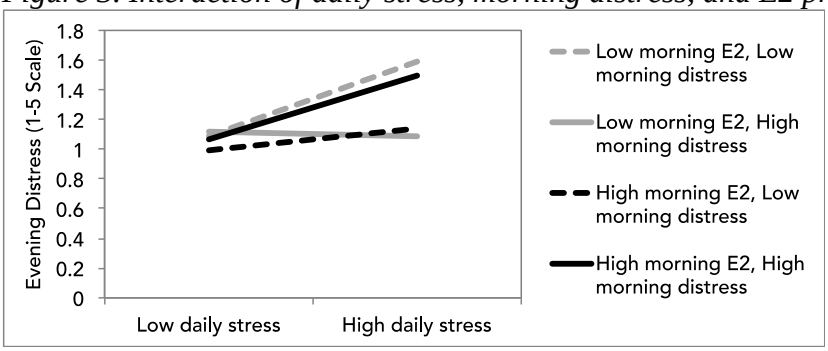


Figure 3. Interaction of daily stress, morning distress, and E2 predicting evening distress



18. Extent of Clinical Activities Initiated and Completed. Items 18(A) and 18(B) should be completed for all research projects. If the project was restricted to secondary analysis of clinical data or data analysis of clinical research, then responses to 18(A) and 18(B) should be "No."

18(A) Did you initiate a study that involved the testing of treatment, prevention or diagnostic procedures on human subjects?

_____Yes

___X__No

18(B) Did you complete a study that involved the testing of treatment, prevention or diagnostic procedures on human subjects?

_____Yes
___X__No

If "Yes" to either 18(A) or 18(B), items 18(C) – (F) must also be completed. (Do NOT complete 18(C-F) if 18(A) and 18(B) are both "No.")

18(C) How many hospital and health care professionals were involved in the research project?

_____Number of hospital and health care professionals involved in the research project

18(D) How many subjects were included in the study compared to targeted goals?

_____Number of subjects originally targeted to be included in the study
_____Number of subjects enrolled in the study

Note: Studies that fall dramatically short on recruitment are encouraged to provide the details of their recruitment efforts in Item 17, Progress in Achieving Research Goals, Objectives and Aims. For example, the number of eligible subjects approached, the number that refused to participate and the reasons for refusal. Without this information it is difficult to discern whether eligibility criteria were too restrictive or the study simply did not appeal to subjects.

18(E) How many subjects were enrolled in the study by gender, ethnicity and race?

Gender:
_____Males
_____Females
_____Unknown

Ethnicity:
_____Latinos or Hispanics
_____Not Latinos or Hispanics
_____Unknown

Race:
_____American Indian or Alaska Native
_____Asian
_____Blacks or African American
_____Native Hawaiian or Other Pacific Islander
_____White
_____Other, specify:_____
_____Unknown

18(F) Where was the research study conducted? (List the county where the research study was conducted. If the treatment, prevention and diagnostic tests were offered in

more than one county, list all of the counties where the research study was conducted.)

19. Human Embryonic Stem Cell Research. Item 19(A) should be completed for all research projects. If the research project involved human embryonic stem cells, items 19(B) and 19(C) must also be completed.

19(A) Did this project involve, in any capacity, human embryonic stem cells?

_____Yes
___X__ No

19(B) Were these stem cell lines NIH-approved lines that were derived outside of Pennsylvania?

_____Yes
___X__ No

19(C) Please describe how this project involved human embryonic stem cells:

20. Articles Submitted to Peer-Reviewed Publications.

20(A) Identify all publications that resulted from the research performed during the funding period and that have been submitted to peer-reviewed publications. Do not list journal abstracts or presentations at professional meetings; abstract and meeting presentations should be listed at the end of item 17. **Include only those publications that acknowledge the Pennsylvania Department of Health as a funding source** (as required in the grant agreement). List the title of the journal article, the authors, the name of the peer-reviewed publication, the month and year when it was submitted, and the status of publication (submitted for publication, accepted for publication or published.). Submit an electronic copy of each publication or paper submitted for publication, listed in the table, in a PDF version 5.0.5 (or greater) format, 1,200 dpi. Filenames for each publication should include the number of the research project, the last name of the PI, and an abbreviated title of the publication. For example, if you submit two publications for Smith (PI for Project 01), one publication for Zhang (PI for Project 03), and one publication for Bates (PI for Project 04), the filenames would be:

Project 01 – Smith – Three cases of isolated
Project 01 – Smith – Investigation of NEB1 deletions
Project 03 – Zhang – Molecular profiling of aromatase
Project 04 – Bates – Neonatal intensive care

If the publication is not available electronically, provide 5 paper copies of the publication.

Note: The grant agreement requires that recipients acknowledge the Pennsylvania Department of Health funding in all publications. Please ensure that all publications listed acknowledge the Department of Health funding. If a publication does not acknowledge the funding from the Commonwealth, do not list the publication.

Title of Journal Article:	Authors:	Name of Peer-reviewed Publication:	Month and Year Submitted:	Publication Status (check appropriate box below):
1.None				☐Submitted ☐Accepted ☐Published
2.				☐Submitted ☐Accepted ☐Published
3.				☐Submitted ☐Accepted ☐Published

20(B) Based on this project, are you planning to submit articles to peer-reviewed publications in the future?

Yes____X____ No_____

If yes, please describe your plans:

Upon satisfactory completion of data analysis, I plan to prepare a journal article for submission to a health psychology focused journal. Although the sample size of the study is relatively small, the data are a unique combination of intensive longitudinal survey data and daily hormonal data during pregnancy. As such, I think this work will be publishable in a high-impact outlet.

21. Changes in Outcome, Impact and Effectiveness Attributable to the Research Project. Describe the outcome, impact, and effectiveness of the research project by summarizing its impact on the incidence of disease, death from disease, stage of disease at time of diagnosis, or other relevant measures of outcome, impact or effectiveness of the research project. If there were no changes, insert "None"; do not use "Not applicable." Responses must be single-spaced below, and no smaller than 12-point type. DO NOT DELETE THESE INSTRUCTIONS. There is no limit to the length of your response.

None.

22. Major Discoveries, New Drugs, and New Approaches for Prevention Diagnosis and Treatment. Describe major discoveries, new drugs, and new approaches for prevention, diagnosis and treatment that are attributable to the completed research project. If there were no major discoveries, drugs or approaches, insert "None"; do not use "Not applicable." Responses must be single-spaced below, and no smaller than 12-point type. DO NOT DELETE THESE INSTRUCTIONS. There is no limit to the length of your response.

None.

23. Inventions, Patents and Commercial Development Opportunities.

23(A) Were any inventions, which may be patentable or otherwise protectable under Title 35 of the United States Code, conceived or first actually reduced to practice in the performance of work under this health research grant? Yes_____ No___X_____

If "Yes" to 23(A), complete items a – g below for each invention. (Do NOT complete items a - g if 23(A) is "No.")

a. Title of Invention:

b. Name of Inventor(s):

c. Technical Description of Invention (describe nature, purpose, operation and physical, chemical, biological or electrical characteristics of the invention):

d. Was a patent filed for the invention conceived or first actually reduced to practice in the performance of work under this health research grant?
Yes_____ No____

If yes, indicate date patent was filed:

e. Was a patent issued for the invention conceived or first actually reduced to practice in the performance of work under this health research grant?
Yes_____ No____
If yes, indicate number of patent, title and date issued:
Patent number:
Title of patent:
Date issued:

f. Were any licenses granted for the patent obtained as a result of work performed under this health research grant? Yes_____ No____

If yes, how many licenses were granted?_____

g. Were any commercial development activities taken to develop the invention into a commercial product or service for manufacture or sale? Yes___ No____

If yes, describe the commercial development activities:

23(B) Based on the results of this project, are you planning to file for any licenses or patents, or undertake any commercial development opportunities in the future?

Yes_____ No____X_____

If yes, please describe your plans:

24. Key Investigator Qualifications. Briefly describe the education, research interests and experience and professional commitments of the Principal Investigator and all other key investigators. In place of narrative you may insert the NIH biosketch form here; however, please limit each biosketch to 1-2 pages. *For Nonformula grants only – include information for only those key investigators whose biosketches were not included in the original grant application.*

I (Christopher Burke, Principal Investigator) hold a B.S. in physics and psychology from Carnegie Mellon University (2003) and a Ph.D. in psychology (minor: quantitative psychology) from New York University (2008). In my undergraduate career, I completed coursework in calculus, linear algebra, and statistics, in addition to the standard psychology curriculum. In my doctoral program, I completed seven semesters of graduate-level statistics courses and applied advanced statistics in my dissertation to earn a quantitative minor. These courses included longitudinal modeling, structural equation modeling, and psychometrics, all

of which play a role in the present project. The lab I was trained in (advisors: Pat Shrout and Niall Bolger) uses longitudinal designs (particularly daily diary designs) to investigate stress and social support processes in romantic relationships. To make maximal use of these difficult-to-collect data, I learned to be creative with statistical analyses, and by the end of graduate school I had two first-author publications (Burke, Shrout, & Bolger, 2007; Burke, Shrout, & Bolger, 2008) in which I developed novel longitudinal models to existing data to answer questions of interest (specifically regarding individual differences in trajectories of depressive symptoms surrounding bereavement). My dissertation work used a daily diary design to investigate how the association between support receipt and distress varies over time leading up to an acute stressor (namely, the state Bar Exam for graduating law students). I tested and found support for a specific hypothesis that receiving social support would become associated with increased distress as this self-relevant stressor (i.e., closely connected to the individual's sense of self) approached. The trajectories of distress over time followed a nonlinear trajectory, so I devised a way to model these trajectories while also testing whether the association between support receipt and distress varied over time. This work is now in press in *Personal Relationships* (Burke & Goren, in press).

Since arriving at my current position as an Assistant Professor of Psychology at Lehigh University in 2008, I have continued to engage in community-based studies of stress, with a particular emphasis on stress processes during pregnancy. Prior to the current study, I had conducted a preliminary study of approximately 30 women to investigate stress and social support processes during pregnancy and their relationship to risk for postpartum depression. This study revealed, consistent with my doctoral work, that women reacted more negatively to receiving support related to the self-relevant domains of pregnancy, childbirth, and motherhood than to support related to other domains. In addition, those women who exhibited more negative responses to pregnancy, childbirth, and motherhood related support reported higher levels of depressive symptoms postpartum than those women who reported lower levels, even after adjusting for prenatal levels of depression.

Thus, I have extensive experience not only in developing and applying advanced statistical methods, but also in designing and carrying out community-based research studies.

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