Evaluation of At-Home Sample Timing for Diurnal Hormone Level Characterization

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Research Questions

- **Measurement Method Agreement**
  - Is there significant additive or proportional bias between the booklet and MEMS measuring cap sample times?

- **Sample Timing Adherence**
  - What proportion of samples fell within ± 7.5 minutes (good) and ± 15 minutes (adequate) of the target times for the 30-min and 10-hour post-waking collections?

- **Diurnal Hormone Patterns**
  - What is the change in hormone levels from waking to 30 minutes post waking?
  - What is the change per hour in hormone levels after 30 minutes post waking?

Data Overview

- 31 Subjects
  - 3 Days of Samples
  - 4 Samples/Day
- Exclusions
  - Cortisol ≥ 80 nmol/L
  - DHEA ≥ 5.205 nmol/L
  - Subject 3037 removed
    - Multiple high DHEA readings
- Missingness
  - Booklet Times (9.4%)
  - MEMS Times (16.4%)

Table 1: Summary Statistics

Variable	Stat	Overall	Collection Sample			
			Wake	30-mins	Lunch	10-hours
Booklet Time Since Wake (hrs)	Missing n (%)	35 (9.4%)	5 (5.4%)	6 (6.5%)	11 (11.8%)	13 (14.0%)
	Mean (SD)	4.00 (4.39)	0.01 (0.06)	0.57 (0.16)	5.38 (1.41)	10.69 (1.40)
MEMS Time Since Wake (hrs)	Missing n (%)	61 (16.4%)	16 (17.2%)	23 (24.7%)	12 (12.9%)	10 (10.8%)
	Mean (SD)	4.54 (4.54)	0.09 (0.15)	0.84 (0.58)	5.39 (1.33)	10.98 (1.65)
Sleep Diary Wake Time (hrs)	Missing n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Mean (SD)	6.87 (1.43)	6.87 (1.43)	6.87 (1.43)	6.87 (1.43)	6.87 (1.43)
Cortisol (nmol/L)	Missing n (%)	18 (4.8%)	3 (3.2%)	4 (4.3%)	5 (5.4%)	6 (6.5%)
	Mean (SD)	5.68 (5.34)	7.30 (6.04)	9.12 (4.93)	3.22 (2.29)	2.98 (4.54)
DHEA (nmol/L)	Missing n (%)	19 (5.1%)	5 (5.4%)	4 (4.3%)	5 (5.4%)	5 (5.4%)
	Mean (SD)	0.90 (0.87)	1.63 (1.07)	1.03 (0.68)	0.48 (0.43)	0.44 (0.55)

Analysis Methods

- Agreement Model
  - Linear Mixed-Effect Model
  - MEMS Cap Time by Booklet Time
  - Tests
    - Intercept = 0
    - Slope = 1

- Diurnal Hormone Pattern Models
  - Piecewise Linear Mixed Effect Model
  - Break at 30 Minutes
  - Log Hormones by Booklet Time
  - Tests
    - Wake – 30 min Change
    - After 30 min Change

Results

Agreement

- MEMS Cap times were 10 minutes later than Booklet times at wake (p-value < 0.001; 95% CI: 4, 16).

- Bias does not change significantly with time (p-value = 0.2).

Adherence

- Higher adherence for booklet times than MEMS times.
  - $\pm$7.5 – 21.1% higher
  - $\pm$15 – 19.5% higher
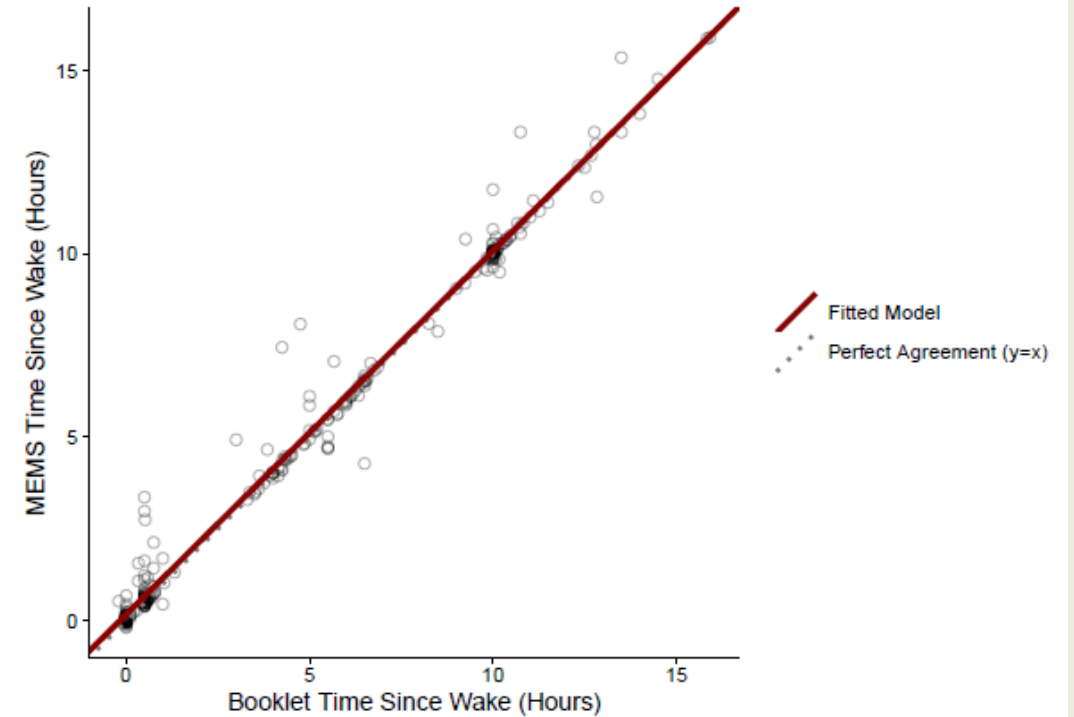

Figure 1: Plot of Booklet vs MEMS Cap Times with LMM Fit

Table 3: Adherence Rates by Recording Method

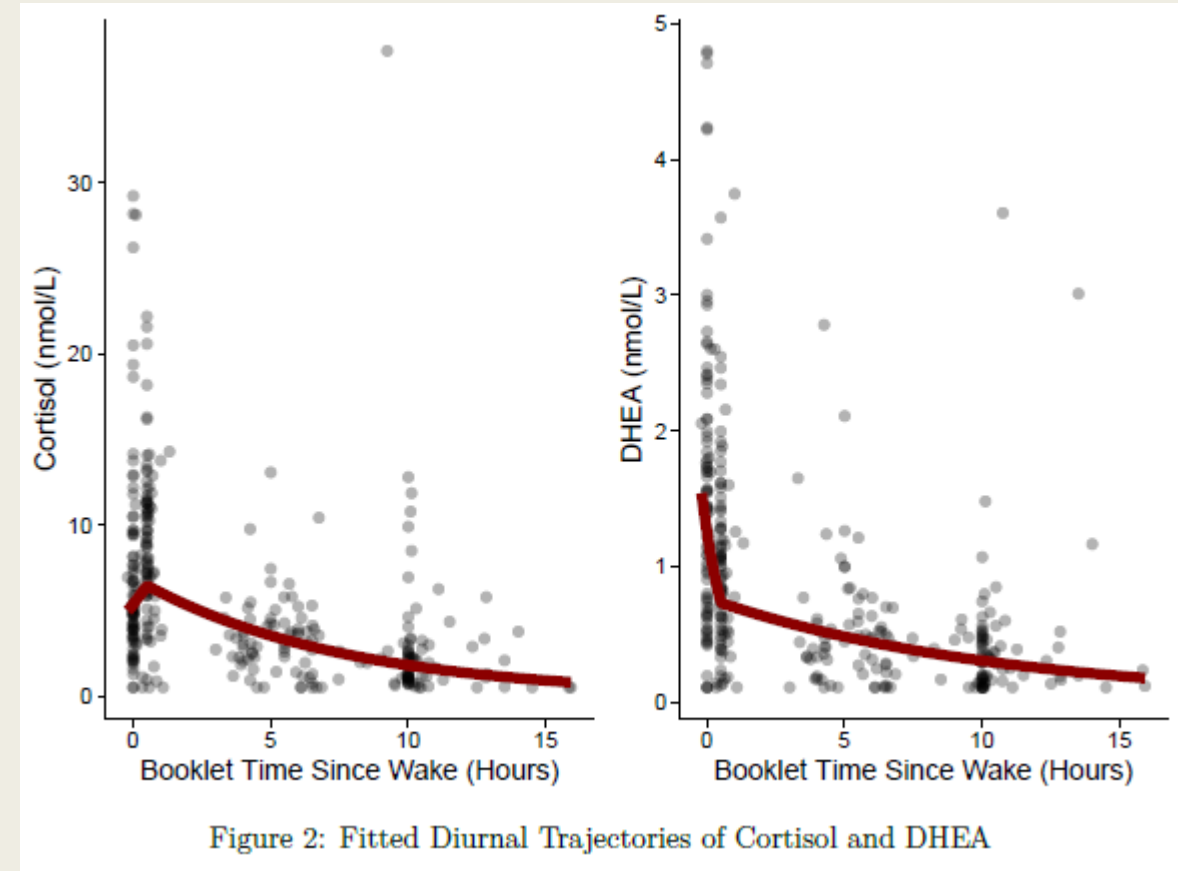| Recording Method	Adherence Thresholds	
	15-Minute Window	30-Minute Window
MEMS Cap	41.8%	54.2%
Booklet	62.9%	73.7%

Results

Cortisol

- From wake to 30 minutes, cortisol increased 20% on average (p-value = 0.09; 95% CI: -3, 59). **Not Significant**

- After 30 minutes post waking, cortisol decreased 13% per hour on average (p-value < 0.001; 95% CI: 11, 14) .

DHEA

- From wake to 30 minutes, DHEA decreased 41% on average (p-value < 0.001; 95% CI: 30, 51).

- After 30 minutes post waking, DHEA decreased 9% per hour on average (p-value < 0.001; 95% CI: 7, 10).

Figure 2: Fitted Diurnal Trajectories of Cortisol and DHEA

Discussion & Limitations

- Booklet MEMS Agreement
  - Generally high a with some bias (MEMS later than Booklet)
- Adherence
  - ~20% higher for Booklet than MEMS
- Diurnal Patterns
  - Cortisol rose then fell (expected)
  - DHEA fell rapidly then more slowly (unexpected)

- Limitations
  - Small sample size (31 subjects)
  - Subjective sleep diary wake times