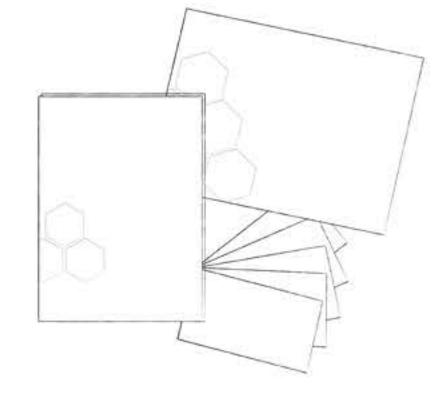
### MONITORING ESTRADIOL PATCH THERAPY WITH A VALIDATED DRIED URINE ASSAY

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# OBJECTIVE

- Estradiol (E2) patches are one of the most commonly used menopausal hormone therapy (MHT) formulations, and, as a result, are also one of the most studied.
- Most of these studies used serum testing, the most common tool for monitoring therapy in both research and clinical practice; however, a great deal of intra- and inter-subject variability exists in serum levels.
- Urine may provide a representation of serum E2 levels over a 24-hour period while being non-invasive and easier to collect.
- The aim of this study was to evaluate a multi-spot, dried urine assay to determine if it may be a viable option for monitoring MHT administered via transdermal (TD) E2 patch.

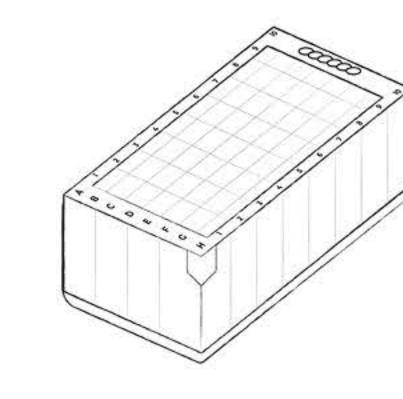


DUTCH collection kits are sent to the patient's home or can be given to the patient during a visit with their provider.



Urine is collected at 4-5 different times throughout the day on 4-5 fluid collection cards. This process is completed at the patient's home or



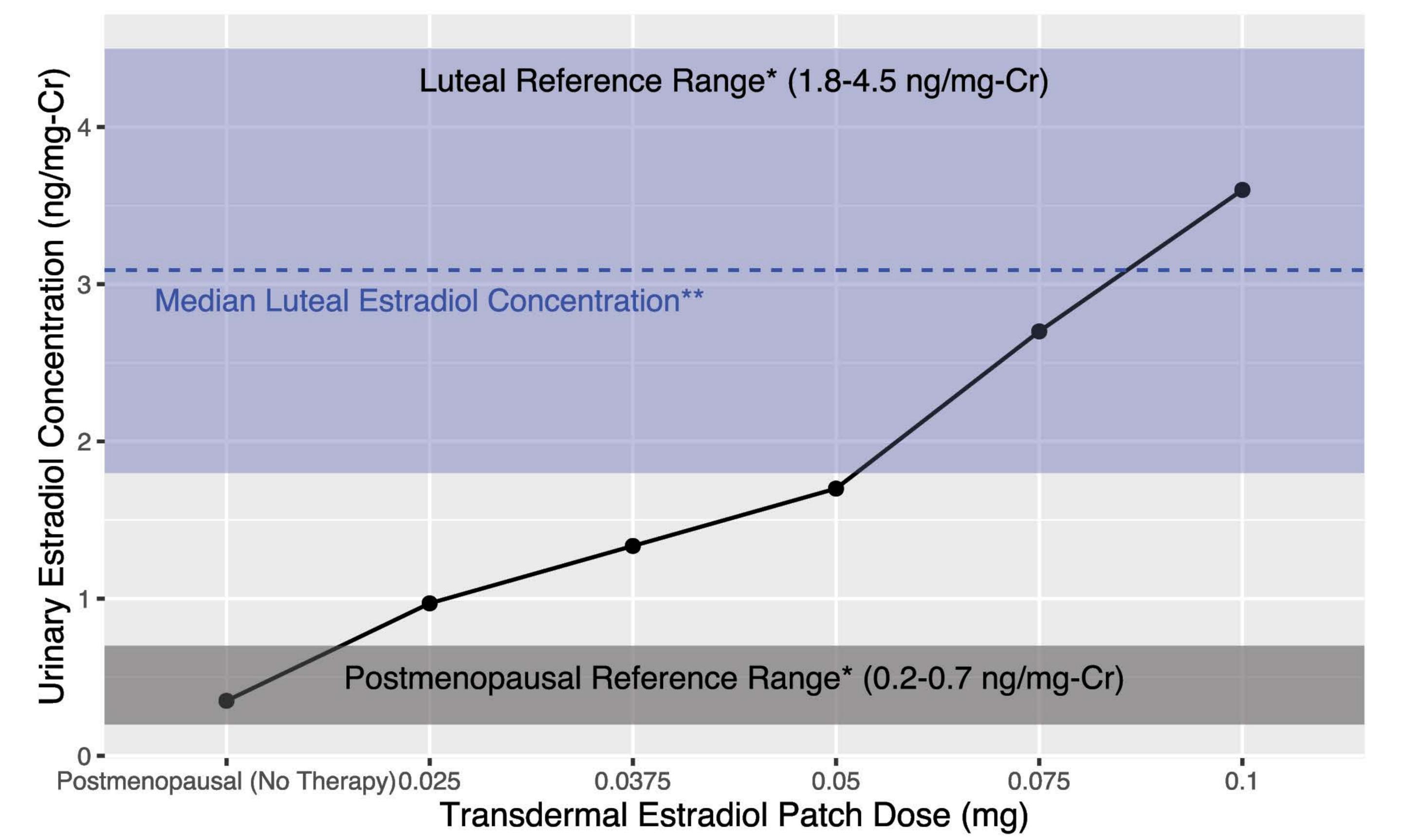


Once the urine is dry, the patient ships the collection cards back to the laboratory. When the samples arrive at the laboratory, the urine collections are extracted.

### DESIGN

- This study utilized data from a retrospective observational study, Precision Analytical Retrospective Data Correlation (NCT04305093).
- The dataset from this larger study contained measures of multiple urinary markers obtained via a 4-spot dried urine sampling method.
- For this analysis, we used a subset of the data that included only the urinary profiles of premenopausal women (n = 16,308), PMP women not on MHT (n = 17827), and PMP women using TD E2 patches (n = 1350).
- Urinary E2 was measured using gas chromatography/tandem mass spectrometry (GC-MS/MS).
- The nonparametric Jonckheere-Terpstra trend test was used to assess for ordered differences across groups to determine if expected dose-proportional increases in urinary E2 excretion were seen with increasing doses of transdermal E2 patches.

#### MEDIAN ESTRADIOL CONCENTRATIONS BY DOSE



\*Reference ranges are those established by Precision Analytical, a CLIA-certified clinical laboratory. \*\*Median luteal estradiol concentration of premenopausal women included in the study

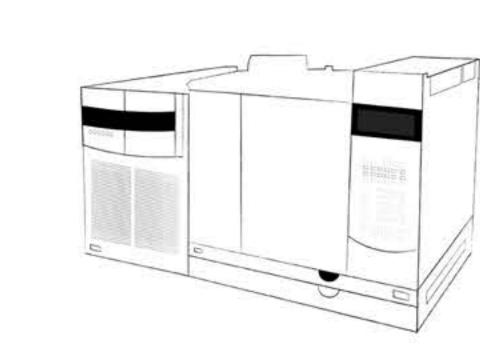
#### RESULTS

- Increasing doses of E2 patches resulted in dose-proportional increases of median (IQR) E2 concentrations.
- A stepwise, dose-proportional, ordered trend existed for E2 with each increase in TD E2 patch dose (Jonckheere-Terpstra trend test all with p<0.0001).

## KEY TAKEAWAYS

- The DUTCH testing model is a viable method of approximating systemic exposure when patients are using a TD E2
- DUTCH is a potential monitoring tool for MHT in both the clinical and research setting.





The amount of urine extracted from each collection card is determined by taking individual creatinine measurements from each sample. This results in a "weighted average."

The "weighted average" sample is then analyzed using gas chromatography coupled with tandem mass spectrometry.

After internal review by both clinical laboratory personnel and clinical consultants, the results are made available to the provider in an interpretaactionable insights.

### CONCLUSION

- This study demonstrated that a validated dried urine assay is a viable method of monitoring changes in PMP women's urinary E2 profiles in response to MHT with differing TD E2 patch doses.
- Because the urine collection process is simpler and urinary E2 potentially represents serum E2 levels over a 24-hour period,¹ the dried urine assay used in this study may provide an attractive alternative or complement to serum for exploring not only the changes in the urinary estrogen profile, but also TD E2 patches' efficacy and effectiveness.



#### Abbreviations

TD: Transdermal

- DUTCH: Dried Urine Test for Comprehensive Hormones
- E2: Estradiol
- GC-MS/MS: Gas Chromatography-Tandem Mass Spectrometry
- IQR: Interquartile Range MHT: Menopausal Hormone Therapy
- PMP: Postmenopausal

#### References

1. Newman M, Pratt SM, Curran DA, Stanczyk FZ. Evaluating urinary estrogen and progesterone metabolites using dried filter paper samples and gas chromatography with tandem mass spectrometry (GC-MS/ MS). BMC Chemistry. 2019;13(1):1-12. doi:10.1186/s13065-019-0539-1

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