Michael Chapman, ND
Medical Education Specialist - Asheville
Pamela W. Smith, M.D., MPH, MS
Technical Issues & Clinical Questions

Please type any technical issue or clinical question into either the “Chat” or “Questions” boxes, making sure to send them to “Organizer” at any time during the webinar.

We will be compiling your clinical questions and answering as many as we can the final 15 minutes of the webinar.

DISCLAIMER: Please note that any and all emails provided may be used for follow up correspondence and/or for further communication.
Need More Resources?

Ensure you have an account!
Case Studies in Management of the Menopausal Patient

Pamela W. Smith, M.D., MPH, MS

May 25, 2016
Disclaimer

• The suggested dosages are for educational purposes only.
• They are suggestions for patients with normal renal and hepatic function.
• They are based upon my research and my personal and professional experiences after reviewing 20,000 saliva tests.
• They are not intended as a substitute for a personalized approach to each patient but are designed instead to be a guideline.
• Genova Diagnostics and Pamela W. Smith, M.D., MPH, MS are not responsible for any adverse effects or consequences resulting from the use of any of these suggestions or preparations in this seminar.
Overview

• Health Considerations for the Menopausal Patient
  – Common Menopausal Symptoms
  – Primary Medical Concerns

• Core Diagnostics for the Management of the Menopausal Woman
  – Salivary Hormones + Genova’s Therapeutic Cohort Results Cover Page

• Hormone Replacement Therapy and Breast Cancer Risk

• Core Therapeutics for the Management of the Menopausal Woman

• Case Studies
Health Considerations for the Menopausal Patient
Symptoms of Menopause

- Hot flashes
- Night sweats
- Vaginal dryness
- Anxiety
- Mood swings
- Irritability
- Insomnia
- Depression
- Migraine headaches
- Memory lapses
- Weight gain
- Loss of sexual interest
- Hair growth on face
- Painful intercourse
- Panic attacks
- Weird dreams
- Urinary tract infections
- Vaginal itching
- Lower back pain
- Bloating
- Dizzy spells
- Panic attacks
- Skin feeling crawly
- Flatulence
- Indigestion
- Osteoporosis
- Aching ankles, knees, wrists, shoulders, heels
- Hair loss
- Frequent urination
- Snoring
- Sore breasts
- Palpitations
- Varicose veins
- Urinary leakage
Perimenopause/Menopause
Primary Medical Concerns

Cardiovascular Health

• Estrogen is cardioprotective.
• After menopause → HDL down, LDL up, total cholesterol up

Bone Health

• Declining levels of estrogen in menopause pose the greatest threat to bone health in post-menopausal women
Core Diagnostics for the Management of the Menopausal Woman

- Genova Diagnostics’ Therapeutic Cohort Results Cover Page
- Salivary Sex Hormone Profiles
Genova’s Therapeutic Ranges Cover Page

Genova Diagnostics includes a Therapeutic Ranges Cover Page on four of our salivary sex hormone profiles:

- This cover page provides Therapeutic Ranges for sex hormones based on a select cohort of supplemented peri/menopausal women – and enables clinicians to compare their patient’s results to this treated group of individuals.
- These profiles also include Genova’s standard Reference Ranges which provide comparison of patient results to other relevant healthy cohorts of patients.
Genova’s Therapeutic Range

- Genova Diagnostics’ Therapeutic Range specifically refers to the range of results that were established from a cohort of patients receiving therapeutic hormone treatment.

- Because the therapeutic cohort comprises women who are being treated with hormone therapy due to symptoms or health problems, the therapeutic range does not indicate whether a specific individual’s test results are “normal” or “abnormal”.
  - A detailed explanation of the Therapeutic Range Cover Page can be found on Genova’s website at the Endocrine University.
How Do I Interpret the Graphic Representation of the Therapeutic Range?

* The therapeutic ranges depicted are for informational purposes only, and were derived from a cohort of perimenopausal women ranging in age from 37-62 years. All women were treated with bioidentical hormone therapy (HT) utilizing combinations of the following: Biest (transdermal), Progesterone (oral micronized), Testosterone (transdermal); and 7-keto-DHEA (oral).

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How Do I Interpret the Graphic Representation of the Therapeutic Range?

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Core Therapeutics for the Management of the Menopausal Woman
Core Therapeutics: Biodentical Hormone Replacement Therapy

Prescribing Hormones

• Before prescribing hormones it is very important to know how much of each hormone that the body makes in a day!
## Twenty-Four-Hour Production Rates of Sex Steroids in Women At Different Stages of the Menstrual Cycle

<table>
<thead>
<tr>
<th>Sex Steroids</th>
<th>Early Follicular</th>
<th>Preovulatory</th>
<th>Midluteal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progesterone (mg)</td>
<td>1.0</td>
<td>4.0</td>
<td>25.0</td>
</tr>
<tr>
<td>17-hydroxy-progesterone (mg)</td>
<td>0.5</td>
<td>4.0</td>
<td>4.0</td>
</tr>
<tr>
<td>Dehydroepi-androsterone (mg)</td>
<td>7.0</td>
<td>7.0</td>
<td>7.0</td>
</tr>
<tr>
<td>Androstenedione (mg)</td>
<td>2.6</td>
<td>4.7</td>
<td>3.4</td>
</tr>
<tr>
<td>Testosterone (mcg)</td>
<td>144.0</td>
<td>171.0</td>
<td>126</td>
</tr>
<tr>
<td>Estrone (mcg)</td>
<td>50.0</td>
<td>350.0</td>
<td>250.0</td>
</tr>
<tr>
<td>Estradiol (mcg)</td>
<td>36.0</td>
<td>380.0</td>
<td>250.0</td>
</tr>
</tbody>
</table>
Start Low and Go Slow!
It Is All About Balance!
Do Not Give Estrogen by Mouth for HRT
Estrogen Given by Mouth Can...

- Increase blood pressure
- Increase triglycerides
- Increase estrone
- Cause gallstones
- Elevate liver enzymes
- Increase SHBG (decreases testosterone)
- Interrupt tyrptophan metabolism and consequently serotonin metabolism
- Lower growth hormone
- Increase prothrombic effects
- Increase CRP
- Increase carbohydrate cravings
Methods of Dispensing Hormones Transdermally

• Can put in syringe: best to use 1 mL so that the hormone is dispensed over a wider area for better absorption. Use a 10 mL syringe
  – Larger syringes are hard for the patient to use and see the dosages
• Best not to dispense in less than 0.5 mL
• Can instead put in MegaPump. This pump comes in 30 mL, 75 mL, and 150 mL sizes
• The 30 mL and 75 mL dispenses 0.5 mL
• The 150 mL size dispenses 1.0 mL
HRT: Disease Risk Including Breast Cancer Risk
In a 2013 study: researchers estimated that over the past decade between 18,600 to 91,600 postmenopausal women, ages 50-59 years old, who had had a hysterectomy may have died prematurely because they did not take estrogen.

Another study which was a meta-analysis from 27 published studies showed a 28% reduction in mortality in menopausal women under age 60 who used hormone replacement therapy and the participants also had improved quality of life

Studies have shown that progesterone does NOT induce estrogen-stimulated breast cell proliferation


References


References


HRT and Breast Cancer Risk (Cont.)

• Natural progesterone has been shown to decrease the risk of developing breast cancer

• A study looked at 80,000 postmenopausal women for 8 years using different kinds of HRT
  – It found that women who used estrogen in combination with synthetic progestin had a 69% increased risk of developing breast cancer when compared to women who never took HRT
  – Women who used progesterone in combination with estrogen had no increased risk in developing breast cancer compared to women that did not use HRT and also had a decreased risk in developing breast cancer compared to the women that used progestin
Reference

• Another study done by the same researchers found a 40% increased risk of developing breast cancer in women who used estrogen with progestin

• In women who used estrogen combined with progesterone there was a trend toward a decreased risk of developing breast cancer

Case Studies
Case #1
Six Day Saliva Test
Menopause Plus

A 6-day saliva test is very beneficial to do for peri-menopausal women since their hormones may change over time if they do not want to do a 28-day test.
Peri-Menopausal Women

• You start the test on day 16 of their cycle
• If you are going to do a one day test then day 20 or 21 of their cycle is best
• If the patient really needs to do a 28-day test but will not do one for one reason or another then have them do a one day test on day 4 of their cycle and another one day test on day 21 of their cycle
  – For younger women a 28-day always gives you more information
**Case #1: Six Day Test**

### Menopause - Salivary Profile

#### Therapeutic Cohort Results

<table>
<thead>
<tr>
<th>Hormone</th>
<th>Average Result</th>
<th>1st</th>
<th>2nd</th>
<th>3rd</th>
<th>4th</th>
<th>5th</th>
<th>6th</th>
<th>Therapeutic Range*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estradiol (E2)</td>
<td>6.6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2.9-13.7 pmol/L</td>
</tr>
<tr>
<td>Estrone (E1)</td>
<td>11.6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5.5-20.1 pmol/L</td>
</tr>
<tr>
<td>Estriol (E3)</td>
<td>98</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&lt;=135 pmol/L</td>
</tr>
<tr>
<td>Testosterone</td>
<td>43</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>34-183 pmol/L</td>
</tr>
<tr>
<td>Progesterone</td>
<td>260</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>174-1,417 pmol/L</td>
</tr>
<tr>
<td>P/E2 Ratio</td>
<td>39</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>29-192</td>
</tr>
</tbody>
</table>

* The therapeutic ranges depicted are for informational purposes only, and were derived from a cohort of premenopausal women ranging in age from 37-62 years. All women were treated with bioidentical hormone therapy (HT) utilizing combinations of the following: Bioidentical (transdermal), Progesterone (oral micronized), Testosterone (transdermal), and 7-keto-DHEA (oral).

† Patient results with Genova's standard reference ranges are reported on the following pages.
Case #1: Six Day Test

### Salivary Hormone Results

<table>
<thead>
<tr>
<th>Sample #</th>
<th>Estrone (E1) (pmol/L)</th>
<th>Estradiol (E2) (pmol/L)</th>
<th>Estriol (E3) (pmol/L)</th>
<th>Progesterone (pmol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>11.9</td>
<td>6.4</td>
<td>&lt;70</td>
<td>282</td>
</tr>
<tr>
<td>2</td>
<td>10.6</td>
<td>6.8</td>
<td>102</td>
<td>215</td>
</tr>
<tr>
<td>3</td>
<td>12.2</td>
<td>6.6</td>
<td>89</td>
<td>284</td>
</tr>
<tr>
<td>Average</td>
<td>11.6</td>
<td>6.6</td>
<td>96</td>
<td>260</td>
</tr>
</tbody>
</table>

### Hormone Levels

**Average Estradiol (pmol/L):** 6.6

**Average Estrone (pmol/L):** 11.6

**Average Progesterone (pmol/L):** 260

**Average Testosterone (pmol/L):** 43

**Average Estriol (pmol/L):** 96

**PIE2 Ratio:** 39

**Reference Ranges:**

- **Estrone (E1):**
  - Follicular: 2.5-8.0 pmol/L
  - Peak: 4.5-19.1 pmol/L
  - Luteal: 2.8-8.2 pmol/L
  - Menopausal: 3.5-7.4 pmol/L
  - Male: 10.0-13.0 pmol/L

- **Estradiol (E2):**
  - Premenopausal: 120-650 pmol/L
  - Menopausal: 470-1350 pmol/L
  - Male: 440-707 pmol/L

- **Estriol (E3):**
  - Menopausal: 146-669 pmol/L
  - Male: 144-629 pmol/L

- **Progesterone:**
  - Menopausal: <= 135 pmol/L
  - Male: 23-189
  - Luteal: 26-141
  - Menopausal: 33-116
Norms for Estrogens on 6-Day Test

- **Estradiol**
  - Follicular: 2.8-8.8 pmol/L
  - Peak: 4.5-19.1 pmol/L
  - Luteal: 2.8-8.2 pmol/L
  - Menopausal: 3.7-9.4

- **Estrone**
  - 4.7-18.9 pmol/L

- **Estriol**
  - <133 pmol/L
Cycling women very rarely need estrogen replacement

The exception to this is menstrual migraines at peri-menopause

If the patient develops menstrual migraines or if they become more common or much more severe peri-menopausally then start:

- Biest Cream 0.10 mg as 1mL in Versabase
- Sig: apply qd to thigh or buttock. Rub in for two minutes. Rotate sites
Peri-Menopause

- **Oral** administration of E4M capsules (if issues with insomnia and better breast protection)
  - Progesterone 25 to 200 mg days 14-25
  - May need to give low dose days 4-13

- **Topical** administration
  - Progesterone
    - 10-30 mg days 14-25
    - May need to give low dose on days 4-13
Norms for Progesterone on 6-Day Saliva Test

- Follicular: 120-593 pmol/L
- Peak: 328-1385 pmol/L
- Luteal: 145-797 pmol/L
- Menopausal: 163-669 pmol/L

- Can be given transdermally, PO, or transvaginally
  - Doses are for transdermal and PO
Case #2
Patient Now On HRT
### Case #2: Patient on HRT

**Patient:** Jane Doe  
**DOB:**  
**Sex:** F  
**MRN:**

---

**One Day Hormone Check - Salivary Profile**

### Therapeutic Cohort Results

<table>
<thead>
<tr>
<th>Hormone</th>
<th>Result</th>
<th>1st</th>
<th>2nd</th>
<th>3rd</th>
<th>4th</th>
<th>5th</th>
<th>Therapeutic Range*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estradiol (E2)</td>
<td>45</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2.9-13.7 pmol/L</td>
</tr>
<tr>
<td>Estriol (E1)</td>
<td>12.8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5.5-20.1 pmol/L</td>
</tr>
<tr>
<td>Estriol (E3)</td>
<td>&gt;70</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&lt;=155 pmol/L</td>
</tr>
<tr>
<td>Testosterone</td>
<td>34</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>34-183 pmol/L</td>
</tr>
<tr>
<td>Progesterone</td>
<td>295</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>174-1,417 pmol/L</td>
</tr>
<tr>
<td>P/E2 Ratio</td>
<td>68</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>29-192</td>
</tr>
</tbody>
</table>

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† Patient results with Genova's standard reference ranges are reported on the following pages.
Case #2:
Patient on HRT

### Salivary Hormone Results

<table>
<thead>
<tr>
<th>Hormone</th>
<th>Unit</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estradiol</td>
<td>pmol/L</td>
<td>4.5</td>
</tr>
<tr>
<td>Testosterone</td>
<td>pmol/L</td>
<td>34</td>
</tr>
<tr>
<td>Estrone</td>
<td>pmol/L</td>
<td>12.8</td>
</tr>
<tr>
<td>Progesterone</td>
<td>pmol/L</td>
<td>295</td>
</tr>
<tr>
<td>Estriol</td>
<td>pmol/L</td>
<td>&lt;70</td>
</tr>
<tr>
<td>P/E2 Ratio</td>
<td></td>
<td>66</td>
</tr>
</tbody>
</table>

**Reference Ranges**

**Estradiol**
- Follicular: 2.8-8.8 pmol/L
- Peak*: 4.5-19.1 pmol/L
- Luteal: 2.8-8.2 pmol/L
- Menopausal: 3.7-0.4 pmol/L
- Male: 3.1-7.4 pmol/L
  
  *Peak = Days 11 and 12

**Testosterone**
- Premenopausal: 34.1-18 pmol/L
- Menopausal: 34.1-18 pmol/L
- Male: 110-513 pmol/L

**Estrone**
- Menopausal: 4.7-18.9 pmol/L

**Progesterone**
- Follicular: 120-593 pmol/L
- Peak*: 328-1386 pmol/L
- Luteal: 145-797 pmol/L
- Menopausal: 163-569 pmol/L
- Male: 141-529 pmol/L

*Peak = Days 18 and 20

**Estriol**
- Menopausal: <= 133 pmol/L

**P/E2 Ratio**
- Follicular: 33-159
- Luteal: 25-141
- Menopausal: 33-116

*Genova Diagnostics*
Menopausal Women
For menopausal women a one day saliva test is perfect since her hormones are now stable and are not changing.
Case #3
Menopausal Woman
One Day Saliva Test
Case #3: One Day Test

One Day Hormone Check - Salivary Profile

### Therapeutic Cohort Results

<table>
<thead>
<tr>
<th>Hormone</th>
<th>Result</th>
<th>Quintile Distribution</th>
<th>Therapeutic Range*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estradiol (E2)</td>
<td>25</td>
<td>1st: 20% 2nd: 80%</td>
<td>2.9-10.7 pmol/L</td>
</tr>
<tr>
<td>Estriol (E1)</td>
<td>7.3</td>
<td>1st: 50% 2nd: 50%</td>
<td>6.5-20.1 pmol/L</td>
</tr>
<tr>
<td>Estradiol (E1)</td>
<td>114</td>
<td>1st: 10% 2nd: 20%</td>
<td>&lt;=186 pmol/L</td>
</tr>
<tr>
<td>Testosterone</td>
<td>&lt;50</td>
<td>1st: 50% 2nd: 50%</td>
<td>34-185 pmol/L</td>
</tr>
<tr>
<td>Progesterone</td>
<td>179</td>
<td>1st: 10% 2nd: 20%</td>
<td>174-1,417 pmol/L</td>
</tr>
<tr>
<td>F/E2 Ratio</td>
<td>62</td>
<td>1st: 30% 2nd: 70%</td>
<td>29-192</td>
</tr>
</tbody>
</table>

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† Patient results with Genova’s standard reference ranges are reported on the following pages.
### Case #3: One Day Test

**Salivary Hormone Results**

<table>
<thead>
<tr>
<th>Hormone</th>
<th>Value</th>
<th>Reference Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estradiol pmol/L</td>
<td>2.9</td>
<td>Follicular: 2.8-8.8 pmol/L, Peak*: 4.5-19.1 pmol/L, Luteal: 2.8-8.2 pmol/L, Menopausal: 3.7-9.4 pmol/L, Male: 3.1-7.4 pmol/L</td>
</tr>
<tr>
<td>Testosterone pmol/L</td>
<td>&lt;30</td>
<td>Prenopausal: 34-148 pmol/L, Menopausal: 34-148 pmol/L, Male: 110-513 pmol/L</td>
</tr>
<tr>
<td>Estrone pmol/L</td>
<td>7.3</td>
<td>Menopausal: 4.7-18.9 pmol/L</td>
</tr>
<tr>
<td>Estriol pmol/L</td>
<td>114</td>
<td>Menopausal: &lt;= 133 pmol/L</td>
</tr>
</tbody>
</table>
DHEA
Case #3: One Day Test

Salivary Cortisol and DHEA

**Cortisol**
Reference Range
- 1 Hour After Rising
  - 7AM - 9AM: 0.27-1.18 mcg/dL
  - 11AM - 1PM: 0.10-0.41 mcg/dL
  - 3PM - 5PM: 0.05-0.27 mcg/dL
  - 10PM - 12AM: 0.03-0.14 mcg/dL

**Hormone**
Reference Range

<table>
<thead>
<tr>
<th>Hormone</th>
<th>Reference Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>DHEA 7am - 9am</td>
<td>71-640 pg/mL</td>
</tr>
<tr>
<td>DHEA: Cortisol Ratio/10,000</td>
<td>115-1,188</td>
</tr>
</tbody>
</table>
DHEA Replacement

- DHEA should be in the middle of the green section for optimal health
- Normal DHEA: 71-640 pg/mL
- Women are much more sensitive to DHEA than men, so start with low dosages
- In younger women you may not need to replace DHEA since the cause of low DHEA is usually due to stress. Balance cortisol and the DHEA level will rise
Clinical Pearl on DHEA

• DHEA balances cortisol
• If cortisol levels are abnormal then treat, do not just give DHEA hoping that cortisol levels will come up
• If cortisol is abnormal and you just give DHEA without working on the abnormal cortisol levels then the next time that you measure DHEA, the levels will be even lower
Cortisol
Case #3: One Day Test

Salivary Cortisol and DHEA

Cortisol:
- Reference Range:
  - 1 Hour After Rising:
    - 7AM - 9AM: 0.27-1.18 mcg/dL
    - 11AM - 1PM: 0.10-0.41 mcg/dL
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Hormone Reference Range

<table>
<thead>
<tr>
<th>Hormone</th>
<th>Reference Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>DHEA 7am - 9am</td>
<td>100</td>
</tr>
<tr>
<td>71-640 pg/mL</td>
<td></td>
</tr>
<tr>
<td>DHEA: Cortisol Ratio/10,000</td>
<td>151</td>
</tr>
<tr>
<td>115-1,188</td>
<td></td>
</tr>
</tbody>
</table>
Treatment of Hyperadrenalism

- Replacement of DHEA with adrenal support
- Adaptogenic herbs
- Essential Nutrients
- Calming herbs
- Stress reduction techniques
- If cortisol is high in the evening then add phosphatidylserine 300 mg which may be taken any time of the day
Melatonin
Case #3: One Day Test
Melatonin Replacement in Women

- High levels of melatonin in the morning usually mean that cortisol levels were too low in the am
- If melatonin levels are too high any time of the day or night then serotonin levels may go down
- Middle of the night level is done with the lights off otherwise the reading will not be accurate
Questions?

Explore www.gdx.net for more information and educational resources, including...

- **LEARN GDX** – Brief video modules
- **LIVE GDX** – Previous webinar recordings
- **GI University** – Focused learning modules
- **Conferences** – Schedule of events we attend
- **Test Menu** – Detailed test profile information
- **MY GDX** – Order materials and get results

Moderator: Michael Chapman, ND

Presenter: Pamela W. Smith, M.D., MPH, MS
Additional Education Materials:

WWW.GDX.NET

Sample Reports, Support Guides, Kit Instructions, FAQs, Payment Options, and much more!
LearnGDX Seminar Series

• One-day event on June 11th, 2016
• Located in Fort Lauderdale, FL
• Speakers include Dr. Pamela Smith & Dr. Andrea Girman
• Open to all account holders for $299
• Registration includes a Menopause Plus Salivary Profile
Additional Questions?

Please schedule a complimentary appointment with one of our Medical Education Specialists for questions related to:

- Diagnostic profiles featured in this webinar
- How Genova’s profiles might support patients in your clinical practice
- Review a profile that has already been completed on one of your patients

We look forward to hearing from you!
Upcoming **LIVE** GDX Webinar Topics

June 2016

— *The Steroidogenic Pathway: Understanding What Influences Each Step*

  • Ellen Antoine, DO

Register for upcoming **LIVE** GDX Webinars online at [WWW.GDX.NET](http://WWW.GDX.NET)
Case Studies in Management of the Menopausal Patient
Pamela W. Smith, M.D., MPH, MS

May 25, 2016

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