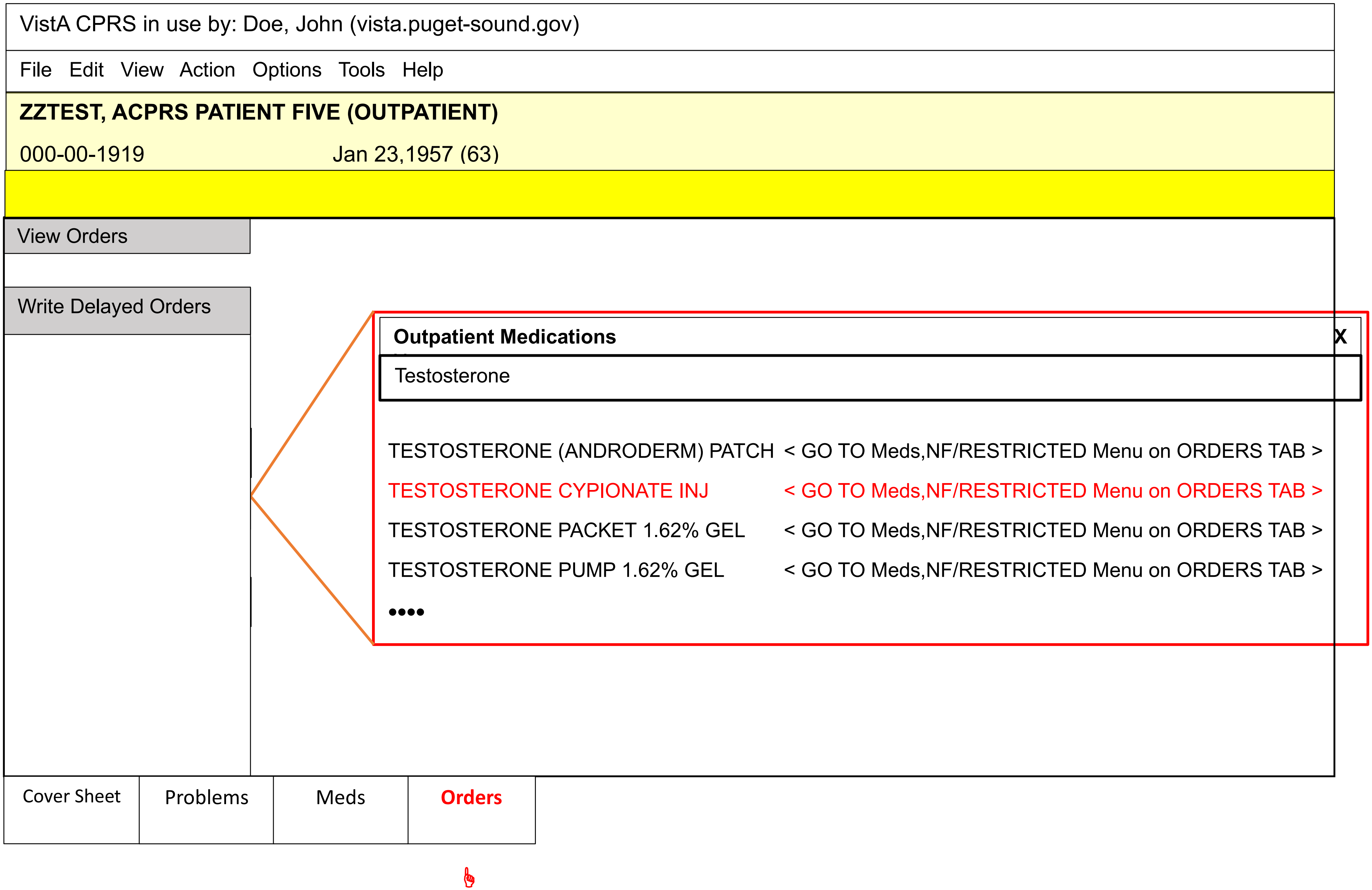
Supplementary Figure 1A. Ordering a New Testosterone Prescription



Supplementary Figure 1B. NEW NF or RESTRICTED Meds Menu

NEW N/F or RESTRICTED Meds (NOTE LINK to menu for previously approved meds)

****

<< NON-FORMULARY DRUG REQUEST >>

<< RESTRICTED DRUG REQUEST >>

<< ALLERGY OR ADVERSE DRUG REACTION >>

****

<< PREVIOUSLY APPROVED NF/RESTRICTED MED >>

<< Specific BRAND NAME Drugs (N/F) >>

****

A

(N/F) Abatacept (Open Dose) IV 0.2, 4 then q 4wk

••••

••••

••••

••••

••••

••••

T

Teriflunomide 14 mg QDay (N/F)

Testosterone Ordering Information

••••

••••

••••

Supplementary Figure 1C. If FREE Testosterone or Other Labs are Not Available

Testosterone Ordering Information

Initial Lab Testing/Evaluation for Hypogonadism

Reminder: Please review patient's FREE Testosterone

IF FREE Testosterone is NORMAL, patient does not have hypogonadism

Do not select one from the list below, but rather select DONE

IF FREE Testosterone is LOW, proceed with Testosterone ordering

IF FREE T or other labs are NOT AVAILABLE, order lab

☞ Testosterone, Free & wkly bnd panel, LH, FSH and CBC

Testosterone Panel

- ☐ Testosterone Free & wkly bnd panel
- ☐ LH
- ☐ FSH
- ☐ CBC

Select ONE of the Following:

Testosterone Ordering, NEW Prescription

Testosterone Ordering, FIRST RENEWAL Prescription

Testosterone Ordering, SECOND RENEWAL or GREATER Prescription

This is the second renewal or greater. Patient has already been evaluated

for adherence, efficacy, and safety after Testosterone initiation

Select DONE and renew existing order

Supplementary Figure 1D. Documented Organic Cause or No Documented Organic Cause

Testosterone Ordering Information

Initial Lab Testing/Evaluation for Hypogonadism

Reminder: Please review patient's FREE Testosterone

IF FREE Testosterone is NORMAL, patient does not have hypogonadism

Do not select one from the list below, but rather select DONE

IF FREE Testosterone is LOW, proceed with Testosterone ordering

IF FREE T or other labs are NOT AVAILABLE order lab

Testosterone, Free & wkly bnd panel, LH, FSH and CBC

Select ONE of the Following:

☞ Testosterone Ordering, NEW Prescription

Testosterone Ordering, FIRST RENEWAL Prescription

Testosterone Ordering, SECOND RENEWAL or GREATER Prescription

This is the second renewal or greater. Patient has already been evaluated for adherence, efficacy and safety after Testosterone initiation

Select DONE and renew existing order

Template RESTRICTED DRUG REQUEST TESTOSTERONE PADR

■ (Click to activate)

○ After reviewing medical records, the patient has a documented organic (congenital, structural, or destructive) cause of primary or secondary hypogonadism, or patient is female-to-male transgender under VA care

○ If NO documented organic (congenital, structural, or destructive) cause of primary or secondary hypogonadism, BEFORE testosterone treatment is started, the following should be documented:

Supplementary Figure 1E. Patient has Prior Organic Cause of Hypogonadism

Template RESTRICTED DRUG REQUEST TESTOSTERONE PADR

Information: [Automatically imported from electronic health record]

Encounter diagnosis:

05/14/2019@06:35:22 E23.0 (ICD-10) Hypopituitarism rank: PRIMARY

Prov. Narr. – Hypopituitarism

☞ ● After reviewing medical records, the patient has a documented organic (congenital, structural or destructive) cause of primary or secondary hypogonadism, or patient is female-to-male transgender under VA care.

☞ ■ Order a NEW prescription for Testosterone

○ If NO documented organic (congenital, structural or destructive) cause of primary or secondary hypogonadism, BEFORE testosterone treatment is started, the following should be documented:

Progress Note text: [Automatically generated from template]

Testosterone Medication Request

After reviewing medical records, the patient has documented organic (congenital, structural or destructive) cause of primary or secondary hypogonadism, or patient is female-to-male transgender under VA care.

A new prescription for testosterone was placed.

Supplementary Figure 1F. Patient has No Prior Organic Cause of Hypogonadism

Template RESTRICTED DRUG REQUEST TESTOSTERONE PADR

☞ ● If NO documented organic (congenital, structural, or destructive) cause of primary or secondary hypogonadism,

BEFORE testosterone treatment is started, the following should be documented:

☞ ■ Signs and symptoms of T deficiency for which T treatment is being prescribed (check all that apply)

More Specific:

- ☐ Poor sexual development
- ■ Low sexual desire (libido)
- ☐ Reduced sexual activity
- ☐ Reduced or no spontaneous erections
- ☐ Loss of axillary/pubic hair
- ■ Hot flushes/sweats
- ☐ Breast tenderness/enlargement/gynecomastia
- ☐ Small testes (less than 6 cc)
- ■ Infertility
- ☐ Osteoporosis/low-trauma fracture

Less Specific:

- ☐ Erectile dysfunction
- ☐ Reduced muscle mass and strength
- ☐ Depressed mood/dysthymia
- ☐ Reduced motivation/initiative/self-confidence
- ☐ Low energy, fatigue
- ☐ Increased sleepiness
- ☐ Poor concentration/memory
- ☐ Unexplained normocytic anemia

Supplementary Figure 1F (continued). Patient has No Prior Organic Cause of Hypogonadism

☞ ■ Low morning, fasting total T and/or free T levels (calculated free T or free T by equilibrium dialysis) on TWO separate days

Recommend free & weakly bound T or free T by equilibrium dialysis if condition that alters sex hormone-binding-globulin (SHBG) or borderline low total testosterone level: [Conditions specified below]

- Obese
- Type 2 diabetes mellitus
- Age > 70 years
- Use of glucocorticoids, progestins or androgenic steroids
- Active hepatitis or hepatic cirrhosis
- HIV disease
- Symptomatic thyroid disease (hypothyroidism or hyperthyroidism)
- Nephrotic syndrome
- Acromegaly
- OR
- Total T between 200 – 400 ng/dL (2.0 – 4.0 ng/mL)

No data available for TESTOSTERONE, FREE (calc) [Automatically imported from electronic health record]

☞ ■ LH and FSH levels ONCE at the same time as T level [Interpretation below]

Cause of hypogonadism

IF LH and FSH are HIGH, the patient has Primary Hypogonadism, i.e., a testicular disorder

IF LH and FSH are LOW or NORMAL, the patient has Secondary Hypogonadism, i.e., a hypothalamic or pituitary disorder #

Consider potentially reversible functional disorder causing low testosterone that may not require testosterone treatment:

- Recent acute illness
- Obesity/sleep apnea
- Nutritional deficiency/Excessive exercise
- Opioid/Corticosteroid/Anabolic steroid or other steroid use
- Severe organ failure /Systemic illness

Supplementary Figure 1F (continued). Patient has No Prior Organic Cause of Hypogonadism

☞ ■ No contraindications or exclusions to testosterone treatment:

Active prostate or breast cancer

Caution in men with:

* Unevaluated nodule or induration on digital rectal examination

* Unevaluated prostate-specific antigen (PSA) > 4 ng/mL or > 3 ng/mL for men with high risk for prostate cancer, such as African-American, first-degree relative with prostate cancer or Agent Orange exposure

* Hematocrit > 48% at baseline, or > 50% for men living at high altitude, or > 54% at renewal

* Severe lower urinary tract symptoms (LUTS) associated with benign prostatic hypertrophy (e.g., indicated by American Urological Association (AUA)/International Prostate Symptom Score (IPSS) > 19

* Uncontrolled or poorly controlled congestive heart failure

* Desire for fertility in the near-term (6 to 12 months)

* Myocardial infarction or stroke within last 6 months

* Thrombophilia or history of unprovoked deep vein thrombosis (DVT) or pulmonary embolism (PE)

* History of adverse reaction to injectable or topical T products

* History of anabolic steroid abuse or dependence

☞ ■ Benefits and risks of testosterone treatment discussed

Benefits

Induce sexual development

Improve sexual function (especially libido)

Improve energy and mood

Improve muscle mass and strength

Improve bone density

Supplementary Figure 1F (continued). Patient has No Prior Organic Cause of Hypogonadism

Risks

- Erythrocytosis
- Prostate biopsy (especially if monitoring PSA)
- Formulation-specific (e.g., transfer to women and children with transdermal T gel or solution)
- Gynecomastia (rare)
- Sleep apnea (rare)

Unknown risks but caution

- Cardiovascular events (myocardial infarction and stroke)
- Venous thromboembolism
- Prostate cancer

Hematocrit < 49% at baseline, taken within 6 months prior to starting Testosterone treatment

16.5 % L* (01/31/2020 09:43) [Automatically inserted from electronic health record]

Consult Endocrinology, if:

- Know hypothalamic/pituitary/testicular disease
- Severely low T (e.g., total T < 1.5 ng/mL) AND low LH/FSH
- High prolactin level
- Possible adrenal insufficiency (weight loss, low blood pressure, low sodium)
- New-onset headaches or visual changes
- T treatment is being considered AND:
  - Fertility desired
  - Previous prostate cancer
  - CV event in last 6 months

Supplementary Figure 1G. Testosterone Formulations and Supplies Menu

Testosterone Medications
First Line:
Testosterone Cyp 200mg IM Q2Weeks x 6Months (R)
Testosterone Cyp 200mg IM Q4Weeks x 6Months (R)
Testosterone Injections Supplies
Second Line:
Testosterone 1% Gel Pkt 50mg Topically QAM (R)
Testosterone 1.62% Gel Pkt 1.25gm Topically QAM (R)
Testosterone 1.62% Gel Pkt 2.5gm Topically QAM (R)
Testosterone 1.62% Gel 1 Pump 20.25mg Topically QAM (R)
Testosterone 1.62% Gel 2 Pumps 40.5mg Topically QAM (R)
Third/Fourth Line:
Testosterone 2mg/24hr Topical Patch QHS (R)
Testosterone 4mg/24hr Topical Patch QHS (R)