Screening Forms

Level 1: Title and Abstract Screening

1. Is this a potentially relevant record addressing 1. the benefits or harms (note:only SRs examining Viagara studies for harms data to be included; all other drugs include original studie for harms) of a pharmaceutical treatment (oral, topical, intraurethral, injectable, or intracavernosal) for male erectile dysfunction? OR 2. the sensitivity or specificity of testosterone/LH/FSH/prolactin in identifying a glandular disorder as a cause of ED OR 3. the prevalence of a hormonal (testosterone/LH/FSH/prolactin) disorder in association with male erectile dysfunction?
    - Yes
    - No
    - Can't tell

2. Please indicate which of the following best describes the current record –
    - Original study
    - Narrative review
    - Systematic review/meta-analysis
    - Guideline
    - Comment/Opinion piece
    - Letter to the editor
    - Can't tell

3. Is this an English Language Record? (this question is optional)
    - Yes
    - No
    - Can't tell

Level 2: Full Text Relevance Screening

1. **Which of the following best describes the attached record: *(please check all that apply)***
    - ❑ A study examining the measurement of testosterone and/or other androgen hormone, FSH, LH, Prolactin (but not GnRH, Inhibin, Activin, or Follistin) OR the sensitivity or specificity of hormones in ED screening/diagnosing OR prevalence of reversible hormonal disorders in males with erectile dysfunction

    - ❑ A study examining an oral medication in the treatment of [efficacy/effectiveness (for all drugs) and/or harm outcomes] in male erectile dysfunction in relevant a population (if yes; please indicate in the text box if this is a viagra monotherapy study)

- ❑ A systematic review of harms associated with Viagra
- ❑ A study examining an intramuscular injectable medication in the treatment of male erectile dysfunction
- ❑ A study of an injectable medication into the penis (intracavernosal) OR intraurethral pellet (alprostadil/MUSE, misoprostol, enprostil, arbabprostil, unoprostone) in the treatment of male erectile dysfunction
- ❑ A study examining a topical (patch or cream) or intranasal medication in the treatment of male erectile dysfunction
- ❑ None of the above (e.g., not relevant, animal study, etc.)
- ❑ Can't tell
- ❑ A study that examines any harm(s) (e.g., priapism; penile fibrosis/corporal fibrosis only) for injectable medications in males with ED (Note: treatment and/or f/u must be of >=6 months in duration)
- ❑ A study that examines any harm(s) (e.g., priapism; penile fibrosis/corporal fibrosis only) for injectable medications in males with ED - treatment and/or f/u of less than 6 months in duration
- ❑ A study with treatment and/or f/u >= 6 months in duration that DOES NOT examine harm(s) for injectable medications in males with ED

2. Level of Evidence for this report:

- ❑ Systematic Review
- ❑ RCT parallel design, RCT cross-over, or RCT factorial design
- ❑ Controlled clinical trial (non-RCT)
- ❑ Multiple prospective cohort(s)
- ❑ Case-control
- ❑ Cross-sectional
- ❑ Before-and-after
- ❑ Single prospective cohort
- ❑ Single retrospective cohort
- ❑ Case series (non-comparative)
- ❑ Case study

- ❑ Cross-national ecological analysis
- ❑ Other (describe)
- ❑ Can't tell
- ❑ Not applicable (the study is considered to be not relevant)

3. This study meets relevancy requirements and is considered an included study:
Oral medication – only RCTs (Viagra systematic reviews including harms INCLUDED; Viagra RCT effectiveness/efficacy included – EXCEPT in spinal cord population)

- ❑ Yes
- ❑ No
- ❑ Can't tell
- ❑ Not applicable (the study is deemed not relevant in Q#1)

4. This article should be retrieved to supplement introduction/background information for the report:

- ❑ Yes (indicate specific disorder etc.)

5. Additional Notes/Comments

Data Extraction Form

Summary Table- Randomized Controlled Trials

Author, (year)/ Funding source/ QA	Study design characteristics	Participant characteristics	Patient diagnosis details	Intervention	Outcome & measures
Author (year) {REF ID} Funding source:	N screened = N randomized = IG1, n = IG2, n = CG, n = ITT analysis used for primary outcome: Inclusion: Exclusion:	Age, mean (): Race: Co-morbidities, n (%): Previous ED treatment: Smoking status: Body weight: Other:	Concomitant medications, n (%): Duration of ED: Underlying disease, n (%): Psychogenic ED, n (%): Physiologic ED, n (%): Mixed ED, n (%): Other:	IG1: IG2: CG: IG1: Dose: Duration: Frequency: Compliance: IG2: Dose: Duration: Frequency: Compliance: CG: Dose: Duration: Frequency: Compliance: Run In period: Wash out period: Follow up duration:	Primary outcome (erectile function): Other outcomes assessed: Withdrawals/drop-outs/loss to followup, n (%): WDAE, n (%): TAE, n (%): SAE, n (%): Ascertainment of outcomes assessed: Other:

List of abbreviations: RCT=randomized control trial, CC=controlled clinical trials, ED=erectile dysfunction, NA=not applicable, IG=intervention group, CG=comparator/control group, HbA1C= haemoglobin, BMI=body mass index, wk=week(s), mo=month(s), yr=year(s), hr=hour (s), f/u=follow-up, M=male, IIEF= international index of erectile function, GAQ=global assessment question, ECG=electrocardiograms, ▲=increased, ▼=decreased, sign. =significant; vs.=versus, %=percent, max=maximum, kg=kilograms, lbs=pounds, ITT=intent-to-treat (Y = yes, N = no, NR = not reported), AE=adverse event, SAE=serious adverse event, TAE=total adverse event, grp=group, Hx: history, PgE_1; Prostagladin E_1 IC= intracavernosal injection

Quality Assessment Forms

Randomized Controlled Trials (Jadad Scale)

1. Was the study described as randomized (including the use of words such as randomly, random, and randomization)?
    - Yes =1
    - No = 0

2. The method used to generate the sequence of randomization was described and it was appropriate (table of random numbers, computer generated, etc)
    - Appropriate
    - Not appropriate

3. Was the study described as double blind?
    - Yes = 1
    - No = 0

4. The method of double blinding was described and was appropriate (identical placebo, active placebo, dummy, etc)?
    - Yes = 1
    - No = 0

5. Was there a description of withdrawals and dropouts, by treatment group?
    - Yes = 1
    - No = 0

Total Jadad Score: (i.e = 0 - 5)

Allocation Concealment:
1 = yes, 0 = no

A: Adequate
- Sequentially numbered, opaque, sealed envelopes (SNOSE)
- Pharmacy controlled
- Numbered or ordered containers
- Central randomization – e.g. by telephone to a trials office or other method which described elements convincing of concealment – e.g. a secure computer assisted method.

I: Inadequate
- Alternation
- Reference to case record numbers or to dates of birth

U: Unclear
- No mention of an allocation concealment approach at all
- An approach that does not fall into either adequate or inadequate allocation concealment

The Quality Assessment of Studies of Diagnostic Accuracy Included in Systematic Reviews (QUADAS)

Q1: Was the spectrum of patients representative of the patients who will receive the test in practice? Yes/no

Q2. Were selection criteria clearly described? Yes/no

Q3. Is the reference standard likely to correctly classify the target condition? Yes/no

Q4. Is the time period between reference standard and index test short enough to be reasonably sure that the target condition did not change between the two tests? Yes/no

Q5. Did the whole sample or a random selection of the sample, receive verification using a reference standard? Yes/no

Q6. Did patients receive the same reference standard regardless of the index test result? Yes/no

Q7. Was the reference standard independent of the index test (i.e. the index test did not form part of the reference standard)? Yes/no

Q8. Was the execution of the index test described in sufficient detail to permit replication of the test? Yes/no

Q9. Was the execution of the reference standard described in sufficient detail to permit its replication? Yes/no

Q10. Were the index test results interpreted without knowledge of the results of the reference standard? Yes/no

Q11. Were the reference standard results interpreted without knowledge of the results of the index test? Yes/no

Q12. Were the same clinical data available when test results were interpreted as would be available when the test is used in practice? Yes/no

Q13. Were uninterpretable/ intermediate test results reported? Yes/no

Q14. Were withdrawals from the study explained? Yes/no