Nevada Academy of Family Physicians
32nd Annual Summer CME Meeting
July 30–August 1, 2021

Pain Management, Substance Use Disorder, Interventions and the Law

Presented by:
Senator Joseph Hardy, MD, FAAFP
and Weldon (Don) Havins, MD, JD

Approved for 2.0 Prescribed CME

**Meets the NV requirement for Prescribing Controlled Substances CME*

Friday, July 30, 2021
8:00—10:00am

Nevada Academy of Family Physicians • 705 Tahoe St., Ste. A, Reno, NV 89509
775-826-5100 • www.NVAFP.com

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NOTES

PAIN, SUD, INTERVENTIONS, AND NEW STATUTES

Joseph Hardy, M.D.
Associate Dean Clinical Education
Associate Professor
Touro University Nevada College of Osteopathic Medicine

DISCLOSURES

- NO CONFLICTS TO DISCLOSE
- Full-time Associate Professor Touro University of Nevada, College of Osteopathic Medicine since Nov. 1, 2012; Associate Dean for Clinical Education
- Nevada State Senator District #12 since 2010
- Member AAFP, NAFP, CCMS,NSMA
- Fellow ABFM
- Veteran USAF, Major, Medical Corps
- No other outside income affiliations
- 31.5 hours of CME since Nov. 28th on Addictions and Treatments

PRODUCTS OFF-LABEL USES

- It could happen in discussions or questions
- Will identify such either as investigational or not known
- No such product will be recommended

LEGISLATIVE MANDATES AND INTENTIONS

- Use health care extenders
- Apply for Federal waivers
- Programs for Practitioners
- Medicaid Suspension instead of termination for Prisoners
- Federal encouragement of use of Buprenorphine
- Suicide hot-line 9-8-8 funded by surcharge on mobile/landline phones
- Not allowed to buy tobacco products till age 21

INTERCONNECTION BETWEEN PAIN AND MENTAL HEALTH AND SUBSTANCE USE DISORDER

- Chronic pain: quit smoking, counseling, optimize non narcotics
- Alternative means to treat pain. Pain is depressing.
- Complex Regional Pain Syndrome: opioids don't work but rarely.
- Trigeminal neuralgia, the associated increased suicide risk.

PHYSICIAN EXTENDERS

- Pharmacists' collaborative practices (SB229)
- Pharmacists for HIV prescriptions and hormonal birth control (SB190)
- Doulas: work with pregnancy issues
- PAs, NPs, APRNs, Midwifes, Medical Assistants
- Community Health Workers (CHWs?)
- Expansion of Telehealth to include audio only, parity reimbursement (except for workers comp telehealth)
- Peer support organizations credentialing

FEDERAL WAIVERS NEEDED PRIOR TO ALLOWED

- SB420, the "Public Option", effective target 2025-26
- Doula services payments included in the State Medicaid Plan, AB256
- SB154 waivers needed for substance use disorder treatment in institution for mental illness and to treat severe mental illness in an institution for mental disease

MEDICATION ASSISTED TREATMENT, MAT

- Methadone: relaxed rules during pandemic, hopefully will continue
- Buprenorphine: X-waiver requirements relaxed to Notice for Intent on April 28th. Up to 30 patients without mandate for counseling or facilities. Question if still confidential information or necessity for separate charting.
- Naloxone, short and long-acting naltrexone

BUPRENORPHINE QUICK START GUIDE

- **SAMHSA: Substance Abuse and Mental Health Services Administration**
- **https://www.samhsa.gov/sites/default/files/quick-start-guide.pdf**

SBIRT: SCREENING, BRIEF INTERVENTION, REFER TO TREATMENT (AB442)

- **S**creening can be done by physician extenders
- **B**rief Intervention to educate as to risks and opportunities for change
- **R**eferral for Treatment

MOTIVATIONAL INTERVIEWING

- Per Wikipedia: "… is a counseling approach developed in part by clinical psychologists William R. Miller and Stephen Rollnick. It is a directive, client-centered counseling style for eliciting behavior change by helping clients to explore and resolve ambivalence."
- Helps the patients make decisions that they would like to make to change their behaviors and habits to conform to what they vision to what they would like to be/do.
- Commonly used in helping people with substance use disorders.

SCREENING TOOLS FOR AUD, OUD, TUD

- https://www.drugabuse.gov
- NMASSIST (Quick Screen) NIDA-Modified ASSIST
- Opioid Risk Tool
- CAGE:
  1) Ever felt needed to **C**ut down on drinking?
  2) **A**nnoyed by critical people of your drinking
  3) **G**uilty about drinking?
  4) Needed or wanted and **E**ye-opener in the morning?

SBIRT (AB442) QUALIFIES FOR REMUNERATION

- Don't have to be an expert to do SBIRT screening.
- **Screening** can be done by physician, NP, medical assistant, community health worker, pharmacist, PA, can be self-administered by patient
- Don't have to solve all the problems in **Brief Intervention**.
- **Referral for Treatment** can even include peer-based group mediation

EXTRA CREDIT SOCIAL DETERMINANTS OF HEALTH BIPOC (BLACK, INDIGENOUS, PEOPLE OF COLOR)

- Vaccinations for COVID-19
- Sickle Cell Disease pain crises fewer MMEs than metastatic bone pain
- Food Deserts
- Confidence in power structure
- No school for a year w/o adequate support system in poverty zones

NALOXONE

- Shelf life has been lengthened to 3 years from 2 (in Narcan)
- A higher dose, 8 mg, nasally has been produced (Kloxxado)
- In spite of increased availability and no prescription required, narcotic overdoses have been increasing; almost by 30% from 2019-2020.
- Naloxone does not reverse alcohol, cocaine, methamphetamine …
- Fentanyl requires multiple repeated doses of naloxone

Fatal Doses

SCREENING TOOLS FOR AUD, OUD, TUD
HTTPS://WWW.DRUGABUSE.GOV

- NMASSIST (Quick Screen) NIDA-Modified ASSIST
- Opioid Risk Tool
- CAGE:
  - 1) ever felt needed to **C**ut down on drinking?
  - 2) **A**nnoyed by critical people of your drinking.
  - 3) **G**uilty about drinking?
  - 4) Needed or wanted an **E**ye-opener in the morning.

THE WAIVER

- April 28, 2021 SAMHSA approved exemption from perceived road-block in practitioners applying for the requirement for training, counseling and hours of continuing education
- New exemption mandates submitting a Notice of Intent (NOI) to use buprenorphine to treat Opioid Use Disorder. Medication-based Opioid Use Disorder (MOUD or MAT, medication assisted treatment)
- Takes up to 5 minutes to check the boxes and self identify information on a form online found at Buprenorphine waiver, then clicks and scrolls until one sees the "request original waiver", but with a different box added
- SAMHSA links can get to the same place
- Title 42 part 2 CFR protects confidentiality for SUD and ID treatments

ADDICTION NOW USE DISORDER
ADDICTS NOW A PERSON WITH USE DISORDER

- Addiction per NCBI.NIM.Gov
  - Craving for drug or the reward
  - Decreased cognition of significant problems with behavior
  - Dysfunctional emotional response
  - Impairment of behavioral control
  - Inability to consistently abstain

NOW WHAT?

And maybe some answers:

- Medical treatment (MAT) is more effective than moral/legislative/imprisonment
  - "**Where** there is a **demand**, **there will be a supply**" – it's business
    - Adam Smith, *Wealth of Nations*, 1776
    - "El Chapo" Guzman, testimony in Federal Court, 2018
- Choose life over punishment – encourage Naloxone use; encourage MAT use
- Realize that, "there, for the grace of God, go I"
  - 10% of U.S. population is genetically prone to substance use addiction
  - Stop the punishment of innocent patients in pain because there are genetically predisposed to addiction among us

GLOSSARY

- NIDA: National Institute on Drug Abuse
- PCSS: Providers Clinical Support System (All free training, etc.)
- MOUD: medication-based Opioid Use Disorder
- MAT: Medication Assisted Treatment
- DATA 2000: Drug Addiction Treatment Act 2000
- SAMHSA: Substance Abuse and Mental Health Services
- NCBI.nlm.nih: Nat'l center biotechnology.nat'l library of medicine NIH
- EPCS: Electronic Prescribing of Controlled Substances (for Sch II-III)
- UD: use disorder, such as SUD, OUD, TUD, CUD, Etc.
- ASAM: American Society of Addiction Medicine

QUESTIONS ?

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NOTES

Controlled Substances (CS) Mandates, including amendments in AB 239 of 2019

(effective June 3, 2019)

Weldon (Don) Havins, MD, JD, LLM (Health Law)
Emeritus Professor
Medical Jurisprudence and Ophthalmology
Touro University Nevada

DISCLOSURES

NO CONFLICTS TO DISCLOSE
Received NO Commercial Support

Weldon (Don) Havins, MD, JD

wehavins.com
All course materials may be downloaded from this website

Learning Objectives

- Describe a licensee's duty to report conduct in violation of a Board statute or regulation
- List the diagnostic exceptions to the mandates for treating pain with a controlled substance
- Know the requirements for a written prescription of controlled substances
- Identify what tests are required of a patient before the initial prescription of a controlled substance for pain
- Articulate three components in a Prescription Medication Agreement
- Describe the mandates of SBIRT (AB442)

SBIRT CME mandate – AB442
2 hrs of training

Screening, **b**rief **i**ntervention and **r**eferral to **t**reatment approach to substance use disorder means

- an evidence-based method of delivering early intervention and treatment to persons who have or are at risk of developing a substance use disorder

- **Required** of physicians, PAs, APRNs, dentists, optometrists and podiatrists.

SBIRT CME mandate – AB442
2 hrs of training

SBIRT training consists of:

1. Screening to assess the severity of substance use and identify the appropriate level of treatment;
2. Brief intervention to increase awareness of the person's substance use and motivation to change his or her behavior; and
3. Referral to treatment for persons who need more extensive treatment and specialty care for substance use disorder

SBIRT CME mandate – AB442
2 hrs of training

Required of physicians, PAs, APRNs, dentists, optometrists and podiatrists

within 2 years after initial licensing

if licensed on January 1, 2024, must complete the 2 hours to renew license after that date

- A licensed physician may use SBIRT to satisfy CME in the substance use, addictive disorders and prescribing of opioids OR any requirement in ethics or pain management

SBIRT CME mandate – AB442
2 hrs of training

A physician, PA or APRN who holds a registration to treat opioid dependency with narcotic medications (Drug Addition Treatment Act of 2000) is exempt from SBIRT for the first license renewal after January 1, 2024.

After meeting the first SBIRT continuing education requirement, a physician, PA, APRN, dentist, optometrist or podiatrist can use either SBIRT credits or Opioid prescription and addiction CE for license renewal, but may not use SBIRT to satisfy required continuing education in ethics

SBIRT CME mandate – AB442
2 hrs of training

A physician, PA, or APRN who obtains a registration to treat opioid dependency with narcotic medications (Drug Addiction Treatment Act of 2000) is exempt from the training required for SBIRT for one period of licensure.

The Physician or PA may use such registration to satisfy 4 hours of the total number of hours of continuing education required by the licensing Board during one period of licensure.

Cultural Competency CME Mandate

AB327

A psychiatrist, PA supervised by a psychiatrist, nurse …must receive 2 hours of continuing education in cultural competency and diversity, equity and inclusion.

- This must address persons from different cultural backgrounds, including:

i. persons from various gender, racial and ethnic backgrounds; ii, persons from various religious backgrounds; iii, lesbian, gay, bisexual, transgender and questioning persons; iv, children and senior citizens; v, veterans; vi, persons with mental illness; vii, persons with an intellectual disability, developmental disability or physical disability; and viii, other populations designated by the applicable licensing Board.

Cultural Competency CME Mandate

AB327

- The biennial minimum 2 hours of instruction for each psychiatrist and each supervised PA may include the training provided pursuant to NRS 499.103.

NBME Existing Mandate to Report Violations

NRS 630.3062 The following acts, among others, constitute grounds for initiating disciplinary action or denying licensure:

6. **Failure to report any person** the licensee knows, or has reason to know, **is in violation of the provisions of this chapter or the regulations of the Board** within **30 days** after the date the licensee **knows or has reason to know** of the violation.

NRS 630.3062 The following acts, among others, constitute grounds for initiating disciplinary action or denying licensure:

3. Making or filing a report which the licensee knows to be false, **failing to file a** record or **report as required by law** or knowingly or willfully obstructing or inducing another to obstruct such filing.

NBOM Existing Mandate to Report Violations

NRS 633.511(1) The grounds for initiating disciplinary action pursuant to this chapter are:

(p) **Failure to report any person the licensee knows, or has reason to know, is in violation of the provisions of this chapter or the regulations of the Board within 30 days after the date the licensee knows or has reason to know of the violation.**

(o) Making or filing a report which the licensee knows to be false, **failing to file a record or report that is required by law** or knowingly or willfully obstructing or inducing another to obstruct the making or filing of such a record or report.

NRS 630.2535; NRS 631.344; NRS 632.2375; NRS 633.473; NRS 635.116; NRS 636.2881

Each (of the six) Board shall, by regulation, require each **practitioner certified or registered to dispense CS** to complete **2 hours of training relating to the misuse and abuse of CS, the prescribing of opioids or addiction during each relicensure period**.

These CMEs may be used to satisfy 2 hours of any continuing education requirement.

(FYI, AB 105, effective July 1, 2017, requires **2 CME** hours **every four (4) years** in **suicide prevention**.) By June 30, 2021, physicians, PAs, APRNs must comply.

NRS 639.23507

Practitioners treating patients for cancer, sickle cell disease, hospice, or palliative care are required to: satisfy *bone fide* patient rule, query PMP, obtain informed consent, which may be verbal, and issue a valid prescription.

A practitioner may issue a CS II, III, IV or an opioid in Schedule V for the treatment of a patient diagnosed with cancer or sickle cell disease or who is receiving hospice or palliative care without obtaining a patient utilization report if this will unreasonably delay care of the patient – obtain PMP later.

NRS 639.23507

PMP Mandate – Before initial CS prescription

Practitioner must obtain a PMP utilization report on the patient **before issuing** an **initial** prescription for a CS (II, III, IV) **and** at least **every 90 days** thereafter.

The practitioner shall:

a. Review the PMP (patient utilization) report, and
b. Determine whether the patient has been issued another prescription for the same CS for ongoing treatment; if so, the practitioner shall not prescribe the CS, **unless the practitioner determines that issuing the prescription is medically necessary.**

NRS 453.162; NRS 639.2353

Each prescription for Controlled Substances (CS) II, III, and IV must include:

i. DEA number of the prescriber
ii. ICD 10 diagnosis
iii. Fewest number of days to consume the quantity of CS prescribed; number of refills

(Example: Tylenol # 3, q. 4-6 h, 10 days. How many pills? 6 x 10 = 60)

Controlled Substances (CS) NOT for Pain (checklist)

- ✓ Check the PMP before prescribing , and every 90 days thereafter for same CS
- ✓ Review the PMP report
- ✓ Determine whether the patient has been issued another prescription for the same CS for ongoing treatment; if so, the practitioner shall **not** prescribe the CS, **unless it is medically necessary**
- ✓ Prescription: ICD 10 Diagnosis code; DEA # ; Minimum days to consume at maximum dosage

USING CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN

NRS 639.235

Before issuing an **initial** prescription for CS (II, III, IV) **for the treatment of pain**, a practitioner must:

1. Have established a **bone fide relationship** with the patient (a *bona fide* relationship between the patient and the person prescribing the controlled substance shall be deemed to exist if the **patient was examined in person, electronically, telephonically or by fiber optics, including, without limitation, through telehealth, within or outside this State or the United States by the person prescribing the controlled substances within the 6 months immediately preceding the date the prescription was issued**)

NRS 639.23911

Before issuing a prescription for a CS (II, III, IV) for the treatment of pain, a practitioner must:

2. Establish a **preliminary diagnosis** of the patient and a **treatment plan** tailored toward treating the pain of the patient and the cause of that pain;
3. Document in the MR the reasons for prescribing the CS instead of an alternative treatment that does not require the use of a CS;

NRS 639.23911, NRS 639.23912

Before issuing an initial prescription for CS (II, III, IV) for the treatment of pain, a practitioner must:

4. Perform an evaluation and risk assessment which must include:
   a. Obtaining and reviewing a **relevant medical history**
   b. Conducting a **physical exam directed to the source of the patient's pain and within the scope of practice of the practitioner**
   c. **If the prescription is for a quantity of a CS II, III, or IV that is intended to be used in not less than 30 days,**
      i. **Making** a good faith effort to obtain and review **any** MRs from **any other provider** who have provided care to the patient **that are relevant to the prescription, and**
      i. **Documenting** efforts to obtain the MRs and conclusions from review in the MR of the patient
   d. Assessing the **mental health** and **risk of abuse, dependency and addiction** of the patient using "methods supported by peer-reviewed scientific research and validated by a nationally recognized organization" (Beck's Depression Inventory; POMI)

BOP R047-18AP

Sec. 5(2) – "good faith effort" … practitioner may consider:

a. The time needed to provide care to the patient;
b. The nature of the practice of the practitioner; and
c. Whether **the benefit of prescribing the controlled substance without obtaining the medical record outweighs the risk of doing so**.

(no apparent conflict with other NRS statutes)

NRS 639.239112; NRS 639.23912

e. Obtain **informed consent** to use a CS for the treatment of pain from:
   i. The patient, if the patient is 18 years of age or older or legally emancipated and competent to give such consent;
   ii. The parent or guardian of a patient who is less than 18 years of age and not legally emancipated; or
   iii. The legal guardian of a patient of any age who has been adjudicated mentally incompetent.

NRS 639.23911; NRS 639.23912(2)

The **informed consent** must include, **where applicable,** information concerning:

1. potential risks and benefits of treatment using the CS
   - ➢ including if a form of the CS that is designed to deter abuse is available
   - ➢ the risks and benefits of using that form
2. proper use of the controlled substance
3. any alternative means of treating the symptoms of the patient and the cause of such symptoms
4. the important provisions of the treatment plan established for the patient

NRS 639.23011; NRS 639.23912(2)

The informed consent must include:

5. the risks of dependency, addiction and overdose during treatment using the CS
6. methods to safely store and legally dispose of the CS
7. the manner in which the practitioner will address requests for refills of the prescription
8. if the patient is a woman between 15 and 45
   - the risks to a fetus of chronic exposure to CS during pregnancy
   - the risks of fetal dependency on the CS and neonatal abstinence syndrome

NRS 639.23911; NRS 639.23912(2)

The informed consent must include:

9. if the CS is an opioid
   - the availability of an opioid antagonist without a prescription, and
   - if the patient is an unemancipated minor
     - the risks that the minor will abuse or misuse the CS or divert the CS for use by another person, and
     - ways to detect such abuse, misuse or diversion

NRS 639.23912(3)

A practitioner shall document a conversation in which a patient provided informed consent that meets the requirements … in the medical record of the patient.

If a patient provides informed written consent, the practitioner must include the document on which the informed consent is recorded in the medical record of the patient.

NRS 639.2391

Acute Pain Treatment with a CS – including an opioid

Unless the practitioner determines that the prescription is medically necessary, a practitioner shall not prescribe CS II, III, or IV for acute pain for more than 14 days and, if the CS is an opioid, and the patient has never been issued an opioid or it has been more than 19 days since initial prescription for an opioid, prescription may not exceed 90 MMEs per day.

NRS 639.23911

If **a practitioner** prescribes a CS (II, III, IV) for the treatment of pain, **the practitioner** shall not issue more than one additional prescription that increases the dose of the CS unless the practitioner meets with the patient, in person or using telehealth, to reevaluate the treatment plan.

Initial Prescription for CS (II, III, IV) for Pain

Same as not for pain list, plus: (checklist)

- ✓ Bone fide relationship
- ✓ If **acute pain:** CS for no more than 14 days; if prescribing an opioid, no more than 90 MMEs if opioid naïve, **unless medically necessary**
- ✓ Evaluation and risk assessment
  - i. **Relevant** medical history
  - ii. Physical exam **directed to the source of the patient's pain and within the scope of practice of the practitioner**
  - iii. **If the prescription is intended for 30 days or more**, document good faith effort to obtain and review prior **relevant** medical records, and document conclusions of review in patient's MRs

Initial Prescription for CS (II, III, IV) for Pain (checklist)

iv. Access mental health and risk of abuse, dependency, and addiction with qualifying tests

- ✓ Preliminary diagnosis and treatment plan to treat the patient's pain and the cause of the patient's pain
- ✓ Document in the MR the reasons for prescribing the CS instead of an alternative treatment that does not require the use of a CS

Initial Prescription for CS (II, III, IV) for Pain

- ✓ Obtain an **informed consent** to use a CS for the treatment of pain from the appropriate authority (person, parent, legal representative)
  - ✓ The informed consent must include, **when applicable,** the required elements, plus, if an opiate, four (4) additional elements, and recorded in patient's MR.
  - ✓ If the informed consent is written, included a copy in the patient MR.

No more than one increase in dose of the CS for pain unless re-evaluation of treatment plan in-person or using telehealth

BOP mandate (new)

The Board shall develop and disseminate to each professional licensing board that licenses a practitioner, other than a veterinarian, or **make available on the Internet website of the Board [of Pharmacy]** an explanation or a technical advisory bulletin to inform those professional licensing boards of the requirements of NRS 639.23507 and 639.2391 to 639.23916, inclusive, and any regulations adopted pursuant thereto. The Board shall update the explanation or bulletin as necessary to include any revisions to those provisions of law or regulations. The explanation or bulletin must include, without limitation, an explanation of the requirements that apply to specific controlled substances or categories of controlled substances.

NRS 639.23914
Pain Treatment using a CS for > 30 days

If a practitioner intends to prescribe a controlled substance (II, III, IV) for more than 30 days for the treatment of pain, the practitioner must, not later than 30 days after issuing the initial prescription, enter into a **prescription medication agreement** with the patient, which must be:

Documented in the patient s MRs; and updated at least once every 365 days while the patient is using the CS, or updated whenever a change is made to the treatment plan.

NRS 639.23914
Pain Treatment using a CS for > 30 days

A prescription medication agreement must include:

a. The **goals of the treatment** of the patient
b. **Consent** of the patient to testing to monitor drug use when deemed medically necessary by the practitioner;
c. A requirement that the patient take the CS only as prescribed;
d. A prohibition on sharing medication with any other person;

NRS 639.23914
Pain Treatment using a CS > 30 days

A **prescription medication agreement must include:**

e. A requirement that the patient inform the practitioner:
i. Of **any other CS prescribed to or taken** by the patient;
ii. **Whether the patient drinks alcohol or uses marijuana or any other cannabinoid** while using the CS
iii. Whether the patient has been treated for side effects or complications relating to the use of the CS, including whether the patient has experienced an overdose; and
iv. **Each state in which the patient has previously resided or had a prescription for a CS filled**;

NRS 639.23914
Pain Treatment using a CS > 30 days

A prescription medication agreement **must** include:

f. Authorization for the practitioner to conduct random counts of the amount of the CS in the possession of the patient;
g. The reason the practitioner may change or discontinue treatment of the patient using the CS; and
h. Any other requirements that the practitioner may impose.

Using a CS for the treatment of pain for >30 days

Prescription Medication Agreement

- ✓ must contain all 10 elements (plus any additional desired by the practitioner)
- ✓ must be renewed every 365 days, and updated after any change in the treatment plan

NRS 639.23913
Pain Treatment using a CS > 90 days

Before prescribing a CS (II, III, IV) to continue to treat pain for 90 days or more, a practitioner must:

a. Require the patient to complete an assessment of the patient's risk for abuse, dependency and addiction that has been validated through peer-reviewed scientific research; (COMM)
b. Conduct an investigation, including appropriate hematological and radiological studies, to determine an evidence-based diagnosis for the cause of the pain;

NRS 639.23913
Pain Treatment using a CS > 90 days

Before prescribing a CS (II, III, IV) to continue **to treat pain** for 90 days or more, a practitioner must:

c. Meet with the patient, in person or using telehealth, to review the treatment plan to **determine whether continuation of treatment using the CS is medically appropriate**; and
d. If the patient has been prescribed a dose of 90 MMEs or more of an **opioid** per day for 90 days or longer, consider referring the patient to **a specialist**

NRS 639.2391
Pain Treatment using a CS

If practitioner prescribes more than 365 days of CS pain medication (II, III, IV) in 365 days, practitioner must document in MR the reasons, or

for a larger quantity of CS (II, III, IV) than will be used in 90 days, the prescriber must document in the MR the reasons.

NRS 639.23913
Pain Treatment using an opioid

If the practitioner decides to continue to prescribe a dose of 90 MMEs or greater per day, the practitioner must develop and document in the patient's MRs a revised treatment plan which must include an assessment of the increased risk for adverse outcomes.

Using a CS (II, III, IV) for the treatment of Pain > 90 days
(checklist)

- ✓ complete another assessment for the patient's risk of abuse, dependency, or addiction (COMM test)
- ✓ conduct an investigation to determine an evidenced-based diagnosis for the cause of the pain
- ✓ meet with patient, in-person or telehealth, to determine whether continuation with a CS for the treatment of pain is medically appropriate
- ✓ if patient is on a dose of 90 MMEs or greater, consider referring to a specialist
- ✓ if continuing 90 MMEs or >, document in MR the revised treatment plan, including risk for adverse outcomes

NRS 453.164

- Board of Pharmacy (BOP) may access the PMP to identify any suspected fraudulent, illegal, unauthorized or otherwise inappropriate activity related to prescribing, dispensing, or use of a CS.
- Discovered information shall be reported to law enforcement or licensing board.
- Dispensing Licensees must present proof of authorization to access the PMP to be relicensed [by BOP for CS certificate].

To NRS 453 (Controlled Substances) the following section is added:

The authority of the Board [of Pharmacy] *to take disciplinary action to enforce the provisions of this chapter is not limited by the authority of any other regulatory body that may be authorized or required to take disciplinary action for the same conduct with respect to any license, registration, certificate or other professional designation issued and regulated by that regulatory body.*

BOP R013-18AP

Sec. 5. The Executive Secretary of the BOP may suspend or terminate, before a hearing, the Internet access of a practitioner or other person to the PMP if the practitioner or other person accesses the database in violation …

NRS 630.323; NRS 631.364; NRS 632.352; NRS 633.574; NRS 635.152; NRS 636.338

If **licensing Board Executive Director (ED)** receives complaint from law enforcement, BOP, or any other source, that the licensee has:

- has issued a fraudulent, illegal, unauthorized or inappropriate CS prescription, or
- a pattern of such prescribing, or
- a patient (of the licensee) who has acquired, used or possessed a CS (II thru IV) as above, then:

"review and evaluation"
NRS 630.323; NRS 631.364; NRS 632.352; NRS 633.574; NRS 635.152; NRS 636.338

- ED, or designee, must notify licensee as soon as practicable (may delay notification if criminal investigation ongoing)
- **ED, or designee**, reviews PMP licensee's information
- After "**review and evaluation**," if ED, or designee, determines that the licensee may have issued a fraudulent, illegal, unauthorized or inappropriate prescription, the **ED, or designee, may refer for criminal prosecution** & **the Board must proceed as if a written complaint had been filed against the licensee**.
- After conducting an investigation and a hearing, if licensee is found guilty, the licensing Board must impose appropriate disciplinary action, to include additional CMEs.

NRS 630.323; NRS 631.364; NRS 632.352; NRS 633.574; NRS 635.152; NRS 636.338

If the Board determines from investigation that the public health, safety, or welfare, of any patient is at risk of imminent or continued harm, the Board may summarily suspend licensee's authority to prescribe CS (II, III, IV) pending a determination upon the conclusion of a hearing to consider a formal complaint against the licensee.

NRS 630.323; NRS 631.364; NRS 632.352; NRS 633.574; NRS 635.152; NRS 636.338

The licensing Board must hold a hearing and render a decision **concerning [whether to file] the formal complaint** within **60 days** of the summary suspension order for the Medical Board, Nursing Board, Podiatric Board, and Optometric Board,

Or, within **180 days** for Osteopathic Medical Board and Dental Board.

Touro University Nevada

NRS 630.323; NRS 631.364; NRS 632.352; NRS 633.574; NRS 635.152; NRS 636.338

The licensing Board shall adopt regulations providing for disciplinary action against a licensee for inappropriately prescribing a CS (II, III, IV) or violation of any statutes or regulations of the BOP, to include additional continuing education concerning prescribing CS II, III, IV.

Touro University Nevada

NRS 630.23916

The BOP may adopt any regulations necessary or convenient to enforce the provisions of NRS 639. Such regulations may impose additional requirements concerning the prescription of CS II, III, IV **for the treatment of pain.**

A practitioner who violates any provision of this act or any furthering regulations is:

a. Not guilty of a misdemeanor; and [is]
b. Subject to professional discipline.

Touro University Nevada

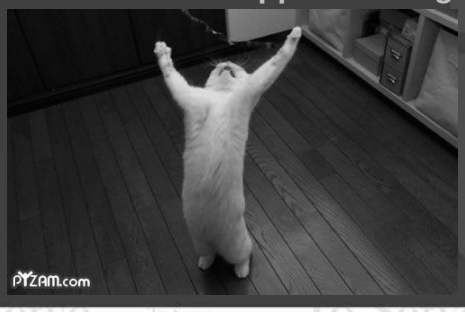
In Summary, AB239 (2019)

- Mandates for initial prescription for all controlled substances – materially improved
- Mandates for prescribing controlled substances for pain less than 30 days – materially improved
- Mandates for prescribing controlled substances for 30 days or more – no significant change

- The **BOP** now has authority to independently discipline licensees of other Boards as to their CS certificate

Touro University Nevada

Thank God He Stopped Talking!!!



Touro University Nevada

Nevada Academy of Family Physicians
32nd Annual Summer CME Meeting
July 30–August 1, 2021

NOTES

Nevada Academy of Family Physicians
32nd Annual Summer CME Meeting
July 30–August 1, 2021

What is New in Psychopharmacology for Primary Care Physicians to Know?

Presented by:
Mujeeb U. Shad, MD, MSCS

Approved for 1.0 Prescribed CME

Visit nvafp.com for any available handouts

Friday, July 30, 2021
10:15—11:15am

Nevada Academy of Family Physicians
32nd Annual Summer CME Meeting
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Nevada Academy of Family Physicians
32nd Annual Summer CME Meeting
July 30–August 1, 2021

Pre-Operative Clearance

Presented by:
Gaurav Zirath, MD, MBA

Approved for 1.0 Prescribed CME

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Friday, July 30, 2021
11:15am—12:15pm

Nevada Academy of Family Physicians
32nd Annual Summer CME Meeting
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32nd Annual Summer CME Meeting
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Management of Hyperlipidemia in the Family Medicine Setting

Presented by:
Michael J. Bloch, MD, FACP, FASH

Approved for 1.0 Prescribed CME

Friday, July 30, 2021
1:30—2:30pm

Nevada Academy of Family Physicians • 705 Tahoe St., Ste. A, Reno, NV 89509
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Management of Hyperlipidemia in the Family Medicine Setting

Diagnosis, Management, and the Role of Emerging Lipid-Lowering Therapies

Michael J. Bloch, MD, FAHA, FASH, FNLA, FSVM, FACP
Associate Professor, University of Nevada School of Medicine
Medical Director, Renown Vascular Care
Renown Institute for Heart and Vascular Health
President, Blue Spruce Medical Consultants, PLLC
Reno, Nevada

Disclosures

Michael J. Bloch, MD, FAHA, FASH, FNLA, FSVM, FACP, has a financial interest/relationship or affiliation in the form of:

Consultant and/or Advisor for Amarin Corporation; Amgen Inc.; Bristol Meyers Squibb; Esperion Therapeutics, Inc.; Janssen Pharmaceuticals, Inc.; Medtronic; Novartis Pharmaceuticals Corporation; and ReCor Medical, Inc.
Grant/Research Support from ReCor Medical, Inc.
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Housekeeping Notes

Thank you to Penn State University and PVI, PeerView Institute for Medical Education for providing this session, and to Novartis Pharmaceuticals Corporation for providing the educational grant for this activity.

You should have received a link to the online evaluation or a printed copy of the program evaluation.

Evaluation: **PeerView.com/Hyperlipidemia-Survey-UCU**

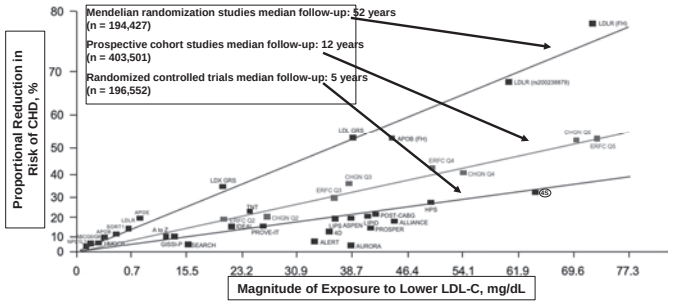
Your evaluation of the program is very important in helping us to better meet your current and future medical education needs. We welcome your opinions and comments.

Please feel free to ask questions at the end of the presentation

Early Detection and Diagnosis of Hyperlipidemia

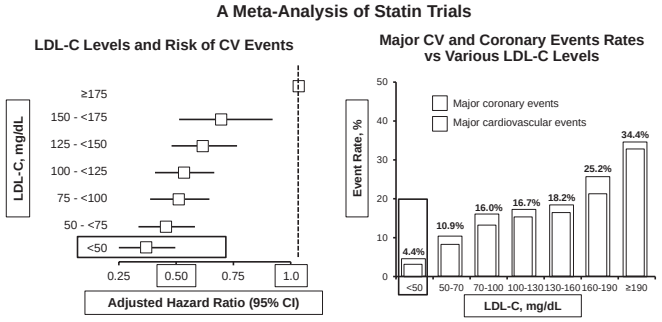
Current Standards of Care, Guideline Recommendations, and Unmet Needs

Genetics, Interventional, Observational Data[1]



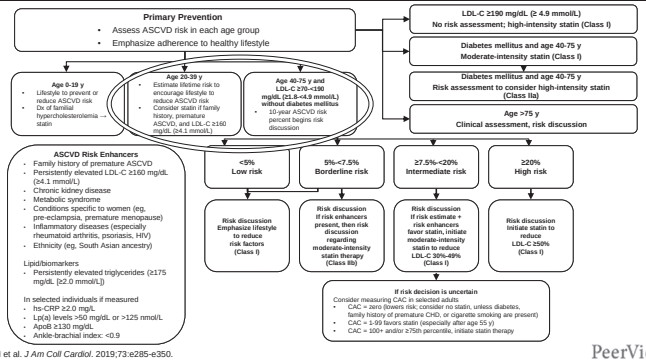
1. Ference BA et al. *Eur Heart J.* 2017;38:2459-2472.

Very Low Levels of Atherogenic Lipoproteins and the Risk of Cardiovascular Events[1]



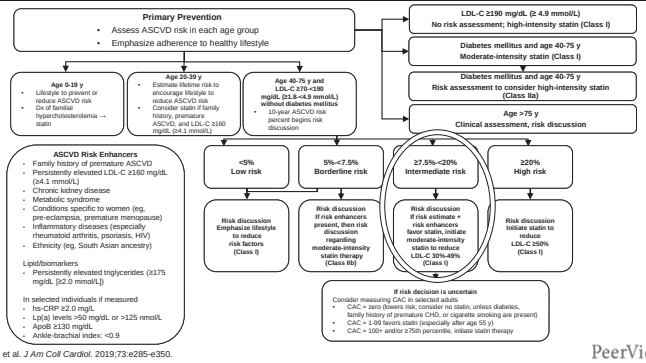
1. Boekholdt S et al. *J Am Coll Cardiol.* 2014;64:485-494.

2018 Blood Cholesterol Guidelines: Role of Risk Estimation in Primary Prevention[1]



1. Grundy SM et al. *J Am Coll Cardiol.* 2019;73:e285-e350.

2018 Blood Cholesterol Guidelines: Role of Risk Estimation in Primary Prevention[1]



1. Grundy SM et al. *J Am Coll Cardiol.* 2019;73:e285-e350.

Using 10-Year ASCVD Risk Estimate Plus CAC Score to Guide Statin Therapy[1]

Patient's 10-Year ASCVD Risk Estimate	<5%	5%-7.5%	>7.5%-20%	>20%
Consulting ASCVD risk estimate alone	Statin not recommended	Consider for statin	Recommend statin	Recommend statin
Consulting ASCVD risk estimate + CAC				
If CAC score = 0	Statin not recommended	Statin not recommended	Statin not recommended	Recommend statin
If CAC score > 0	Statin not recommended	Consider for statin	Recommend statin	Recommend statin
Does CAC score modify treatment plan?	CAC not effective for this population	CAC can reclasssify risk up or down	CAC can reclasssify risk up or down	CAC not effective for this population

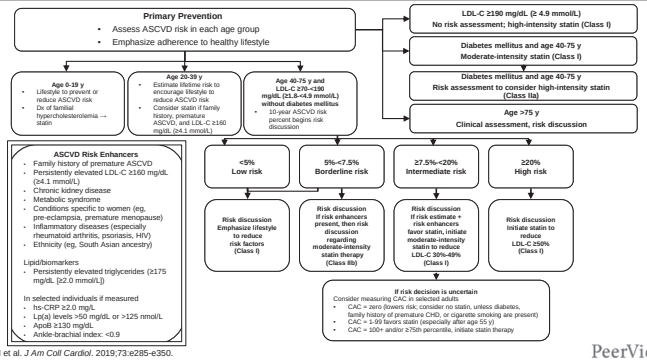
1. Greenland P et al. *J Am Coll Cardiol*. 2018;72:434-447.

2018 Blood Cholesterol Guidelines: Candidates for CAC Measurement Who Might Benefit From Knowing Their CAC Score Is Zero[1]

- Patients reluctant to initiate statin who wish to understand their risk and potential for benefit more precisely
- Patients concerned about need to reinstitute statin therapy after discontinuation for statin-associated symptoms
- Older patients (men 55-80 y of age; women 60-80 y of age) with low burden of risk factors who question whether they would benefit from statin therapy
- Middle-aged adults (40-55 y of age) with PCE-calculated 10-year risk for ASCVD 5% to <7.5% with factors that increase their ASCVD risk, although they are in a borderline risk group

1. Grundy SM et al. *J Am Coll Cardiol*. 2019;73:e285-e350.

2018 Blood Cholesterol Guidelines: Role of Risk Estimation in Primary Prevention[1]



1. Grundy SM et al. *J Am Coll Cardiol*. 2019;73:e285-e350.

A Heart-Healthy Lifestyle[1]

In all individuals, emphasize a heart-healthy lifestyle across the lifespan

- A healthy lifestyle reduces ASCVD risk at all ages
- In younger individuals, a healthy lifestyle can reduce development of risk factors and is the foundation of ASCVD risk reduction
- In young adults aged 20-39 years, an assessment of lifetime risk facilitates the clinician-patient risk discussion and emphasizes intensive lifestyle efforts
- In all age groups, lifestyle therapy is the primary intervention for the metabolic syndrome

1. Grundy SM et al. *J Am Coll Cardiol*. 2019;73:e285-e350.

2018 Blood Cholesterol Guidelines: Patients Who Need Primary Prevention[1]

- **Severe hypercholesterolemia**
  Do not need risk-reduction scoring
- **Patients with diabetes**
  Role of assessing ASCVD risk
- **Risk-reduction evaluation in patients without diabetes or severe hypercholesterolemia**

1. Grundy SM et al. *J Am Coll Cardiol*. 2019;73:e285-e350.

Patients With Primary Severe Hypercholesterolemia (LDL-C Levels ≥190 mg/dL)[1]

- **Clinically diagnosed**
  - Patients with primary severe hypercholesterolemia (LDL-C levels ≥190 mg/dL [≥4.9 mmol/L]) have a high risk of ASCVD and premature and recurrent coronary events
  - Dutch Lipid Clinic Network, Simon Broome, MEDPED, AHA criteria
  - FH Diagnosis app
- **Genetically diagnosed**
  - Increased risk with positive mutation
- **No FH diagnosis with LDL >220 mg/dL**
  - Very high risk and warrants aggressive LDL-lowering therapy

1. Grundy SM et al. *J Am Coll Cardiol*. 2019;73:e285-e350.

Criteria for the Clinical Diagnosis of FH[1]

USA: MEDPED Criteria

Age, y	Total Cholesterol (and LCL-C) Levels, mg/dL				Risk
	First-Degree Relative	Second-Degree Relative	Third-Degree Relative	General Population	
<18	220 (155)	230 (165)	240 (170)	270 (200)	
20	240 (170)	250 (180)	260 (185)	290 (220)	98% specificity
30	270 (190)	280 (200)	290 (210)	340 (240)	87% specificity
40+	290 (205)	300 (215)	310 (225)	360 (260)	

UK: Simon Broome Criteria

Total Cholesterol (and LCL-C) Levels, mg/dL	Plus	Risk
Adults: 290 (190) mg/dL	DNA mutation	Definite FH
	Tendon xanthomas in the patient or first- or second-degree relative	Definite FH
Children: 260 (155) mg/dL	Family history of MI at age <50 in a second-degree relative or at age <60 in a first-degree relative, or family history of total cholesterol >290 mg/dL in an adult first- or second-degree relative or 260 (155) mg/dL in a child or sibling aged <16 y	Possible FH

The Netherlands: Dutch Lipid Clinic Criteria

Rating (Points)	Feature	Risk
1	First-degree relative with premature CVD or LDL-C >95th percentile, or personal history of premature peripheral or cerebrovascular disease, or LDL-C 155-189 mg/dL	
2	First-degree relative with tendinous xanthoma or corneal arcus, or first-degree relative child (<18 y) with LDL-C >95th percentile, or personal history of CAD	
3	LDL-C 190-249 mg/dL	
4	Presence of corneal arcus in patients <45 y	Possible FH
5	LDL-C 250-329 mg/dL	
6	Presence of tendon xanthomas	Probable FH
7		
≥8	LDL-C >330 mg/dL, or functional mutation in the *LDLR* gene	Definite FH

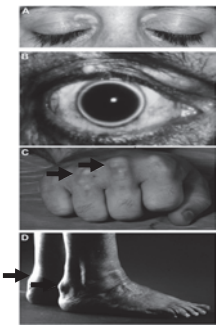
1. Hovingh GK et al. *Eur Heart J*. 2013;34:962-971.

FH Diagnostic Categories[1]

ICD-10 Category	Clinical Criteria	With Genetic Testing Performed
Heterozygous FH	• LDL-C ≥160 mg/dL (4 mmol/L) for children and ≥190 mg/dL (5 mmol/L) for adults and with one first-degree relative similarly affected or with premature CAD or with positive genetic testing for an LDL-C–raising gene defect (LDL receptor, apoB, or PSCK9)	• Presence of one abnormal LDL-C–raising gene defect (LDL receptor, apoB, or PSCK9) • Diagnosed as heterozygous FH if gene-raising defect positive and LDL-C <160 mg/dL (4 mmol/L) • Occasionally, heterozygotes will have LDL-C >400 mg/dL (10 mmol/L); they should be treated similarly to homozygotes • Presence of both abnormal LDL-C–raising gene defect(s) (LDL receptor, apoB, or PSCK9) and LDL-C–lowering gene variant(s) with LDL-C <160 mg/dL (4 mmol/L)
Homozygous FH	• LDL-C ≥400 mg/dL (10 mmol/L) and one or both parents having clinically diagnosed FH, positive genetic testing for an LDL-C–raising gene defect (LDL receptor, apoB, or PSCK9), or autosomal-recessive FH • If LDL-C >560 mg/dL (14 mmol/L) or LDL-C >400 mg/dL (10 mmol/L) with aortic valve disease or xanthomata at <20 y of age, homozygous FH highly likely	• Presence of two identical (true homozygous FH) or nonidentical (compound heterozygous FH) abnormal LDL-C–raising gene defects (LDL receptor, apoB, or PSCK9); includes the rare autosomal-recessive type • Occasionally, homozygotes will have LDL-C <400 mg/dL (10 mmol/L)
Family history of FH	• LDL-C level not a criterion; presence of a first-degree relative with confirmed FH	• Genetic testing not performed

1. Gidding S et al. *Circulation*. 2015;132:2167-2197.

Visible Signs of FH[1]



Bilateral xanthelasma (<25 y of age)

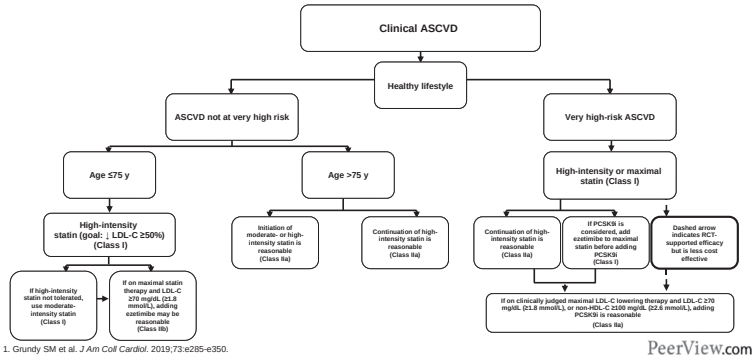
Bilateral corneal arcus (<45 y of age)

Extensor tendon xanthoma of hand (any time)

Extensor tendon xanthoma of achilles (any time)

1. Genest J et al. *Can J Cardiol*. 2014;30:1471-1481.

Secondary Prevention: 2018 AHA/ACC Cholesterol Guidelines[1]



1. Grundy SM et al. *J Am Coll Cardiol*. 2019;73:e285-e350.

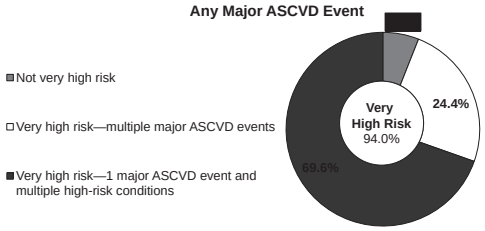
Very High-Risk ASCVD[1]

Major ASCVD Events
Recent ACS (within the past 12 mo)
History of MI (other than recent ACS event listed above)
History of ischemic stroke
Symptomatic PAD (history of claudication with ABI <0.85, or previous revascularization or amputation)
High-risk conditions
High-Risk Conditions
Age ≥65 years
Heterozygous familial hypercholesterolemia
History of prior coronary artery bypass surgery or percutaneous coronary intervention outside of the major ASCVD event(s)
Diabetes mellitus
Hypertension
CKD (eGFR 15-59 mL/min/1.73 m^2)
Current smoking
Persistently elevated LDL-C (LDL-C ≥100 mg/dL [≥2.6 mmol/L]) despite maximally tolerated statin therapy and ezetimibe
History of CHF

"Very high risk" includes a history of multiple major ASCVD events *or* 1 major ASCVD event and multiple high-risk conditions

1. Grundy SM et al. *Circulation*. 2019;139:e1082-e1143.

Link Between Major ASCVD Events and the "Very High Risk" Category of the 2018 AHA/ACC Cholesterol Guidelines[1]



Percentage of patients who met the "very high risk" definition

- 94.0% of all patients with any major ASCVD event
- 100% of patients with 2 or more prior major ASCVD events
- 92.1% of patients with 1 prior major ASCVD event

94% of patients with a recent ACS, history of MI, ischemic stroke, or symptomatic PAD meet the 2018 AHA/ACC cholesterol guidelines' definition of "very high risk"

1. Muntner P et al. *Cardiovasc Drugs Ther*. 2021 Mar 4 [Epub ahead of print].

Lowering LDL-C Reduces ASCVD[1,2]

Study	Statin	Mean Baseline LDL-C, mg/dL	Mean LDL-C Reduction, %	% Reduction in Coronary Events
Primary Prevention				
WOSCOPS	Pravastatin 40 mg	192	26	31 (P < .001)
AFCAPS/TEXCAPS	Lovastatin 20-40 mg	150	25	37 (P < .001)
ASCOT	Atorvastatin 10 mg	133	35	36 (P < .001)
HOPE-3	Rosuvastatin 10 mg	128	26	24 (P < .002)
JUPITER	Rosuvastatin 20 mg	108	44	44 (P < .000001)
Secondary Prevention				
4S	Simvastatin 20-40 mg	188	35	34 (P < .0001)
CARE	Pravastatin 40 mg	139	32	24 (P = .003)
LIPID	Pravastatin 40 mg	150	25	24 (P < .0001)

Landmark statin clinical trials show that LDL-C is *strongly* associated with increased CVD risk

CTTC meta-analysis showed that for every 1 mmol/L (38.7 mg/dL) reduction in LDL-C, there is a 20%-25% reduction in major CV endpoints
Statins are the mainstay of therapy!

1. Maron DJ et al. *Circulation*. 2000;101:207-213. 2. Cholesterol Treatment Trialists Collaboration. *Lancet*. 2010;376:1670-1681.

Statin-Associated Side Effects[1]

The 2018 ACC/AHA Multisociety Cholesterol Guideline preferred the label *statin-associated side effects* because a "large majority of patients are able to tolerate statin rechallenge with an alternative statin or alternative regimen, such as reduced dose or in combination with nonstatins." In patients at increased ASCVD risk with severe statin-associated muscle symptoms or recurrent statin-associated muscle symptoms despite appropriate rechallenge, it is reasonable to use RCT-proven nonstatin therapy that is likely to provide net clinical benefit

— Class of Recommendation IIa; Level of Evidence B-R

1. Grundy SM et al. *Circulation*. 2019;139:e1082-e1143.

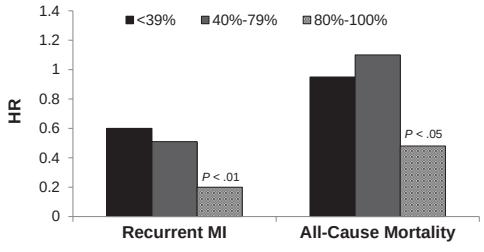
Frequency of Statin-Associated Side Effects[1,2]

Side Effect	Frequency
Myalgia	Infrequent (1%-5%) in RCTs; frequently reported (5%-20%) in clinical settings
New-onset type 2 diabetes mellitus	Dependent on presence of DM risk factors
Myositis/myopathy, rhabdomyolysis	Rare
Elevated liver transaminases	Rare or infrequent
Hepatic failure	Rare
Memory/cognition	Rare

1. Grundy SM et al. *Circulation*. 2019;139:e1082-e1143. 2. Newman CB et al. *Arterioscler Thromb Vasc Biol*. 2019;39:e38-e81.

Effect of Statin Adherence[1,2]

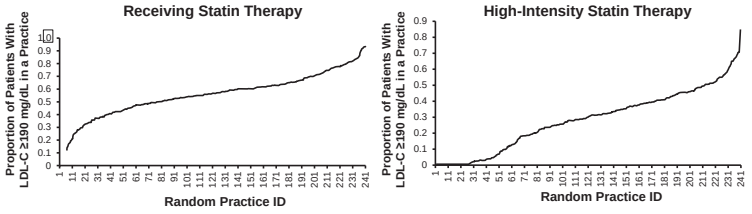
Effect of Statin Adherence in Patients With History of MI, N = 15 trials
3 levels of adherence compared with no statin therapy



Only adherence ≥80% was associated with significant reductions in risk of recurrent MI and all-cause mortality

1. Wei L et al. *Heart*. 2002;88:229-233. 2. Simpson RJ et al. *J Clin Lipidol*. 2010;4:462-471.

Heterogeneity of Usage of Lipid-Lowering Therapies[1]



Provider-level variables (physician vs APP); **practice-level variables** (geographical location of the practice, number of years that the practice is participating in the PINNACLE registry); **patient-level variables** (age, sex, insurance status [private vs public, vs others], history of hypertension, diabetes, smoking, history of ischemic heart disease, ischemic stroke, or PAD)

1. Virani SS et al. *Circ Cardiovasc Qual Outcomes*. 2018;11:e004652.

Patients With a Prior Event Are Suboptimally Managed

- From a national survey in the **GOULD** registry, **67%** of physicians believe in lowering LDL-C to <50 mg/dL (11% to <70 mg/dL)[1]
- **However, <30% below 70 mg/dL and <10% below 55 mg/dL with limited combination prescription**

GOULD	MI ≤1 Year (n = 259)
High-intensity statin	61.8%
Ezetimibe	8.5%
PCSK9i	3.1%

- **SWEDEHEART** national registry of LDL-C lowering therapies post-ACS[2]

SWEDEHEART: Stepwise Treatment	Actual Registry Data	Theoretical Application of 2019 ESC/EAS Guidelines
High-intensity statin	87%	100%
Ezetimibe	3%	76%
PCSK9i	0.02%[a]	51%

[a] 13/44,890 prospective patients; excluded from the analysis because so few.
1. Arnold SV. *JAMA Netw Open*. 2020;3:e203032. 2. Ballantyne CM, Virani SS. *Eur Heart J*. 2020;41:3910-3912.

Evidence-Based Statin Use in Patients With LDL-C >190 mg/dL in PINNACLE Registry (N = 49,447 in 241 Practices)[1]

Therapy	n (%)
Statin use	28,950 (58.5%)
High-intensity statin use	15,791 (32%)
Ezetimibe use	4,194 (8.5%)
PCKS9i use	732 (1.5%)
Statin and ezetimibe	3,070 (6.2%)
Statin and PCSK9i	342 (0.7%)
Statin, ezetimibe, and PCSK9i	157 (0.32%)

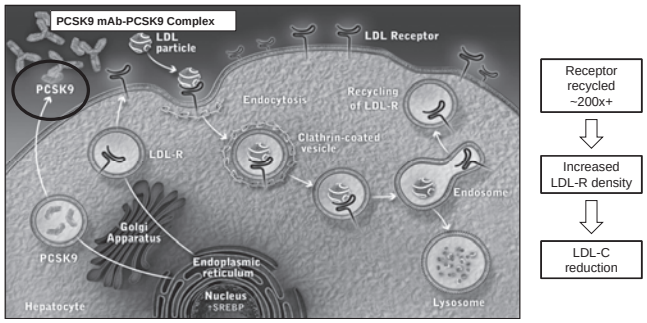
1. Virani SS et al. *Circ Cardiovasc Qual Outcomes*. 2018;11:e004652.

Guideline Recommendations vs Current Practice

- Evidence and new guidelines have advanced much faster than practice patterns of most recent registry and real-world data
- High-risk patients are frequently not on high-intensity statin therapy and have persistent elevations of LDL-C
- Increased evidence of nonstatin therapy to lower LDL-C further have led to changes in all major guidelines, but there is very little utilization in clinical practice of combination therapy for lipids despite extensive use for HTN and DM

Currently Approved and Emerging Lipid-Lowering Therapies
The Latest Evidence and Practice-Based Recommendations

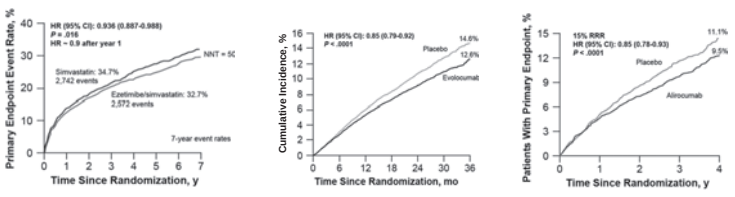
Impact of PCSK9 Inhibitors on LDL Receptor Expression[1]



1. Blanchard V et al. *Pathology*. 2019;51:177-183.

Additive Risk Reduction Using Nonstatin Agents

IMPROVE-IT[1] | **FOURIER[2]** | **ODYSSEY OUTCOMES[3]**



1. Cannon CP et al; IMPROVE-IT Investigators. *N Engl J Med*. 2015;372:2387-2397. 2. Sabatine MS et al; FOURIER Steering Committee and Investigators. *N Engl J Med* 2017;376:1713-1722. 3. Schwartz GG et al; ODYSSEY OUTCOMES Committees and Investigators. *N Engl J Med*. 2018;379:2097-2107.

Getting LDL-C to <70 mg/dL[1]

- Cohort of 631,855 patients with ASCVD, aged 40-85 y from the VA system, meeting FOURIER study criteria
  - 49.9% were on high-intensity statins
  - 47.5% were on moderate-intensity statins
  - 2.6% were on a statin/ezetimibe combination

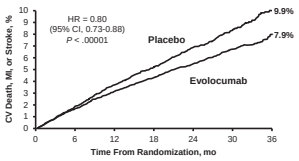
Predicted Percent With LDL-C <70 mg/dL With Treatment Intensification	
Titration to high-intensity statin therapy alone	18.7%
Addition of ezetimibe therapy alone	50.7%
Titration to high-intensity statin therapy plus ezetimibe use	59.8%

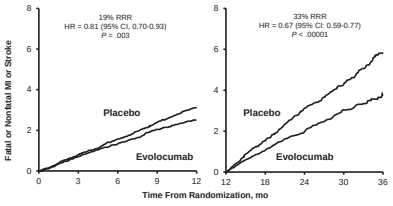
1. Virani SS et al. *Circulation*. 2017;135:2572-2574.

FOURIER Trial: Landmark Analysis[1,2]

- 27,564 high-risk patients with established CV disease (prior MI, prior stroke, or symptomatic PAD) and LDL-C ≥70 mg/dL or non-HDL-C ≥100 mg/dL
- Randomized to evolocumab (140 mg Q2W or 420 mg QMO) or placebo (Q2W or QMO) for a median of 26 mo

Key Secondary Endpoint:
CV Death, MI, or Stroke



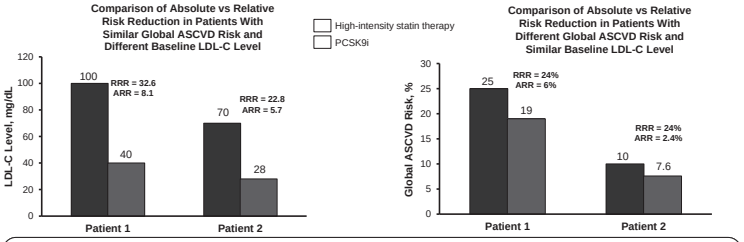


1. Sabatine MS et al. *N Engl J Med*. 2017;376:1713-1722 2. Sabatine MS et al; FOURIER Steering Committee & Investigators. 2017 American College of Cardiology Annual Meeting (ACC 2017).

What Have We Learned From Subsequent Analyses of PCSK9 Inhibitor Outcomes Trials?

- Reduction in total/recurrent CV events
- Evidence of safety of very low levels of LDL-C
- Clinical evidence from subanalyses regarding outcomes benefits
- Identify higher-risk patients who have demonstrated benefit with PCSK9i therapy

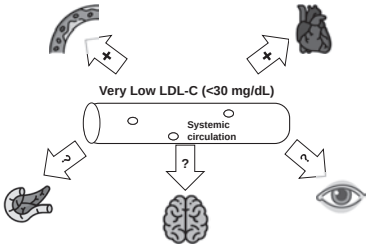
Rationale for Pushing LDL-C Levels Even Lower[1]



- **Lower achieved LDL-C levels correlate with a decreased burden of atherosclerosis and better clinical outcomes in secondary prevention**
- **The concern for adverse effects with very low LDL-C levels is not backed by the literature, and side effects appear to be medication specific**

1. Bayoumy K et al. *Curr Cardiovasc Risk Rep*. 2019;13:23.

How Low Is Safe? The Frontier of Very Low LDL-C (<30 mg/dL)[1]



Benefits
- Coronary atherosclerotic plaque regression
- Statistically significant reduction in the composite of
  - Cardiovascular death
  - Myocardial infarction
  - Ischemic stroke
  - Coronary revascularization
  - Unstable angina

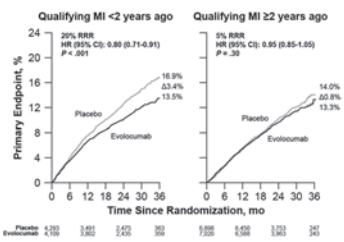
Potential Side Effects
- **New-onset diabetes mellitus:** Possible association; long-term follow-up is required
- **Hemorrhagic (intraparenchymal) stroke:** Possible association; long-term follow-up is required
- **Cataract:** Unclear is there is a true association; long-term follow-up is required
- No data support any association with cancer, hepatobiliary toxicity, neurocognitive impairment, hypogonadism, hematuria

There is a paucity of data on the benefits and safety of attaining and maintaining LDL-C <15 mg/dL over the long term

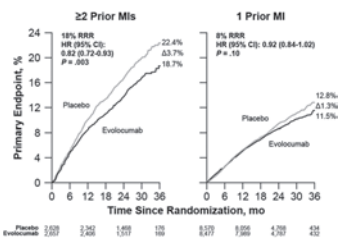
1. Karagiannis AD et al. *Eur Heart J*. 2021 Jan 19 [Epub ahead of print].

FOURIER: Evolocumab Benefit by Extent of Timing and Number of MIs[1]

Greater Benefit Among Patients With MI <2 Years Ago



Greater Benefit Among Patients With Multiple MIs



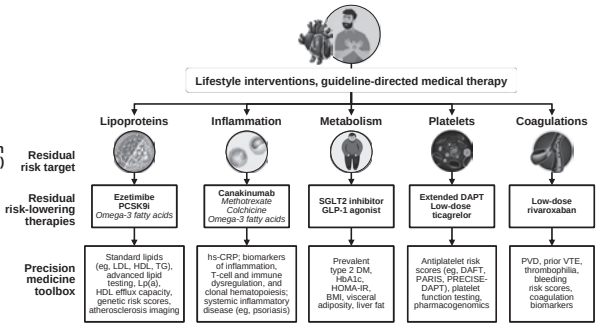
1. Sabatine MS et al. *Circulation*. 2018;138:756-766.

Current and Novel Emerging Therapeutic Options for LDL Lowering and ASCVD Risk Reduction[1]

Current Nonstatin Therapies
- Ezetimibe
- Bile acid sequestrants
- PCSK9is
- **BA**
- **AngPTL3 inhibition (evinacumab-dgnb)**

Icosapent Ethyl

Emerging Options
- **Inclisiran**
- **Lipoprotein(a) reduction**

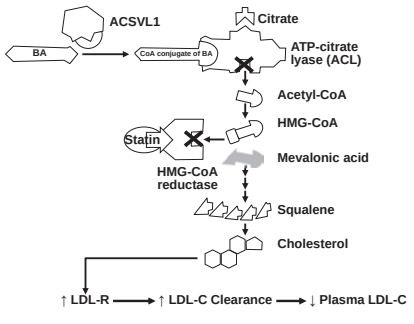


1. Patel KV et al. *Circulation*. 2018;137:2551-2553.

Bempedoic Acid Mechanism of Action

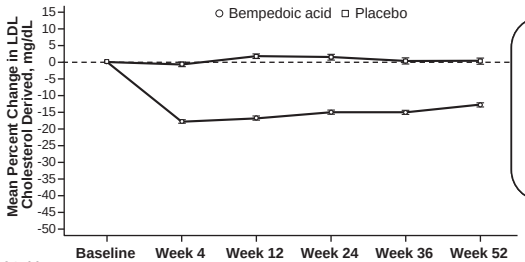
Converted to the CoA Conjugate of Bempedoic Acid, the Active Form, Only in Liver

- BA acts in same cholesterol biosynthesis pathway as statins
- BA targets ACL, an enzyme upstream of HMG-CoA reductase
- Upregulates LDL receptors and lowers LDL-C
- Specific isozyme (ACSVL1) that converts BA into an active drug is not present in skeletal muscle



1. Ray KK et al; CLEAR Harmony Steering Committee. European Society of Cardiology 2018 Congress (ESC 2018).

Mean % Change From Baseline in LDL-C Over 52 Weeks in Patients With ASCVD or HeFH: Bempedoic Acid vs Placebo[1,2]



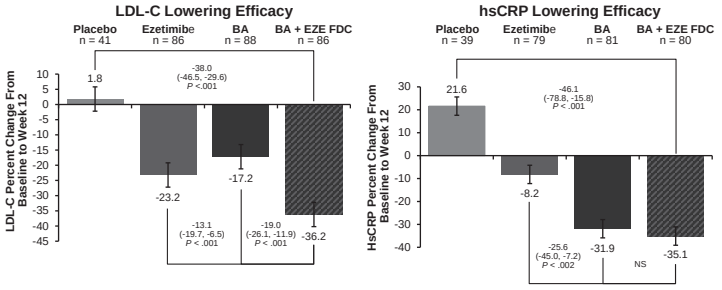
No. of Subjects	Baseline	Week 4	Week 12	Week 24	Week 36	Week 52
Bempedoic acid	2,010	1,934	1,922	1,882	1,491	1,831
Placebo	999	980	978	954	756	922

FDA-approved as adjunct to diet and maximally tolerated statin therapy for treatment of adults with HeFH or established ASCVD who require additional LDL-C lowering

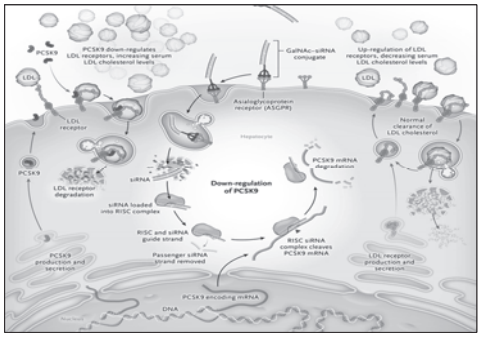
1. Nexletol (bempedoic acid) Prescribing Information. https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/211616s000lbl.pdf. 2. Ray KK et al; CLEAR Harmony Steering Committee. ESC 2018.

Fixed-Dose Bempedoic Acid/Ezetimibe[1]

- Phase 3 study
- N = 301 with HeFH or ASCVD randomized to placebo, ezetimibe, BA, or BA/EZE



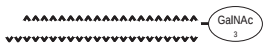
1. Ballantyne CM et al. *Eur J Prev Cardiol*. 2020;27:593-603.



GalNAc-siRNA Conjugates Facilitate Rapid Hepatic Uptake[1]

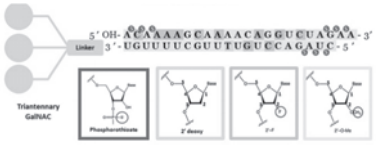
Asialoglycoprotein Receptor (ASGPR)

- Highly expressed in hepatocytes only
- High rate of uptake



Inclisiran

- siRNA conjugated to N-acetylgalactosamine
- Subcutaneous administration
- Targeted delivery to hepatocytes



1. Zimmermann TS et al. *Mol Ther*. 2017;25:71-78.

Inclisiran[1,2]

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Two Phase 3 Trials of Inclisiran in Patients with Elevated LDL Cholesterol

Kausik K. Ray, M.D., M.Phil., R. Scott Wright, M.D., David Kallend, M.D., Wolfgang Koenig, M.D., Lawrence A. Leiter, M.D., Frederick J. Raal, Ph.D., Jenna A. Bisch, B.A., Tara Richardson, B.A., Mark Jaros, Ph.D., Peter L.J. Wijngaard, Ph.D., and John J.P. Kastelein, M.D., Ph.D., for the ORION-10 and ORION-11 Investigators*

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

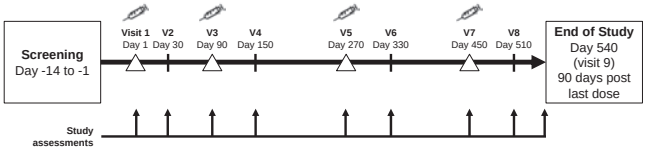
Inclisiran for the Treatment of Heterozygous Familial Hypercholesterolemia

Frederick J. Raal, M.D., Ph.D., David Kallend, M.B., B.S., Kausik K. Ray, M.D., M.Phil., Traci Turner, M.D., Wolfgang Koenig, M.D., R. Scott Wright, M.D., Peter L.J. Wijngaard, Ph.D., Danielle Curcio, M.B.A., Mark J. Jaros, Ph.D., Lawrence A. Leiter, M.D., and John J.P. Kastelein, M.D., Ph.D., for the ORION-9 Investigators*

1. Ray KK et al; ORION-10 and ORION-11 Investigators. *N Engl J Med*. 2020;382:1507-1519.
2. Raal FJ et al; ORION-9 Investigators. *N Engl J Med*. 2020;382:1520-1530.

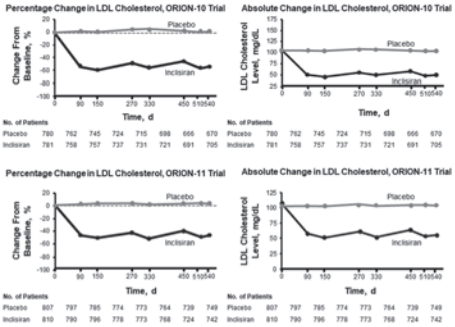
Study Design: ORION-10 and ORION-11[1]

Randomized 1:1 Inclisiran 300 mg vs Placebo – With Maximally Tolerated Statins



1. Ray KK et al. *N Engl J Med*. 2020;382:1507-1519.

Efficacy of Inclisiran in ORION-10 and ORION-11[1]



1. Ray KK et al. *N Engl J Med*. 2020;382:1507-1519.

Safety: ORION-10 and ORION-11[1]

Parameter	ORION-10		ORION-11	
	Placebo (n = 778)	Inclisiran (n = 781)	Placebo (n = 804)	Inclisiran (n = 811)
AEs, n (%)	582 (74.8)	574 (73.5)	655 (81.5)	671 (82.7)
≥1 event leading to treatment discontinuation	17 (2.2)	19 (2.4)	18 (2.2)	23 (2.8)
≥1 serious AE, n (%)	205 (26.3)	175 (22.4)	181 (22.5)	181 (22.3)
Fatal AE	11 (1.4)	12 (1.5)	15 (1.9)	14 (1.7)
Death from CV causes	5 (0.6)	7 (0.9)	10 (1.2)	9 (1.1)
Cancer-related death	3 (0.4)	1 (0.1)	3 (0.4)	3 (0.4)
New, worsening, or recurrent cancer	26 (3.3)	26 (3.3)	20 (2.5)	16 (2.0)
Other CV AEs, n (%)[a]				
Prespecified exploratory cardiovascular endpoint	79 (10.2)	58 (7.4)	83 (10.3)	63 (7.8)
Fatal or nonfatal myocardial infarction	18 (2.3)	20 (2.6)	22 (2.7)	10 (1.2)
Fatal or nonfatal stroke	7 (0.9)	11 (1.4)	8 (1.0)	2 (0.2)
Injection-site AEs, n (%)[b]				
Any reaction	7 (0.9)	20 (2.6)	4 (0.5)	38 (4.7)
Mild	7 (0.9)	13 (1.7)	3 (0.4)	23 (2.8)
Moderate	0	7 (0.9)	1 (0.1)	15 (1.8)
Severe	0	0	0	0
Persistent	0	0	0	0

[a] The exploratory cardiovascular endpoint comprised a *Medical Dictionary for Regulatory Activities*–defined cardiovascular basket of nonadjudicated terms, including those classified within cardiac death, and any signs or symptoms of cardiac arrest, nonfatal myocardial infarction, or stroke. [b] Injection-site adverse events included the preferred terms injection-site erythema, injection-site hypersensitivity, injection-site pruritus, injection-site rash, and injection-site reaction.

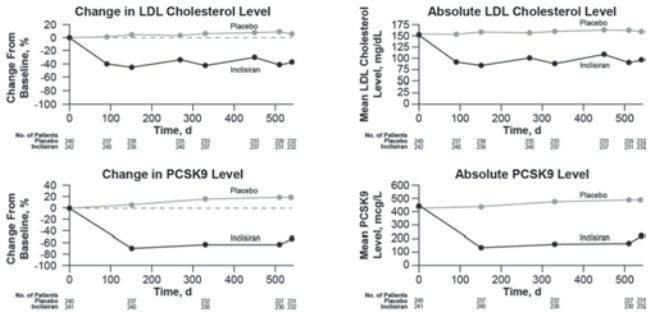
1. Ray KK et al. *N Engl J Med*. 2020;382:1507-1519.

Safety: ORION-10 and ORION-11[1] (Cont'd)

Parameter	ORION-10		ORION-11	
	Placebo (n = 778)	Inclisiran (n = 781)	Placebo (n = 804)	Inclisiran (n = 811)
Frequent AEs, n (%)				
Diabetes mellitus	108 (13.9)	120 (15.4)	94 (11.7)	88 (10.9)
Nasopharyngitis	–	–	90 (11.2)	91 (11.2)
Bronchitis	30 (3.9)	46 (5.9)	–	–
Dyspnea	33 (4.2)	39 (5.0)	–	–
Hypertension	42 (5.4)	42 (5.4)	54 (6.7)	53 (6.5)
Upper respiratory tract infection	33 (4.2)	39 (5.0)	49 (6.1)	52 (6.4)
Arthralgia	–	–	32 (4.0)	47 (5.8)
Osteoarthritis	–	–	40 (5.0)	32 (3.9)
Back pain	39 (5.0)	39 (5.0)	–	–
Liver function				
Alanine aminotransferase >3x ULN	2 (0.3)	2 (0.3)	4 (0.5)	4 (0.5)
Aspartate aminotransferase >3x ULN	5 (0.6)	4 (0.5)	4 (0.5)	2 (0.2)
Alkaline phosphatase >3x ULN	3 (0.4)	5 (0.6)	2 (0.2)	1 (0.1)
Bilirubin >2x ULN	3 (0.4)	4 (0.5)	8 (1.0)	6 (0.7)
Kidney function: creatinine >2 mg/dL	30 (3.9)	30 (3.8)	11 (1.4)	5 (0.6)
Muscle: creatine kinase >5x ULN	8 (1.0)	10 (1.3)	9 (1.1)	10 (1.2)
Hematology: platelet count <75 x 10^9/L	0	1 (0.1)	1 (0.1)	0

1. Ray KK et al. *N Engl J Med*. 2020;382:1507-1519.

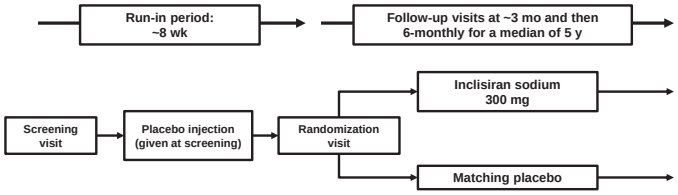
Inclisiran Change in LDL-C and PCSK9 in FH Patients[1]



1. Raal FJ et al; ORION-9 Investigators. *N Engl J Med.* 2020;382:1520-1530.

ORION-4: Long-Term Cardiovascular Outcomes Study[1]

- **Study aims:** Assess the effect of inclisiran on major CV events
- The study will randomize ≥15,000 participants aged ≥55 years with pre-existing CV disease between inclisiran sodium 300 mg and matching placebo for a median of about 5 y



1. https://www.pcsk9forum.org/wp-content/uploads/Inclisiran-and-the-ORION-programme.pdf.

ORION-4: Long-Term Cardiovascular Outcomes Study[1] (Cont'd)

Primary Endpoint

Composite of major CV events, defined as:

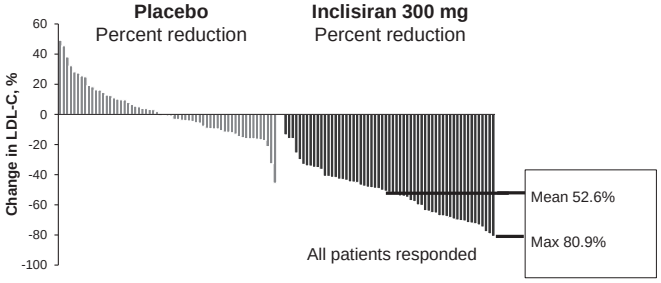
- Coronary death,
- Myocardial infarction,
- Fatal or nonfatal ischemic stroke, *or*
- Urgent coronary revascularization procedure

Secondary Endpoints

- Composite outcome of coronary death or myocardial infarction
- Cardiovascular death

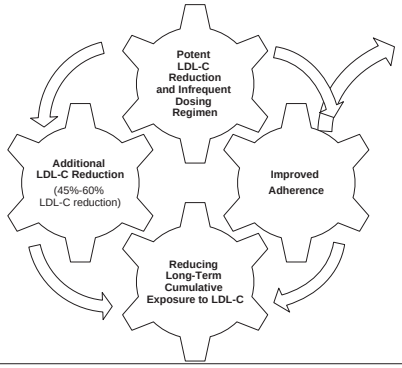
1. https://www.pcsk9forum.org/wp-content/uploads/Inclisiran-and-the-ORION-programme.pdf.

Efficacy: Two-Dose Starting Regimen Individual Patient Responses (%) at Day 180[1]



1. Ray KK et al. *N Engl J Med.* 2017;376:1430-1440.

Combination Therapy With Inclisiran: Efficient Way of Providing and Maintaining Additional LDL-C Reductions



Putting the Latest Evidence Into Practice

Expert Insights on Individualizing Care for Patients With Hyperlipidemia

Patient Case 1: 66-Year-Old Woman With FH

- 66-year-old female patient with FH, HTN, and hypothyroidism
- On multiple oral drugs including lipid-lowering agents (rosuvastatin, ezetimibe)
- Nonadherence: Keeps forgetting to take pills

Currently taking

- Rosuvastatin 20 mg
- Ezetimibe 10 mg

Lipid profile

- TC: 224 mg/dL
- HDL-C: 50 mg/dL
- TG: 120 mg/dL
- LDL-C: 150 mg/dL

Screening for FH

- Universal screening for elevated serum cholesterol is recommended
- FH should be suspected when untreated fasting LDL-C or non–HDL-C levels are elevated

Age	LDL-C	Non–HDL-C
Adults (≥20 years)	≥190 mg/dL	≥220 mg/dL
Children, adolescents, and young adults (<20 years)	≥160 mg/dL	≥190 mg/dL

Management of Case 1: 66-Year-Old Woman With FH

- Adherence remains a problem and the most important approach is to ask about it during the visit, have clear messages, and work with patients to reduce barriers
- Consider addition of nonstatin therapy and continue ezetimibe
- PCSK9i (based on outcome data)
- Could consider BA
- Newer drugs on horizon
- Current and emerging treatment options should be able to reduce the burden of ASCVD associated with FH

Patient Case 2: 72-Year-Old Man With MI, T2DM, and Hyperlipidemia

- 72-year-old male patient
- 10-year history of type 2 DM, MI, and hyperlipidemia
- Smokes 2 packs/d
- BP: 142/90 mmHg
- LDL-C: 140 mg/dL; HDL-C: 40 mg/dL; triglycerides: 190 mg/dL
- Tried multiple statins and shown intolerance

Treatment Options for Statin Intolerance[1]

- Change to a different statin
- If the patient is high risk, try all statin options
- Lower statin dose or consider twice-weekly therapy of longer-acting statins
- PCSK9-targeting therapies, ezetimibe, BA, bile acid sequestrants
- Add water-soluble fiber and/or plant stanols/sterols

Clinical Pearls

- ✓ Statin toxicity and AEs can be reduced by avoiding concomitant therapy that may increase risk
- ✓ Twice-weekly or intermittent dosing
- ✓ Lower statin doses generally are less likely to cause AEs
- ✓ Certain statins may be less likely to cause myalgia?
- ✓ Consider nonstatin therapy if necessary

1. Backes JM et al. *Ann Pharmacother*. 2008;42:341-346.

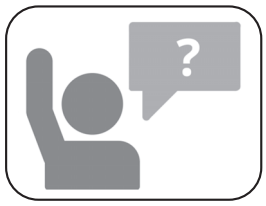
Case 2: Key Take-Home Messages

- In patients with statin intolerance, try all statins before giving up; consider low-dose or intermittent therapy if needed
- High-risk patients require aggressive therapy if LDL-C remains above threshold; consider the urgency to treat early and provide regular adherence assessment
- Newer therapies that can be given at longer intervals may hold the key to improved adherence and strategies for management of large populations
- Heart-healthy lifestyle (smoking cessation)
- Consider adding nonstatin: ezetimibe (20%-25% of LDL-C reduction)
- PCSK9i (45%-60% LDL-C reduction)

Conclusions

- Primary prevention population
  - Assess risk
  - Utilize CAC, risk-modifying factors
  - Identify patients with FH
- Secondary prevention population
  - Identify very-high-risk patients
  - Aggressive LDL lowering: high-intensity statins and nonstatin agents, including ezetimibe, PCSK9 inhibitors, BA, inclisiran

Audience Q&A



Please remember to complete and submit your Program Evaluation

PeerView.com/Hyperlipidemia-Survey-UCU

Thank you and have a good day.

Abbreviations

- BI: ankle brachial index
- ACL: adenosine triphosphate-citrate lyase
- ACS: acute coronary syndrome
- Apo(B):apolipoprotein B
- APP: advanced practice provider
- ARR: absolute risk reduction
- ASCVD: atherosclerotic cardiovascular disease
- ATP: adenosine triphosphate
- BA: bempedoic acid
- CAC: coronary artery calcium
- CKD: chronic kidney disease
- CTTC: Cholesterol Treatment Trialists Collaboration
- EZE: ezetimibe
- FDC: fixed-dose combination
- FH: familial hypercholesterolemia
- GalNAc: N-acetylgalactosamine
- heFH: heterozygous familial hypercholesterolemia
- HMG-CoA: hydroxymethylglutaryl coenzyme A
- hs-CRP: high-sensitivity C-reactive protein
- HTN: hypertension
- Lp(a): lipoprotein(a)
- mAb: monoclonal antibody
- MEDPED: Make Early Diagnoses, Prevent Early Deaths
- MI: myocardial infarction
- mRNA: messenger RNA
- NNT: number needed to treat
- NS: not significant
- PAD: peripheral artery disease
- PCE: Pooled Cohorts Equation
- PCSK9: proprotein convertase subtilisin/kexin type 9
- PCSK9i: proprotein convertase subtilisin/kexin type 9 inhibitor
- Q2W: every 2 weeks
- QMO: every month
- RISC: RNA-induced silencing complex
- RRR: relative risk reduction
- siRNA: small interfering RNA
- T2M: type 2 diabetes mellitus
- TG: triglycerides

Nevada Academy of Family Physicians
32nd Annual Summer CME Meeting
July 30–August 1, 2021

Medical Ethics in Pandemics- Choosing What's Right

Presented by:
Jerry Reeves, MD

Approved for 1.0 Prescribed Ethics CME

Friday, July 30, 2021
2:30—3:30pm

Nevada Academy of Family Physicians
32nd Annual Summer CME Meeting
July 30–August 1, 2021

NOTES

Comagine Health

Medical Ethics in Pandemics- Choosing What's Right

JERRY REEVES MD
Medical Director- Comagine Health
Membership Chair- Clark County Medical Society

Disclosure statement

- This presentation will promote quality or improvements in health care and will not promote a specific proprietary business or commercial interest.
- I have no financial conflicts of interest to disclose
- The information will be well balanced, evidence based and unbiased.

Comagine Health

Qualifications

- Experience and learnings
- Evolving cultures
- Awareness- Reflections
- All physicians eligible in concert with their patients
  - Trusted therapeutic alliance
- No ultimate arbiter- multiple competing factors

Comagine Health

Why Medical Ethics?

- Why required for renewing medical licenses?
  - Unprofessional conduct, malpractice with harm
- Why ethics committees?
  - End of life decisions; informed consent; resource allocation; prevent harm
- The pot and the kettle
  - Laws; regulations; judgments
- What is the problem?
  - Disagreements; distrust; outliers; history
- Is this the solution?
  - Resolve disputes, build trust, continuous improvement, doing right

Comagine Health

In the News

Doctors Settle in SpineFrontier Kickback Cases

Surgeons who admitted accepting "consulting" fees from the Massachusetts-based company for services they did not perform paid the government hefty settlement fines.

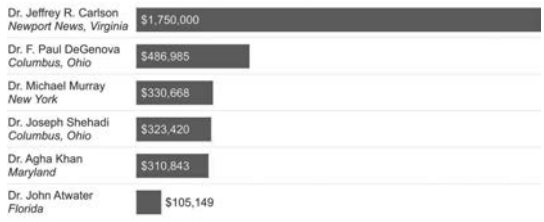


Chart by Hannah Norman/KHN
SOURCE: Department of Justice

KHN

What is medical ethics?

- Conscience
  - Awake to moral standards and socially acceptable actions – patient comes first
    - Morality relies on authority – faith or tradition
    - Ethics relies on facts and values – may evolve (physician-assisted dying)
    - Bias awareness, clear goals, balanced recommendations
  - Deliberation- explore, discuss beliefs, values and facts, follow-through
- Choices with consequences and reactions
  - Using values, facts, and logic to choose a course of action
    - Right from wrong
    - Different value systems- two "rights"
    - Different facts
    - Different logic
  - Consequences may be expected or unexpected
  - Reactions may be positive or negative

Comagine Health

Examples

- Withholding treatment due to budgets or insurance coverage
- Accepting money from pharmaceutical or device manufacturers
- Upcoding
- Romantic involvement with patient
- Covering up a mistake
- Reporting an impaired colleague
- Cherry-picking patients – closing practice
- Defensive medicine- low value care
- Hiding bad news
- Impaired patients' driver's licenses

Comagine Health

Guiding principles

- Autonomy – doctors advise, patients choose
- Distributive Justice- fair distribution of benefits and burdens
- Beneficence- doing good for individuals and public
- Nonmalfeasance- first do no harm
- Transparency
- Respect
- Trust

Interpretation: Limits or affirmation?

Comagine Health

Medical Ethics Domains

- Hospitals
  - Withdrawing treatment, informed consent, peer review, ethics committees
- Private Practices
  - Resource allocation, time management, cultural sensitivity, health literacy
- Clinical Research
  - Informed consent – benefit someone else
  - Institutional review board
- Public Health and Policy
  - Epidemics- infections, opioids, gun violence
  - Prevention- bike helmets, vaccinations
  - Affordability, quality of care, certification, tort reform

Comagine Health

My Choices and My Consequences

- What I choose reshapes me
  - Why this career?
    - The expected – interesting work; helping people; autonomy
    - The unexpected – vicarious trauma; sleep deprivation; burnout
  - Consequences and reactions
    - Fulfillment
    - Withdrawal

Comagine Health

RECOGNIZING BURNOUT

- MASLACH BURNOUT INVENTORY
  - Emotional Exhaustion – work related; "used up"
  - Depersonalization- callous
  - Reduced Personal Accomplishment – sense of failure
- MINI Z BURNOUT SURVEY (AMA)
  - Satisfaction, Stress, Energy Level, Work Control, Documentation Time, Chaos, Values, Team, EHR Proficiency
- PHYSICIAN WELL-BEING INDEX (MAYO)
- INDICATORS
  - Disengagement, Disinterest, Disconnection

Comagine Health

PREVALENCE AND TRENDS BURNOUT SYMPTOMS

- PRIMARY CARE – 79% (HIGHER THAN OTHER CAREERS)
- ALL PHYSICIANS- 68%
- ACADEMIC PHYSICIANS
  - DEPENDENT ON VALUE AND RESPECT (NOT PAY, AGE, GENDER)
- YOUNG, FEMALE, YOUNG CHILDREN, DEBT
- TRENDS- DECREASING THE PAST 6 YEARS
  - AMA, MAYO, STANFORD
  - MORE SYSTEM INTERVENTIONS

Comagine Health

BURNOUT CONSEQUENCES Relationships to Ethics

- MEDICAL ERRORS
- MALPRACTICE SUITS
- ICU MORTALITY
- PATIENT RECOVERY TIME
- PATIENT SATISFACTION
- PATIENT ADHERENCE TO ADVICE
- PRODUCTIVITY/ EFFORT
  - LOSS OF 7 MEDICAL SCHOOL GRADUATING CLASSES/ YEAR (US)
- DEPART CLINICAL PRACTICE
- TURNOVER $$
- 25% HIGHER SUBSTANCE ABUSE
- 2x HIGHER SUICIDE IDEATION
- HIGHER SUICIDES
  - +40% MALES; +130% FEM

Comagine Health

ROOT CAUSES Do Ethics Courses Help?

- EXTRINSIC
  - WORKPLACE CHAOS
  - ADMINISTRATIVE BURDENS
  - EHR DOCUMENTATION BURDENS
  - CHANGING FINANCES
  - OUTDATED TECHNOLOGY
  - REGULATIONS
  - EXPECTATIONS
  - LIFE PHASE DEPENDENCY
    - STUDENTS, RESIDENTS, FELLOWS
    - EARLY, MID, LATE CAREER
- INTRINSIC
  - SOLITARY WORK
    - ISOLATION, LONELINESS
  - DISCONNECTED FROM PEERS
  - SACRIFICE
    - <20% TIME ON MOST MEANINGFUL
  - COMPETITION
  - DRIVEN
  - HESITANT TO SHARE FEARS
    - STIGMA

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SIMILARITIES

- ANXIETY
- DEPRESSION
- SUICIDE IDEATION
- SUBSTANCE USE DISORDER
- POST TRAUMATIC STRESS DISORDER

Comagine Health

SOLUTIONS

- SHARED RESPONSIBILITY – MEASURE, TRACK, IMPROVE
  - HEALTH SYSTEMS, ORGANIZATIONS, INSTITUTIONS
    - DUTY HOURS, SCRIBES, TEAMS, PEER SUPPORT, MEANINGFUL WORK
  - ZERO-BURNOUT PRIMARY CARE PRACTICES (AHRQ STUDY OF 715 PRACTICES)
    - SOLO AND SMALLER PRIMARY CARE PRACTICES- INDEPENDENT FREE CHOICES
    - QI STRATEGIES, TEAMWORK, LEARNING CULTURE, PSYCHOLOGIC SAFETY, FACILITATIVE LEADERS
    - NOT PATIENTS/DAY, EHR CHANGE, MEDICAID INSURANCE
  - GOVERNMENT POLICIES
    - PATIENTS BEFORE PAPERWORK
  - INDIVIDUAL PHYSICIANS
    - MINDFULNESS, COUNSELING, STRESS MANAGEMENT, EXERCISE, SELF-CARE, SMALL GROUPS

Comagine Health

CLARK COUNTY WORKPLACE & PEER RESOURCES

- Hospitals, Medical Groups, Academia –
  - Confidential Wellness Programs
- Employers/ Insurance Plans
  - Employee Assistance Programs
- Physician Coalition Southern Nevada and CCMS
  - Advocacy- Lower Administrative Burdens
  - Education
  - Networking
  - Peer Support

Comagine Health

CLARK COUNTY BEHAVIORAL HEALTH RESOURCES

- SAMHSA Help Line- **1-800-662-HELP (4357)**
- Nevada 211 – Dial 211
- Oasis Counseling – 702 294 0433
- Nevada Psychological Association - (888) 654-0050
- Bridge Counseling- (702) 474-6450
- ROI Counseling- (702) 816-2595
- Community Counseling Center- (702) 369-8700
- Alliance Mental Health- (702) 485-2100
- Focus Mental Health Solutions- (702) 790-2701

Comagine Health

Their Choices and My Consequences

- What they choose reshapes me
  - Curriculum; assignments; policies; covered benefits; pay; priorities; values
  - Masks, social distancing, hand-washing, vaccinations
- Consequences
  - Private freedom versus public good
  - Stress from incongruity of values
- Reactions
  - Hesitancy, refusal, distrust, polarization, conflict

Comagine Health

My Choices and Patients' Consequences

- What I choose affects my patients
  - Prices, availability, accepted insurances, time management, teams
  - Transparency- conflicts of interest, bad news, honesty, minors, privacy protection
  - Clarity of explanations, active listening, trusted therapeutic alliance, compassion
  - Shared decision making, informed consent, control, familiarity, reliability, hope
  - Second opinions, data sharing, apologies
  - Advance directives, care-giver engagement
- Consequences
  - Results- improvements, complications, remediation
- Reactions- patients, peers, family, community

Comagine Health

Patients' Choices and My Consequences

- What my patients choose affects me
  - Lifestyle choices, adherence to recommendations, risky behaviors, vaccinations, transfusions, procedures, readiness to change
  - Belief conflicts – abortion, transfusions, vaccinations, technologies
  - Trust- are you enough like me to like you and trust you?
  - I don't care how much you know until I know how much you care.
- Consequences
  - Patient health outcomes and quality of life
  - My quality scores, career satisfaction, peer perceptions, interpersonal conflict
- Reactions
  - Disagreements- seek first to understand, refer if unresolvable

Comagine Health

Families' Choices and Patients' Consequences

- What families choose affects patients
  - Dementia, frailty, end of life, futile treatments
    - Advance directives, POLST
    - Power of attorney, guardianship
- Consequences
  - Elder abuse, patient wishes
- Reactions
  - Disagreements, conflict resolution
    - Facts or expectations?
    - Define issues, goals, what matters, control issues
    - Respectful language – disconnect machine vs. withdraw life support
    - Safe environment
    - Negotiation

Comagine Health

Payers' Choices and My Consequences

- What payers cover and pay affects me and my staff
  - Credentialing, contracts, performance feedback
  - Covered benefits, discounts, FFS or value-based payments, bundled payments
  - Incentives aligned with values?
  - Administrative complexity and burdens
  - Competition and consolidation
  - Sites of service, telehealth, remote monitoring payments
- Consequences
  - Sustainability
- Reactions
  - Withdrawal
  - Replacement

Comagine Health

Society's Choices and Patients' Consequences

- What our society chooses affects my vulnerable patients
  - Access to jobs, pay, education, food, housing, transportation opportunities
  - Rights of unborn/ women's autonomy
  - Genetic test disclosures
  - Resource allocation in emergencies- age discrimination
  - Society/ culture= cumulative choices of a people over time – variable
- Consequences
  - Inequities, discrimination, poor health, unmet social needs, morbidity, mortality
- Reactions
  - Violence, unrest, polarization

Comagine Health

Roles of physicians

- Science with a heart – my patients
- Learn from mistakes – my practice
- Share best practices – my collaborations
- Prioritize the important over the urgent – my ethical decisions
- Build trust – better outcomes
- Advocacy – our public and organization policies
  - Opioids, gun violence, affordability, precision medicine, Big Data, new technology
  - Genetic testing, organ donations, physician-assisted dying
  - Pandemics- personal freedoms, public good- ethics of selfishness

Comagine Health

CCMS NEVADA

Questions?

Nevada Academy of Family Physicians
32nd Annual Summer CME Meeting
July 30–August 1, 2021

Telemedicine Physical Exams

Presented by:
Christine Quartuccio-Carran, DO
and Funke Adefope, MD, PGY-3

Approved for 1.0 Prescribed CME

Friday, July 30, 2021
4:00—5:00pm

Nevada Academy of Family Physicians
32nd Annual Summer CME Meeting
July 30–August 1, 2021

NOTES

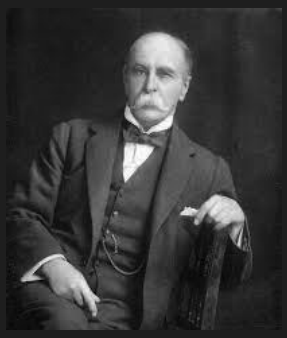
TELEMEDICINE PHYSICAL EXAMS

Chrissy Quartuccio-Carran, D.O.
Funke Adefope, M.D., PGY – 3

INTRODUCTIONS

Objectives

- Describe how to set the scene for your telemedicine visits
- Discuss good "webside" manner
- Review various tips and tricks for performing a telemedicine physical exam
- Discuss benefits and limitations of the telemedicine exam



SIR WILLIAM OSLER
"THERE IS NO MORE DIFFICULT ART TO ACQUIRE THAN THE ART OF OBSERVATION, AND FOR SOME MEN IT IS QUITE AS DIFFICULT TO RECORD AN OBSERVATION IN BRIEF AND PLAIN LANGUAGE."

...THROUGH AN INTERNET CONNECTION – CQC

Set the Scene

- Check your background
  - *Don't sit directly in front of a door*
- Light source in front
- Face is in the middle of the camera ~2ft away from the camera

CONSIDER A VIDEO TEST

Preparing the Patient

Depending on the nature of the visit:

- *Camera angles*
- *Body positioning*
- *Attire*
- *Additional items needed*
  - Blood pressure cuff, light source, weighted objects for strength testing, etc.

Private, safe space

Consent and disclaimers

Good WEBSIDE Manner

- Take a deep breath and smile
- Look directly into the camera when possible
  - *Pin video under the camera*
- Inform the patient what you are doing when looking away
  - *Looking through their chart*
  - *Finding a visual aid to share*
  - *Documenting*

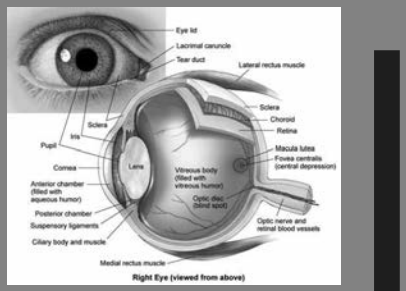
BEGIN THE ENCOUNTER

General Observations

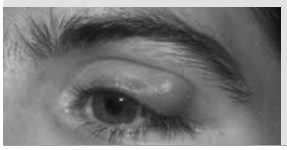
- General appearance
  - *Ill/well appearing, (un) comfortable, fatigued, attentive, distracted, disheveled/unkept*
- Speech pattern
  - *Cognition, fluency*
- Emotional state
- Environment
  - *Potential hazards, people, medications, hygiene, safety*

PHYSICAL EXAM

Vital Signs



EYES

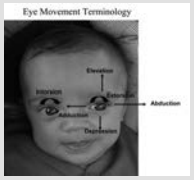


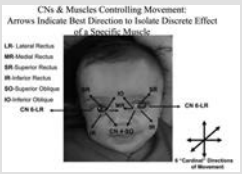
Eyes – Inspection

- Ocular symmetry
- Eye lid symmetry
- Sclera
  - *Injection, icterus*
- Conjunctiva
  - *Injection, pallor, visible crusting or exudate*
- Pupil and iris
  - *Equal, round, reactive?*

Extraocular Movements

- Advise patient
  - *"Look to the left, look to your upper left, look to your lower left"*
  - *"Look to the right, look to your upper right, look to your lower right"*
    - *When looking laterally, you can pause to look for nystagmus

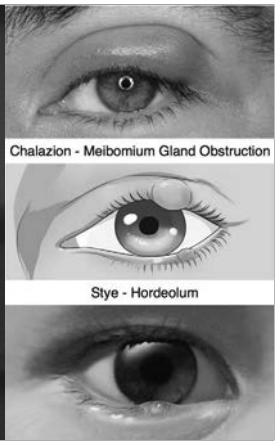


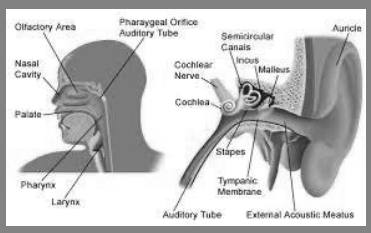


Source: UC San Diego's Practical Guide to Clinical Medicine
https://meded.ucsd.edu/clinicalmed/eyes.html

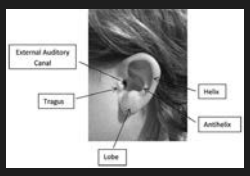
Eyes – Palpation

- Palpation
  - *Wash hands first!*
  - *Lumps/bumps, pain*





EARS, NOSE, THROAT



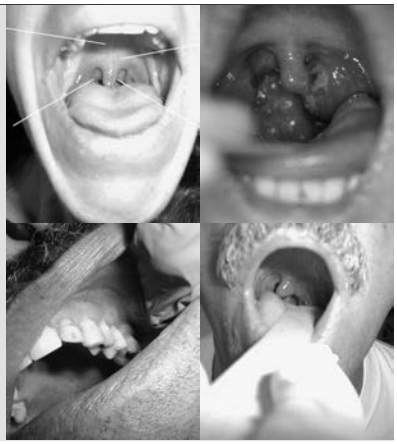
Source: UC San Diego's Practical Guide to Clinical Medicine https://meded.ucsd.edu/clinicalmed/head.html

Ears and Nose

- Inspection of ears and nose
  - *Scars, lesions, masses, discharge*
- "Palpation"/Traction
  - *Helix/lobe*
  - *Tragus*
- Assessment of hearing
  - *Able to hear, asks to repeat questions*

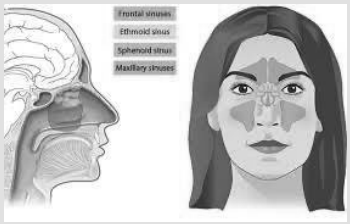
Throat - Inspection

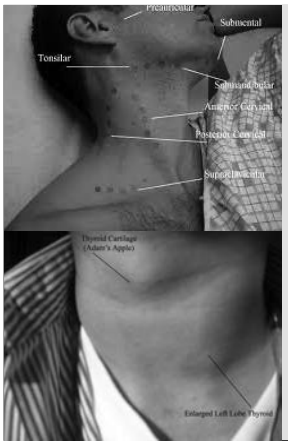
- Lips, teeth and gums
  - *Color, condition of mucosa and dentition*
- Throat
  - *Tonsillar enlargement, exudate, uvula deviation*



Face

- Inspection of face
  - *Symmetry, cranial nerve assessment*
- Palpation of sinuses



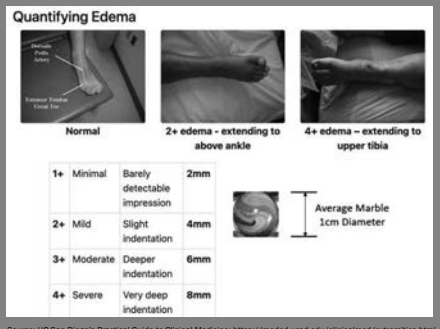


Neck

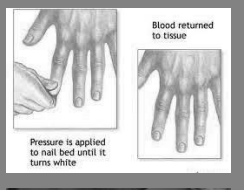
- Inspection
  - *Overall appearance, symmetry, gross evidence of lymphadenopathy or masses*
- Palpation
  - *Enlargement/asymmetry*
  - *Tender or Painful*
- Gross movement
  - *Degrees of flexion, extension, lateral mobility, rotation*

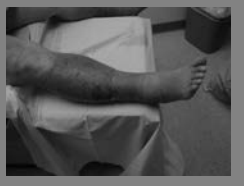
CARDIOVASCULAR

- Limited…
- Capillary refill
- Presence and nature of edema in extremities
  - *Pitting, weeping*
- Signs of cyanosis, skin tone
- Temperature of extremities per patient



Source: UC San Diego's Practical Guide to Clinical Medicine; https://meded.ucsd.edu/clinicalmed/extremities.html



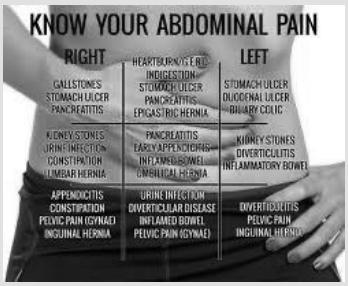


RESPIRATORY

- Assessment of respiratory effort
  - *Tachypnea*
  - *Intercostal retractions, use of accessory muscles, diaphragmatic movement, pursed lip breathing, speaking in full sentences or limited due to shortness of breath*
- "Take a deep breath"
  - *Inspiratory vs expiratory phase*
  - *Audible wheezing?*
- Presence and nature of cough
  - *Frequent, occasional, wet, dry, coarse*

ABDOMEN

- Examination of the abdomen
  - *Lie supine?*
- Palpation
  - *Localize the pain*
  - *"Push in, hold it and let up quicky"*
- Stand and jump and down 3 times



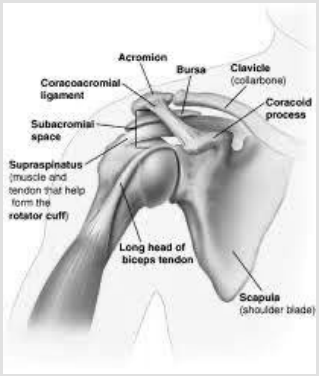
FEB 01, 2021

Musculoskeletal

- Inspection
- Palpation
- Range of motion
- Strength testing
- Neurovascular assessment
- Special tests

Shoulder

- Illicit the primary concern:
  - *Pain*
  - *Weakness*
  - *Decreased ROM*



Consider

Pain without trauma	Pain with cross-arm adduction	Weakness	Decreased range of motion
• *Shoulder impingement or calcific tendinopathy*	• *Acromioclavicular pathology*	• *Complete rotator cuff tear, or nerve pathology*	• *Adhesive capsulitis or severe osteoarthritis*

Shoulder – Inspection

- Rotate 360° to observe joint in all planes
- Assess for:
  - Asymmetry
  - Deformity
  - Abnormal posture
  - Overlying skin changes, atrophy, erythema, and ecchymosis
- Point to the area of maximal tenderness

Shoulder – Palpation

- Sternoclavicular joint
- Clavicle
- Acromioclavicular joint
- Acromion
- Spine of the scapula
- Bicipital groove
- Greater tuberosity of the humerus

Shoulder – Range of Motion

PLANE OF RANGE OF MOTION	*PATIENT BODY POSITIONING*	*NORMAL ROM (DEGREES)*
Abduction	Away from the camera	180
Extension	90 degrees to the side	45 to 60
Flexion	90 degrees to the side for measurement, away from the camera for scapular stability	180
Internal rotation (Subscapularis)	Away from the camera for Apley scratch test	Able to reach vertebral height of T4–T8
	90 degrees to the side, elbow abducted to 90 degrees	90
External rotation (Infraspinatus, Teres Minor)	90 degrees to the side, elbow at the side	90
	90 degrees to the side, elbow abducted to 90 degrees	90

Common Household Items That Can Be Used in Telemedicine Strength Testing

ITEM	APPROX. WEIGHT
Roll of nickels, cup of sugar, or three C cell batteries	0.5 lb (0.23 kg)
Can of soup, block of butter, or 16-oz bottle of water	1 lb (0.45 kg)
Quart of milk or 1-L bottle of soda	2 lb (0.91 kg)
Bag of sugar or 2-L bottle of soda	5 lb (2.27 kg)
Gallon of milk or large bag of potatoes	9 lb (4.08 kg)

Rotator Cuff Strength Testing

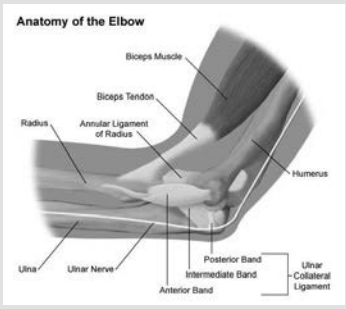
- Supraspinatus
  - *Patient lifts an object in the plane of scaption (90 degrees of abduction and approximately 30 degrees of forward flexion)*
  - *Patient fully abducts the arm and then slowly reverses the motion in the same arc*
    - Test is positive for rotator cuff tear if arm drops suddenly or patient has severe pain (drop-arm sign)
- Infraspinatus and teres minor
  - *Patient lies on unaffected side and externally rotates against gravity or with an object*
- Subscapularis
  - *With the patient facing to the side and the arm internally rotated behind the back, the patient lifts the hand away from the back against gravity (lift-off test)*

NEUROVASCULAR ASSESSMENT

SCAPULAR WINGING

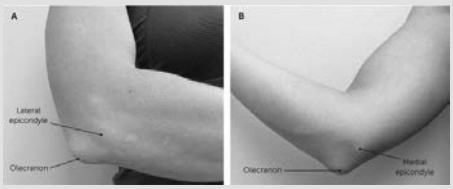
Elbow – Inspection

- Erythema
- Deformity
- Swelling
- Ecchymosis
- Overlying skin changes
- Check biceps and triceps for tendon rupture



Elbow – Palpation

- Lateral epicondyle
- Medial epicondyle
- Olecranon



Elbow - Range of Motion

PLANE OF RANGE OF MOTION	PATIENT BODY POSITIONING	NORMAL ROM (DEGREES)
Flexion	Facing the camera, arm abducted to 90 degrees	135 to 150
Extension	Same as flexion	−10 to 0
Supination	Facing the camera, elbow resting on table with arm to the side and elbow flexed to 90 degrees	75 to 90
Pronation	Same as supination	75 to 90

Consider

Medial epicondylitis

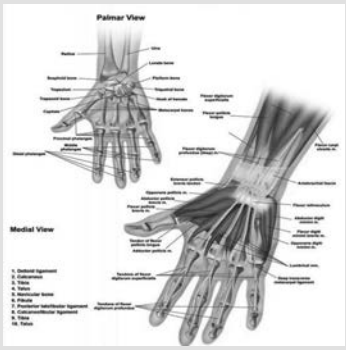
- *Pain that localizes to the medial epicondyle with wrist flexion and pronation while holding a weighted object*

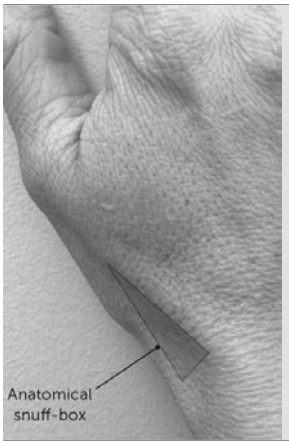
Lateral epicondylitis

- *Pain that localizes to the lateral epicondyle with wrist extension and supination while holding a weighted object*

Hand and Wrist – Inspection

- Deformity
- Swelling
- Ecchymosis
- Overlying skin and nail changes
- Atrophy





Hand and Wrist – Palpation

- Point to the area of maximal tenderness and/or paresthesia.
- Recent trauma → tenderness over the anatomical snuff-box warrants further evaluation for scaphoid fracture

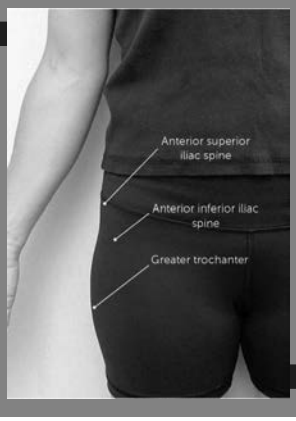
Wrist – Range of Motion

PLANE OF RANGE OF MOTION	PATIENT BODY POSITIONING	NORMAL ROM (DEGREES)
Dorsiflexion	90 degrees to the side	70
Palmar flexion	Same as dorsiflexion	80 to 90
Radial deviation	Facing the camera	20 to 30
Ulnar deviation	Facing the camera	50

TEST	*TECHNIQUE*	*CONDITION*
Finkelstein test	Patient grasps a weighted object and tilts wrist down (ulnar deviation) against gravity	Pain with this maneuver suggests de Quervain tenosynovitis
Froment sign	Patient grasps a piece of paper between thumb and index finger on affected side and attempts to pull it out with opposite hand	Difficulty holding paper suggests ulnar nerve injury
Phalen test	With arms raised to the level of shoulders, patient brings dorsum of hands together in midline, holding in forced flexion for 30 to 60 seconds	Burning, numbness, or tingling in the median nerve distribution suggests carpal tunnel syndrome
Press test	Seated patient pushes their body weight up off a chair using affected wrist[A1]	Focal ulnar wrist pain with this maneuver suggests triangular fibrocartilage complex injuries
Reverse Phalen test	With arms raised to the level of shoulders, patient brings palms together in midline, holding in forced flexion for 30 to 60 seconds	Carpal tunnel syndrome (same as Phalen test)

Hip and Pelvis – Inspection

- Patient standing, facing the camera, with feet shoulder width apart
  - *Hands on top of iliac crests*
  - *Assess symmetry in hand height and anterior/posterior alignment*
    - Asymmetry → consider leg length discrepancy or pelvic rotation
- Point to the most painful area
  - *C sign → intraarticular pathology*



HIP AND PELVIS

PALPATION

Hip – Range of Motion

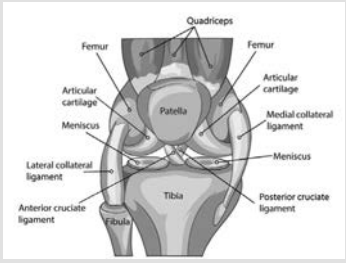
PLANE OF ROM	*PATIENT BODY POSITIONING*	*NORMAL ROM (DEGREES)*
Flexion	90 degrees to the side, standing or supine position; knee is pulled to the chest	120
Extension	90 degrees to the side, standing or prone position, with extended straight leg	10 to 20
Internal rotation	Facing the camera, seated with knee bent to 90 degrees and leg rotated at the hip (not the knee)	40
External rotation	Same as internal rotation	45

Hip – Special Tests

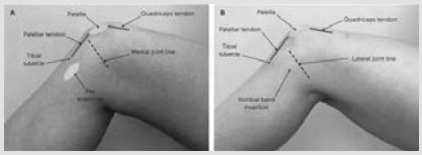
TEST	*TECHNIQUE*	*CONDITION*
FABER (Patrick) test	While the patient is lying on their back, the hip is flexed, abducted to the side, and externally rotated into a "figure of four" position	Sacroiliac joint or intra-articular pathology (depending on localization of pain)
FADIR test	While the patient is lying on their back, the hip is flexed, adducted toward midline, and internally rotated	Pain suggests intra-articular pathology
Trendelenburg test	Patient stands facing away from camera and balances on one foot for 30 seconds	Inability to maintain pelvis stability parallel to the ground suggests pelvic instability (stance leg)

Knee – Inspection

- Observe gait
- Swelling
- Deformity
- Erythema
- Ecchymosis
- Atrophy



Knee – Palpation



- Identify area of maximal pain
- Quadriceps
- Patella
- Patellar tendons
- Iliotibial band insertion
- Tibial tubercle
- Pes anserinus
- joint lines

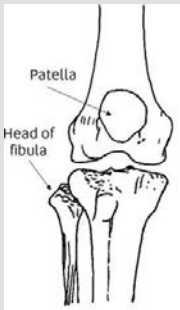
Knee – Range of Motion

PLANE OF ROM	*PATIENT BODY POSITIONING*	*NORMAL ROM (DEGREES)*
Flexion	Affected side facing the camera, seated	130 to 135
Extension	Affected side facing the camera (allows for demonstration of hyperextension if present), standing	−10 to 0

Knee – Special Tests

TEST	*TECHNIQUE*	*CONDITION*
J sign	While seated and facing the camera, patient actively flexes and extends the knee as physician observes patellar motion	Patellar tracking
Single leg squat	While standing and facing the camera, patient squats on one leg for three or four repetitions as physician observes knee alignment and balance	Pelvic instability (stance leg)
Thessaly test	While facing the camera, patient stands on one leg; the supporting leg is flexed 20 to 30 degrees and trunk is rotated back and forth	Pain with a mechanical click or catching sensation suggests meniscal pathology

Ottawa Knee Rules

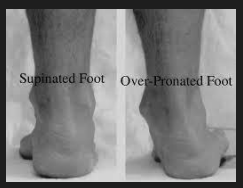


Knee radiography is indicated when:

- Age 55 years or older
- Tenderness at head of fibula
- Isolated tenderness of patella
- Inability to flex to 90 degrees
- Inability to weight bear immediately and in the emergency department (4 steps)

Ankle and Foot – Inspection

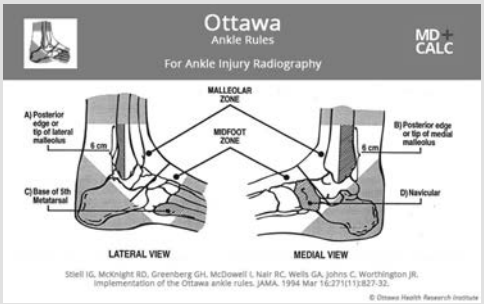
- Patient is barefoot, waring shorts, camera positioned low enough
- Edema
- Gross deformity
- Ecchymosis
- Erythema
- Atrophy



Consider

- Pes cavus or pes planus?
- Face away – count the number of toes that are visible lateral to each ankle
  - *>2 1/2 toes are seen → hyperpronation*
  - *Observe hindfoot and knee alignment, standing and walking, to check for valgus or varus deformity*

Ottawa Ankle Rules



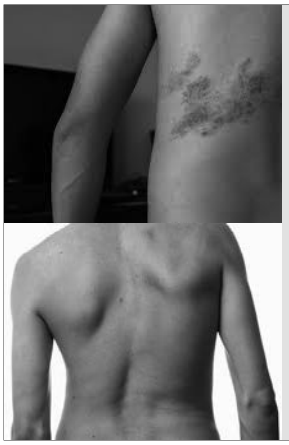
*After a traumatic ankle injury, also palpate the proximal fibular to evaluate for an associated Maisonneuve fracture

Ankle and Foot – Strength Testing

- Can be evaluated against gravity or against resistance with a towel or exercise band
- Capillary refill distal to any injury
- Gross sensation to light touch along dermatomal distributions
- Squeeze test (post-traumatic injury) – patient applies circumferential pressure to the largest part of the calf
  - *Pain along the distal tibiofibular interosseous membrane suggests a high ankle sprain*

Ankle – Range of Motion

PLANE OF ROM	PATIENT BODY POSITIONING	NORMAL ROM (DEGREES)
Dorsiflexion	Affected side facing the camera, seated with knees bent and feet not touching the floor	20
Plantar flexion	Same as dorsiflexion	45
Inversion	Facing the camera, seated with knees bent and feet not touching the floor	30
Eversion	Same as inversion	20

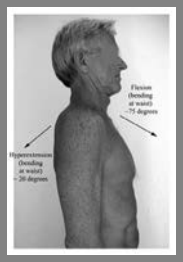


Back – Inspection

- Localize area of pain
- Observe gait
- Asymmetry, curvature or other deformity
- Hypertrophy or Atrophy
- Erythema, ecchymosis, other overlying skin changes

Back – Palpation

- Localize area of pain
  - *Palpate midline over spinous processes to tailbone*
  - *Palpate lateral musculature*



+ Right and left rotation

BACK

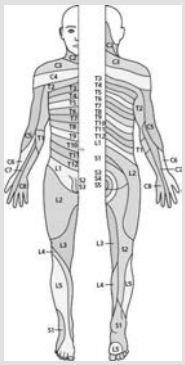
Range of Motion

Back – Strength Testing

- Gait
  - *Observe heel strike, push-off, weight transfer*
- Strength
  - *Squat rise (L4)*
  - *Heel Walk (L5)*
  - *Toe Walk (S1)*
- Functional Strength/Mobility
  - *"Timed Up and Go" test*

Lumbar Spine Dermatomes

- Medial instep (L4)
- Between 1st 2 toes (L5)
- Lateral foot (S1)



Neurologic

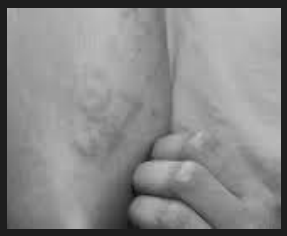
- Assess cranial nerves
  - *Ability to smell, ocular/extraocular movements, pupillary light reflex, face sensation, facial muscles (ask patient to raise eyebrows, frown, close eyes tightly, show teeth, smile, puff out cheeks), hearing (ask patient to rub fingers by ear), shrug shoulders, turn head side to side, tongue movements)*
- Dermatomal distribution of numbness or pain
- Examination of sensation

Psychiatric

- Assess patient's level of alertness and appearance
- Orientation to person, place, time and context
- Recent and remote memory
- Mood and affect
- Pressured speech
- Mood lability

Picture Source: https://akpsi.org/anxiety-and-depression-wellness-checklist/

Skin



- Ability to send pictures?
- Pigmentation, rashes, ulcers, cracking, fissures, mottling, petechiae
  - *Blanching/non-blanching*
  - *May use common objects as reference for size if applicable*
    - Coin, pen, watch, etc.
- Skin turgor and hydration status
  - *Patient can pinch skin, evaluate mucous membranes*

Follow Up

- Patient instructions
- Educational Materials
- Next follow up *In person vs. virtual*

AAFP

A Toolkit for Building and Growing a Sustainable Telehealth Program in Your Practice

SEPTEMBER 2020

This toolkit was developed in partnership with Marvel Health.

RESOURCES

A Checklist for Incorporation of Video Visits (Telemedicine)

For primary care and subspecialty ambulatory practices during the public health emergency due to Coronavirus*

RECOGNIZE THE BENEFITS FOR YOUR PATIENTS AND PRACTICE

- Keep patients safe by reducing their need to travel for health care
- Allow patients to access your practice first instead of the Emergency Department or a commercial telemedicine service
- Enable continuity of care for chronic conditions
- Generate visit-related revenue
- Utilize visual assessment and appropriate physical examination

LICENSURE

- Physicians can provide health care through video visits to patients located anywhere in the country, but must adhere to waivers and actions of the state where they are licensed.
- Click here to check your state's requirements.

REIMBURSEMENT BY PAYERS

- Medicare: Video visits compensated at same rate as in-person care. Qualified providers include: physicians and certain non-physician practitioners such as nurse practitioners, physician assistants and certified nurse midwives. No restrictions on provider location or patient location. For more information:
- Medicaid: Coverage varies by state. Click here to check your state's coverage.
- Commercial payers: Coverage varies by payer. Check with your payers. Click here for additional information.

EQUIPMENT

- Use any phone/tablet/laptop/desktop computer that allows audio and video communication.
- Requirements for HIPAA compliance have been relaxed. You may use:
  - FaceTime or Skype or Zoom
  - Free-standing Telemedicine platform (many are available for free) or
  - Telemedicine product built into your Electronic Health Record (EHR)

Click here for more information.

- Keep your EHR available on the same or second device

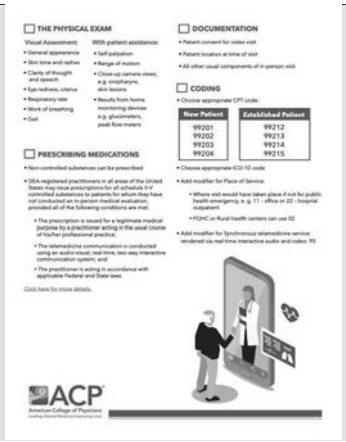
PRACTICE LOGISTICS

- Announce availability of video visits on your website, patient portal, phone system, email to patients
- Prepare a script for your scheduling staff to use when interacting with patients
- Prepare a simple patient guide on how to connect for the visit and email it to them

CONDUCTING THE VISIT

- Ensure that you and the patient are in quiet, private, well-lit locations
- Ensure that you and the patient can see and hear each other clearly
- Verify 2 patient identifiers
- Explain the benefits and limitations of a Telemedicine visit and obtain verbal consent from the patient

*The information provided here contains some regulations that are specific to this emergency period ONLY, and are subject to change at any time.



THE PHYSICAL EXAM

Visual Assessment:
- General appearance
- Skin tone and rashes
- Clarity of thought and speech
- Eye redness, edema
- Respiratory rate
- Work of breathing
- Gait

With patient assistance:
- Self-palpation
- Range of motion
- Close-up camera views, e.g. oropharynx, skin lesions
- Results from home monitoring devices e.g. glucometers, peak flow meters

PRESCRIBING MEDICATIONS

- Non-controlled substances can be prescribed
- DEA-registered practitioners in all areas of the United States may issue prescriptions for all schedule II-V controlled substances to patients for whom they have not conducted an in-person medical evaluation, provided all of the following conditions are met:
  - The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice;
  - The telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system; and
  - The practitioner is acting in accordance with applicable Federal and State laws.

Click here for more details.

DOCUMENTATION

- Patient consent for video visit
- Patient location at time of visit
- All other usual components of in-person visit

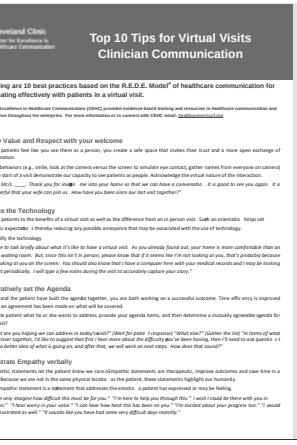
CODING

- Choose appropriate CPT code:

New Patient	Established Patient
99201	99212
99202	99213
99203	99214
99204	99215

- Choose appropriate ICD-10 code
- Add modifier for Place of Service:
  - Where visit would have taken place if not for public health emergency; e.g. 11 - office or 22 - hospital outpatient
  - FQHC or Rural health centers can use 02
- Add modifier for Synchronous telemedicine service rendered via real-time interactive audio and video: 95

ACP American College of Physicians



Cleveland Clinic
Center for Excellence in Healthcare Communication

Top 10 Tips for Virtual Visits Clinician Communication

The following are 10 best practices based on the R.E.D.E. Model© of healthcare communication for communicating effectively with patients in a virtual visit.

The Center for Excellence in Healthcare Communication (CEHC) provides evidence-based training and resources in healthcare communication and service excellence throughout the enterprise. For more information or to connect with CEHC email: healthcarecommc@ccf.org

1. Convey Value and Respect with your welcome

Why? When patients feel like you see them as a person, you create a safe space that invites their trust and a more open exchange of information.

What? Brief behaviors (e.g., smile, look at the camera versus the screen to simulate eye contact, gather names from everyone on camera) at the start of a visit demonstrate our capacity to see patients as people. Acknowledge the virtual nature of the interaction.

How? *"Hello Mich_____. Thank you for invit[illegible] me into your home so that we can have a conversatio[illegible]. It is good to see you again. It is wonderful that your wife can join us. How have you been since our last visit together?"*

2. Introduce the Technology

Why? Orient patients to the benefits of a virtual visit as well as the difference from an in person visit. Such an orientatio[illegible] helps set realistic expectatio[illegible]s thereby reducing any possible annoyance that may be associated with the use of technology.

What? Identify the technology

How? *"I'd like to talk briefly about what it's like to have a virtual visit. As you already found out, your home is more comfortable than an office waiting room. But, since this isn't in person, please know that if it seems like I'm not looking at you, that's probably because I'm looking at you on the screen. You should also know that I have a computer here with your medical records and I may be looking at that periodically. I will type a few notes during the visit to accurately capture your story."*

3. Collaboratively set the Agenda

Why? If you and the patient have built the agenda together, you are both working on a succesful outcome. Time effic ency is improved when an agreement has been made on what will be covered.

What? Ask the patient what he or she wants to address, provide your agenda items, and then determine a mutually agreeable agenda for the visit?

How? *"What are you hoping we can address in today'svisit?" (Wait for patie t response) "What else?" (Gather the list) "In terms of what we'll cover together, I'd like to suggest that first I hear more about the difficulty you've been having, then I'll need to ask questio s to get a better idea of what is going on, and after that, we will work on next steps. How does that sound?"*

4. Demonstrate Empathy verbally

Why? Empathic statements let the patient know we care.Empathic statements are therapeutic, improve outcomes and save time in a visit. Because we are not in the same physical locatio n as the patient, these statements highlight our humanity.

What? An empathic statement is a statement that addresses the empotio n patient has expressed or may be feeling.

How ? *"I can only imagine how difficult this must be for you." "I'm here to help you through this." I wish I could be there with you in person." "I hear worry in your voice." "I can hear how hard this has been on you." "I'm excited about your progress too." "I would feel frustrated as well." "It sounds like you have had some very difficult days recently."*

5. Elicit the patient narrative of the History of Present Illness

Why? Allow patients to feel heard while also providing valuable insight for improved diagnostic accuracy.

What? Allow patients to tell their story, in their own words.

How? *"Tell me more about your [chief concern, worry, etc.]."*

6. Engage in Reflective Listening

Why? Patients don't know what we hear and understand unless we repeat back to them what they have just told us. Repeating back the story helps both the clinician and the patient move forward.

What? Reflective listening is a summary of the key points that a patient has just expressed.

How? *"It sounds like..." or "If I'm hearing you correctly..." or "Let me reflect back that key points you've shared..."*

7. Share diagnosis and information in the context of the patient's perspective

Why? Patients learn best when new information impacts something that personally matters to them. Patients are also more motivated for behavior change when they are aware of how it will benefit something that is important to them.

What? Identify what is most important to the patient, such as the biggest concerns or goal. Then identify how any diagnosis or information and treatment planning might impact what matters most to the patient.

How? *"You have had several low blood sugar events that you can't explain that have occurred this past week." Or "It looks like your son has eye irritation and not pink eye. That means he is not contagious and can go to the birthday party."*

8. Collaboratively develop the treatment plan

Why? Patients will be more evaluate and confident in their capacity to manage their health, leading to improved clinical health outcomes.

What? Provide sufficient information to patients, invite them to share their ideas and preferences, and then incorporate them into the plan.

How? *"I am glad you made a virtual visit appointment, so we can discuss your low blood sugars. There are a number of things you can do to prevent a low blood sugar. First, I would recommend checking your blood sugar more frequently for the next week so that we can get a clearer picture of what is happening. Are you willing to try that?" Or "Strategies to treat eye irritation can include eye drops or just watching and waiting. It is important for your son to wash his hands more frequently and to avoid rubbing his eye, although that is easier said than done. Eye drops may help your son's eye look better, although they are not necessary. Would you like to talk more about eye drops?"*

9. Have the patient repeat back what they understand

Why? Asking patients to repeat what they understand provides an opportunity to correct any misunderstanding or fill in any gaps before the visit ends. It also helps patients recall the information after the visit, and thus, facilitates their health management.

What? Also called teach back, it is the process of asking patients to restate what they understand and what they are going to do next.

How? *"To make sure my recommendations made sense, will you tell me what you heard are the next steps?"*

10. Provide Closure

Why? Patients will look to you for a sign that the work of the visit is done. Since it is an expected practice in relationships, providing close also reinforces the personal connection you have with them.

What? Give a clear signal to the patient that the visit is coming to a close.

How? *"It's time to wrap up our visit for today. I'm so thankful that you didn't wait to share this concern. I will put a note in your chart. I hope you had a good visit and will consider another virtual visit in the future."*

Center for Excellence in Healthcare Communication *http://connect.ccf.org/CEHC*

References

- American Academy of Family Physicians. A Toolkit for Building and Growing a Sustainable Telehealth Program in Your Practice. September 2020. Accessed July 17, 2020. https://www.aafp.org/dam/AAFP/documents/practice_management/telehealth/2020-AAFP-Telehealth-Toolkit.pdf
- American College of Physicians. A Checklist for Incorporation of Video Visits. Accessed 2021 Jul 26 https://www.acponline.org/system/files/documents/practice-resources/health-information-technology/telehealth/video_visit_telemedicine_checklist_web.pdf
- Benziger CP, Huffman MD, Sweis RN, Stone NJ. The Telehealth Ten: A Guide for a Patient-Assisted Virtual Physical Examination. *Am J Med*. 2021;134(1):48-51.
- Choe I. OptumCare Physician. Interview with C. Quartuccio-Carran. 2021 Jul 21.
- Cleveland Clinic. Top 10 Tips for Virtual Visits Clinician Communication. Accessed 2021 Jul 25 file:///Users/cquartuccio/Downloads/media-1.pdf
- Gokal N, Choe I. Approach to the Virtual Physical Exam. OptumCare. 2020.
- Goldberg C. UCSD School of Medicine and VA Medical Center, Practical Guide to Clinical Medicine. Accessed 2021 Jul 20. https://meded.ucsd.edu/clinicalmed/introduction.html
- Showalter G, et al. Telehealth Physical Exam. 2020 Mar 30. Accessed 2021 Jul 16. https://caravanhealth.com/
- Stanford Medicine, Dept. of Medicine. How to Administer a Virtual Physical Exam. Accessed 2021 Jul 16. https://medicine.stanford.edu/news/current-news/standard-news/virtual-physical-exam.html
- Yedlinsky N, Peebles R. Telemedicine Management of Musculoskeletal Issues. *Am Fam Physician*. 2021 Feb 1;103(3):147-154.

"LISTEN TO YOUR PATIENT, HE IS TELLING YOU THE DIAGNOSIS."

— SIR WILLIAM OSLER

Thank you.

Questions?

Nevada Academy of Family Physicians
32nd Annual Summer CME Meeting
July 30–August 1, 2021

NOTES

Nevada Academy of Family Physicians
32nd Annual Summer CME Meeting
July 30–August 1, 2021

Gyn Pearls for the Family Physician

Presented by:
Staci L. McHale, MD, FACOG

Approved for 1.0 Prescribed CME

Friday, July 30, 2021
5:00—6:00pm

Nevada Academy of Family Physicians
32nd Annual Summer CME Meeting
July 30–August 1, 2021

NOTES

GYNECOLOGY PEARLS FOR FAMILY PRACTICE PHYSICIANS

STACI L. MCHALE, MD, FACOG

NEW BEGINNINGS OB-GYN, LAS VEGAS, NEVADA

DISCLAIMER

- I have no financial relationships to disclose
- This presentation does not encompass EVERY aspect of obstetrics and gynecology
- Save questions for the end if you can – raise your hand to interrupt if you must ask before the end!
- Ask ANY question you want about any aspect of gynecology (or pregnancy) – even if it was NOT COVERED in the slides
  - I'll do my best to answer all your questions
  - Engagement is crucial to learning and I want all of you to take home something to improve your practice!

EARLY PREGNANCY

- Your patient calls and says she has a positive home pregnancy test. Now what?
  - Confirm the pregnancy!
    - Urine pregnancy test in your office (if you have the CLIA Waiver)
    - Bloodwork – QUANTITATIVE HCG
      - Does she have bleeding? Order BLOOD TYPE/RH and ANTIBODY SCREEN
      - Does she have history of miscarriage or ectopic? Order PROGESTERONE
  - Don't order an ultrasound yet – HCG over 2000 to see ANYTHING on an ultrasound

EARLY PREGNANCY

- HCG comes back, less than 2000
  - Check repeat HCG in 48 hours. Consider progesterone as well at that time.
  - HCG levels should increase at least 50% every 48 hours, and should double within 72 hours.
    - HCG 200 → 350→600 is still a relatively normal rise
  - Follow levels up to over 2000 BEFORE ordering an ultrasound
- HCG levels should **NEVER EVER DECREASE** in a normal pregnancy
  - Worrisome for ECTOPIC or NON-VIABLE PREGNANCY
  - Refer ASAP to GYN for decrease in HCG levels

PROBLEMS IN EARLY PREGNANCY

- BLEEDING is the number one reason patients call in the first trimester
  - Bleeding in early pregnancy is common, but is NEVER considered "normal"
  - If there is bleeding, you must check BLOOD TYPE/RH and ANTIBODY SCREEN
  - Follow HCGs as above, or refer to GYN for management
  - Bleeding can indicate an increased risk of ectopic pregnancy as well as miscarriage

THREATENED ABORTION (POSSIBLE MISCARRIAGE)

- Ultrasound diagnosis – you can't use HCG levels for this
  - Ultrasound reports might say:
    - Empty gestational sac (normal finding at 4.5 – 5 weeks)
    - Gestational sac with yolk sac (normal finding at 5-6 weeks)
    - Gestational sac with yolk sac and fetal pole, but no cardiac activity (normal finding at 5-6 weeks)
    - Fetal pole with cardiac activity (expected after 6 weeks)
- HCG levels are no longer helpful in this situation – ONLY ULTRASOUND
- One week is all you need to judge pregnancy progress
  - If no advancement on ultrasound in one week, likely a missed abortion or incomplete abortion
    - Missed abortion – miscarriage WITHOUT bleeding
    - Incomplete abortion – miscarriage WITH bleeding, but the pregnancy tissue is still inside

NAUSEA/VOMITING OF PREGNANCY

- A CLOSE SECOND to bleeding for phone calls in the first trimester
  - A good prognostic sign – indicates increasing hormone levels
- Start with over the counter treatment options
  - Doxylamine 25-20 mg (in UNISOM SLEEP TABS – NOT CAPSULES)
  - Vitamin B6 50-100 mg
  - Ginger 100 mg
    - Start all three at bedtime, may take up to three times per day
    - Preventative, not acute treatment
- Prescription meds only if OTC fails
  - PROMETHAZINE 25 mg (tabs and suppositories)
  - Avoid ONDANSETRON (Zofran) if possible
    - Increased risk of fetal cardiac abnormalities with chronic use

LATER IN PREGNANCY (NON-PREGNANCY COMPLAINTS)

- Respiratory
  - Seasonal allergies
    - Cetirizine, loratadine, fluticasone nasal spray, saline nasal spray
  - Asthma
    - Montelukast, albuterol, combined steroid/long acting beta agonist inhalers (Symbicort, Advair)
  - Sinus/Bronchitis
    - Treat the symptoms (dextromethorphan, pseudoephedrine, guaifenesin, acetaminophen, benzonatate RX)
    - If antibiotics are truly needed – azithromycin, amoxicillin-clavulanate, TMP/SMX
- UTIs
  - Always get a culture!
  - Send any positive results to the obstetrician
  - Safe meds (NOT CIPROFLOXACIN)
    - Nitrofurantoin (Macrobid)
    - Cephalexin (Keflex)
    - TMP/SMX (Bactrim DS)

PREGNANCY EMERGENCIES

- Ectopic pregnancy (early pregnancy)
  - Severe pelvic pain, lightheadedness, dizziness, vaginal bleeding
- Severe nausea/vomiting/dehydration (any time)
  - Can't keep down liquids for more than 4 hours
- Vaginal bleeding (second or third trimester)
  - Possible preterm labor or placenta previa
- Pre-eclampsia (usually third trimester)
  - Headache that won't go away with Tylenol
  - Upper abdominal pain
  - Blurred vision
- SEND ALL OF THESE PATIENTS TO EMERGENCY ROOM OR TO LABOR AND DELIVERY

VAGINAL BLEEDING – BREAKING IT DOWN

- Most important - get a good description of the bleeding pattern!
  - How long?
    - Less than 7 days is normal.
  - How heavy (pad count)?
    - Overnight pad only holds 15 mL when soaked
    - Super tampon holds 12 mL when soaked
    - 80 mL is normal menstrual loss
  - How often?
    - Every 25-35 days is normal/regular

VAGINAL BLEEDING – BREAKING IT DOWN

- Menorrhagia vs. metrorrhagia vs. dysfunctional uterine bleeding (DUB)
  - Menorrhagia with regular vs. irregular cycle
    - Menorrhagia with regular cycle (N92.0)
    - Menorrhagia with irregular cycle (N92.1)
  - Metrorrhagia (bleeding lasting more than 7 days)
    - Use the Menorrhagia codes, depending on regularity
  - Dysfunctional uterine bleeding (N93.8)
    - Unpredictability, prolonged episdoes of bleeding 2+ weeks in duration
    - This is often anovulatory
- Oligomenorrhea
  - Cycles longer than 35 days but less than 60 days
- Amenorrhea
  - More than 60 days without bleeding

TOO MUCH BLEEDING (MENORRHAGIA, METRORRHAGIA)

- Most Common Causes of Menorrhagia with Regular Cycle
  - Fibroids, Endometrial Polyps, Thyroid Disease, Hyperprolactinemia. Idiopathic
- Evaluation for Menorrhagia with Regular Cycle
  - Labs – CBC, TSH, Free T4, Luteal Phase Progesterone
  - Ultrasound
- Causes of Menorrhagia with Irregular Cycle
  - Same as regular cycle but also Hormonal Disturbance (PCOS, anovulation)
- Evaluation for Menorrhagia with Irregular Cycle
  - Same as Regular Cycle, but also possible PCOS evaluation, Diabetes evalution

TREATMENT OF HEAVY/PROLONGED BLEEDING

- Get labs FIRST!
- Get ultrasound as early as possible, transvaginal preferred
- Stop the bleeding
  - TXA
  - Norethindrone
  - OCPs

BLEEDING AFTER MENOPAUSE

- Is it truly menopause?
  - Check FSH and estradiol if under age 55 (may be perimenopausal)
  - Check ultrasound regardless of results (transvaginal preferred(
- If truly menopausal bleeding:
  - Concern for endometrial hyperplasia (pre-cancer) or uterine cancer
- Refer to GYN for endometrial biopsy and further evaluation
- Don't give any medication to stop bleeding prior to endometrial biopsy withour asking GYN
  - Progestins can distort endometrial biopsy results and mask abnormalities

THE DREADED PCOS DIAGNOSIS

- How to make the diagnosis
  - Irregular/prolonged cycles
  - Evidence of elevated androgens
  - Appearance of ovaries on ultrasound
- Components of evaluation
  - Lab studies – FSH, LH, TSH, Free T4, DHEA-S, Testosterone Free/Total, Prolactin, Progesterone, 17-hydroxyprogesterone
  - Ultrasound (may want to wait for GYN consult)
    - Ovarian volumes, appearance of ovaries on US
- Extra labs that could be helpful
  - Anti-Mullerian hormone, Hemoglobin A1C, fasting glucose, fasting lipid panel, fasting insulin (no water also!)

MORE PCOS MANAGEMENT

- Cycle regulation
  - OCPs\cyclic hormones
- Treatment of elevated androgens
  - OCPs, spironolactone
- Treatment of insulin resistance
  - Metformin
  - Consideration of GLP-1 agonist (Ozempic >> Trulicity)
- Fertility concerns

VAGINAL DISCHARGE

- Bacterial vaginosis (BV)
  - Fishy odor, yellow or gray in appearance, thin. Vaginal pH > 3.5
  - Not just Gardnerella vaginalis
    - Atopbium vaginae, Megasphera, Bacteriodes
  - Most common infection in the desert/arid areas
- Treatment options:
  - Metronidazole 500 mg BID x 7 d - $
  - Tinidazole 500 mg BID x 5 days, or 2 grams daily x 2 days - $$
  - Metronidazole 0.75% gel vaginally x 5 nights - $$
  - Clindesse cream 1 applicator vaginally x 1 dose - $$$
  - Solosec granules 2 grams orally x 1 dose - $$$

MORE VAGINAL DISCHARGE

- Candida vaginitis
  - Thick white discharge, "cottage cheese", pruritus but no odor. Normal vaginal pH
  - Candida albicans most common, less common = Candida glabrata and Candida parapsilosis
    - Consideration of male hygiene as a cause
    - Always think about diabetes control, possibility of other immunosuppressive conditions
- Treatment options
  - Fluconazole 150 mg x 1 dose (may need daily x 3 days)
  - Over the counter vaginal treatments – always 3 days or longer (avoid one-day treatment)
  - Terconazole 3-day or 7-day treatments vaginal cream
- Trichomonas
  - Looks similar to BV, often more green in color, more frothy
  - Treatment options – same as BV

EVEN MORE VAGINAL DISCHARGE

- Other vaginal/cervical infections to watch
  - Mycoplasma/ureaplasma
    - Treated with doxycycline or azithromycin, partner treatment also
- The root of the problem
  - Lactobacillus and vaginal pH
  - Benefits of probiotics
  - Unique solutions to a common problem

SPECULUM EXAMS

- DO
  - Spread the labia minora before inserting
  - Angle your speculum for insertion
  - Rotate speculum to horizontal as you insert
  - Angle tip of speculum down towards the sacrum to "dip" under the cervix
  - Only open enough to see the entire cervix (to collect Pap and cultures)
  - Relax speculum as you withdraw
- DON'T
  - Use lubricant on your speculum
  - Use a medium or large speculum as your first choice
  - Open wider than you need (ouch!)
  - Keep pushing if your patient has pain

THINGS YOU DO THAT ANNOY YOUR GYNECOLOGY COLLEAGUES (AND WHAT TO DO INSTEAD!)

- Please don't order lipid panels at any time during a pregnancy
- Please don't order "hormone panels"
- Please don't treat vaginal infections without evaluation
- Please don't treat UTIs without a culture (especially during pregnancy)
- Please don't order Pelvic CT or MRI without discussing first with GYN
- Please don't ever give estrogen replacement in a woman with a uterus without ALSO giving progesterone
- Please check for "missing" IUD strings using a Pap brush (mascara brush) before referring

TIME FOR QUESTIONS – ASK ME ANYTHING!

THERE ARE NO DUMB QUESTIONS HERE. PROMISE.

Nevada Academy of Family Physicians
32nd Annual Summer CME Meeting
July 30–August 1, 2021

NOTES