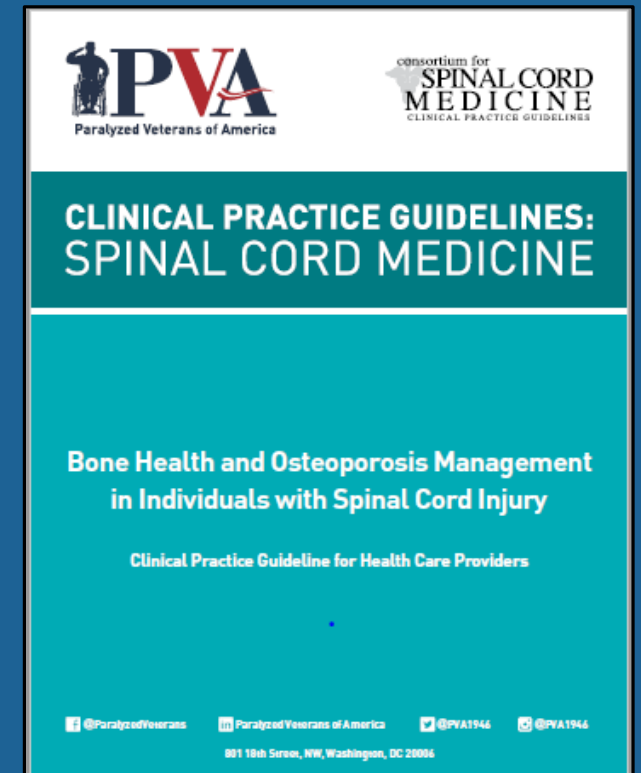


Applications of the SCI Bone Health CPG's to Clinical Practice

Amanda L. Harrington, MD

Lauren Malacarne, DPT



Disclosures

- Dr. Harrington is on the Medical Advisory Committee of the Ryan Shazier Fund for Spinal Cord Rehabilitation

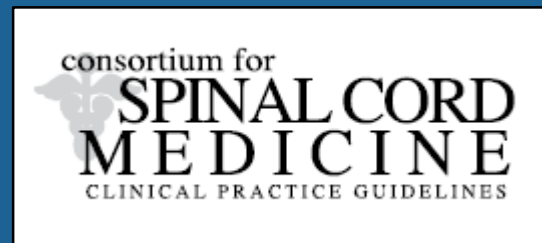
Objectives

- Highlight major recommendations from the new Bone Health Clinical Practice Guidelines (CPG)
- Using a case-based format, introduce applicability of guidelines in clinical practice
- Emphasize bone health as an important comorbidity to manage after spinal cord injury (SCI)

CLINICAL PRACTICE GUIDELINES: SPINAL CORD MEDICINE

Bone Health and Osteoporosis Management in Individuals with Spinal Cord Injury

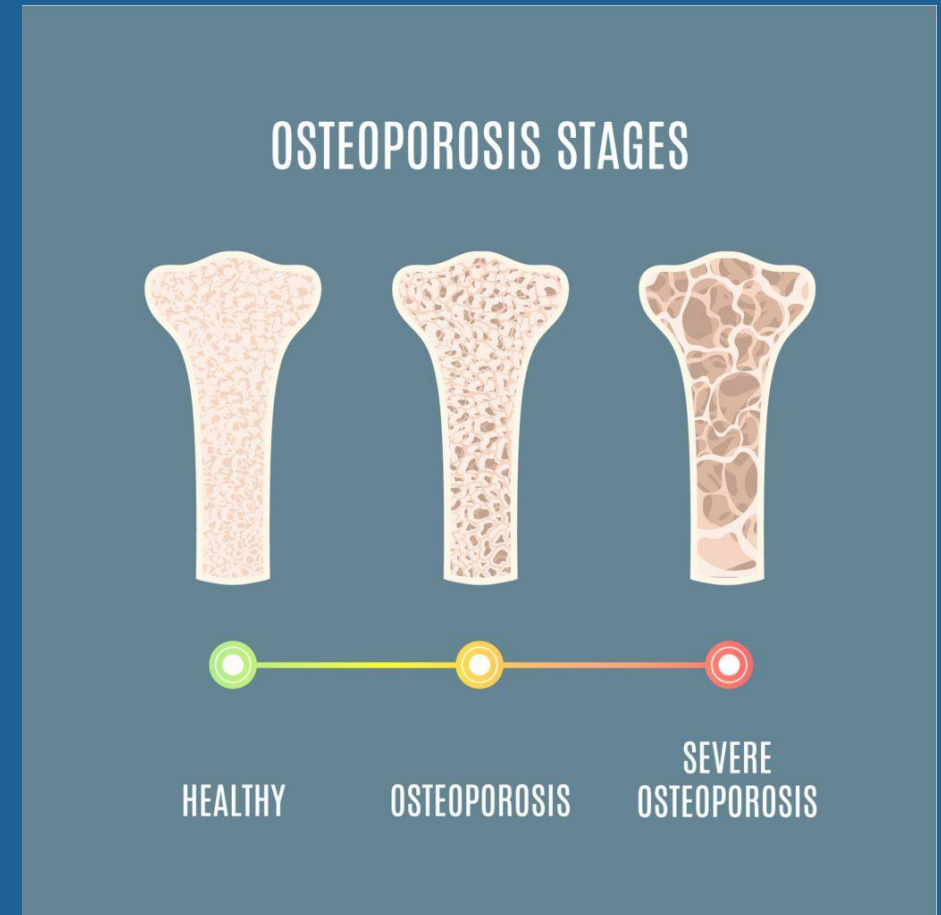
Clinical Practice Guideline for Health Care Providers



Consortium for Spinal Cord Medicine.
Bone Health and Osteoporosis Management
In Individuals with Spinal Cord Injury:
Clinical Practice Guidelines. 2022
Access online at PVA.org

What should you learn today?

- Bone health and osteoporosis after SCI
 - Fractures
 - Falls
- Prevention
- Screening
- Treatment



<https://womansera.com/>

Definitions

- Osteoporosis
- Osteopenia
- Bone Mineral Density (BMD)
 - T-scores
 - Z-scores
- Fragility fracture
- Bone density scan (DEXA scan, DXA scan)

Example medications to treat Osteoporosis

- Alendronate
 - oral
- Zoledronic acid
 - IV
- Denosumab
 - SQ

	Benefits vs. Risk and Burdens	Methodological Strength of Evidence	Implications for Practice: Wording of Recommendation
1A = strong recommendation, high-quality evidence	Benefits clearly outweigh risk and burden or vice versa	Consistent evidence from RCTs without important limitations or exceptionally strong evidence from observational studies	Recommendation can apply to most patients in most circumstances. "We recommend . . ."
1B = strong recommendation, moderate-quality evidence	Benefits clearly outweigh risk and burden or vice versa	Evidence from RCTs with important limitations (inconsistent results, methodological flaws, indirect or imprecise) or very strong evidence from observational studies	Recommendation can apply to most patients in most circumstances. "We recommend . . ."
1C = strong recommendation, low-quality evidence	Benefits clearly outweigh risk and burden or vice versa	Evidence for at least 1 critical outcome from observational studies, case series, RCTs with serious flaws, or indirect evidence	Recommendation can apply to most patients in many circumstances. "We recommend . . ."
1D = strong recommendation, very low-quality evidence	Benefits clearly outweigh risk and burden or vice versa	Evidence has significant flaws. Expert opinion includes evidence in the context of experts' experiences and knowledge or experts' interpretation of uncontrolled case series (e.g., in own practice)	Recommendation can apply to most patients in many circumstances. "We recommend . . ."

Consortium for Spinal Cord Medicine. Bone Health and Osteoporosis Management In Individuals with Spinal Cord Injury: Clinical Practice Guidelines. 2022 Access online at PVA.org

2A = weak recommendation, high-quality evidence	Benefits closely balanced with risks and burden	Consistent evidence from RCTs without important limitations or exceptionally strong evidence from observational studies	The best action may differ depending on patient circumstances or societal values. “We suggest . . .”
2B = weak recommendation, moderate-quality evidence	Benefits closely balanced with risks and burden	Evidence from RCTs with important limitations (inconsistent results, methodological flaws, indirect or imprecise) or very strong evidence from observational studies	The best action may differ depending on patient circumstances or societal values. “We suggest . . .”
2C = weak recommendation, low-quality evidence	Uncertainty in the estimates of benefits, risk, or burden	Evidence for at least 1 critical outcome from observational studies, case series, or RCTs with serious flaws or indirect evidence	Other alternatives may be equally reasonable. “We suggest . . .”
2D = weak recommendation, very low-quality evidence	Very little confidence in estimates of benefits, risk, or burden	Lack of evidence for at least 1 critical outcome from observational studies, case series, or RCTs with serious flaws or indirect evidence	Other alternatives are not able to be assessed. “One may . . .”

Consortium for Spinal Cord Medicine. Bone Health and Osteoporosis Management In Individuals with Spinal Cord Injury: Clinical Practice Guidelines. 2022 Access online at PVA.org

Case 1

- 25 y/o man with T4 complete paraplegia is 6 months post-traumatic SCI
- No pre-existing medical problems
- Denies significant family history of medical illness
- Following up in the outpatient SCI clinic
 - Denies any problems with neurogenic bowel and bladder management
 - Denies significant problems with pain or spasticity
 - Working with OVR to return to work
 - Inquires about what he can do to maintain his health in coming years

Applicable recommendations

- All adults with permanent sensory or motor dysfunction should have a bone density screen as soon as medically stable (1A)
 - Should include hip, distal femur, and proximal tibia (1B)
 - Results can diagnose osteoporosis, predict lower limb fracture risk, and monitor response to therapy (1B)

Alternative to DEXA

- Peripheral quantitative CT can be used as an alternative to bone density (DXA scan) (1B)
 - Can be used to diagnose osteoporosis after SCI
 - Specific results should include volumetric bone mineral density, cross-sectional area, bone mineral content, bone strength index, cortical thickness
- Both trabecular and cortical bone sites in the femur and tibia should be evaluated annually (to monitor regional changes) (1B)

Lab Screening Recommendations

- Regardless of injury duration all persons with SCI should be screened with (1C):
 - Vitamin D 25-OH
 - Complete blood count
 - Ionized calcium
 - Phosphate
 - Intact parathyroid hormone
 - Creatinine and estimated GFR
 - Bone-specific alkaline phosphatase and liver enzymes
 - Hemoglobin A1c
 - TSH
 - 24 hour urine creatinine and calcium

Lab Screening Recommendations

- Pre-Menopausal Women (1D)

- Prolactin
- FSH
- LH
- Estradiol

- Men (1D)

- LH
- FSH
- Morning free testosterone

- May consider (2D)

- Protein electrophoresis in persons over 50 or persons with vertebral fractures of unclear etiology
- 24 hour urinary cortisol or dexamethasone suppression test if Cushing's suspected
- Extra-tissue transglutaminase IgA if celiac disease suspected

Recommended supplementation

- Replete vitamin D 25-OH levels to 80 nmol/L (1B)
 - Vitamin D3 (cholecalciferol) 25-50 mcg/day (1,000-2,000 IU/day)
- Calcium intake (combination of dietary and supplemental) (1B)
 - 1,000mg a day
 - May increase to 1,200 mg a day in women over 50 and men over 70
 - In persons with SCI and history of calcium stones (2D)
 - May reduce calcium intake to 750mg a day (dietary source preferred)

Potential drug therapy - Prevention

- High risk of development of osteoporosis 12-18 months after SCI
 - Anticipate reduction in bone density at the hip and knee
- Recommended to have a risk-benefit discussion about drug therapy in persons with acute SCI whom are primary wheelchair users (1C)
- Consider administration of alendronate, zoledronic acid, or denosumab if the patient has a desire to prevent secondary bone mineral loss (1C)

Case 1

- After his initial injury, our patient completed a traditional course of inpatient rehab, a short course of home health therapy, and a traditional course of outpatient therapy
 - Initial focus on strengthening unaffected muscles, core balance, transfers, and wheelchair skills
 - Now interested in engaging in standing and/or gait training activities
 - He asks you how this relates to his bone health

Applicable Recommendations

- There is no established threshold of bone mineral density for which weight-bearing activities are absolutely contraindicated (1B)
- Clinical risk factors and bone mineral density should be used to evaluate risk factors prior to engaging in weight-bearing (1B)

Rehabilitation Interventions

Potential therapies to prevent and treat low bone mass, osteoporosis, and high fracture risk among individuals with SCI:

- Passive standing
- Overground walking
- Treadmill training
- Neuromuscular electrical stimulation (NMES)
- Functional electrical stimulation (FES)

Therapeutic goal to prevent BMD decline

- Early post-injury when bone mass has not been adversely affected
- Ameliorate or prevent excessive resorption of hip and knee region bone mass

Building or Losing Bone

- Mechanostat theory
 - Bone formation exceeds bone resorption
 - Bone receives intermittent forces that are above a “minimum effective strain”
- Primary mechanical factors sensed within bone that result in changes in the balance between resorption and formation:
 1. External gravitational loading
 2. Muscle contractions

Candidates for Rehab Interventions

- Acute or chronic SCI
- AIS- A, B, C, or D
- Ability to tolerate and engage in electrical stimulation-based therapy if the use of NMES or FES is desired

Definitions- Rehab Interventions

- Passive standing: standing frame, standing wheelchair, long leg braces, or other devices
- Active standing: standing involves some muscle activation (voluntary or by using FES/NMES)
- Walking: overground or on a treadmill, varying amounts of bodyweight support
 - Can include orthoses, exoskeletons, or assistive devices
- Neuromuscular electrical stimulation (NMES): application of a sufficient current to elicit muscle contraction
- Functional Electrical Stimulation (FES): pairing NMES with a functional task
 - cycling, rowing, standing, walking

Considerations Prior to Initiating Rehab Therapies

- Review concurrent medical therapies with potential adverse effects on bone mass accrual and fracture risk
- Assessment of non-BMD risk factors for fracture
- Confirm medical management of calcium and vitamin D

Passive Standing for Prevention

- Prevention of BMD decline
 - Consider passive standing for 1 hour 5 times per week for at least 2 years to reduce BMD decline at the hip and knee regions (2D)
- Clinical Consideration: There are many therapeutic benefits of standing beyond the scope of this CPG

Overground Walking for Prevention

- **No studies** that examined use of walking as an intervention to prevent BMD decline met the criteria for this CPG
- Since walking is recommended for maintaining or improving bone health in the general population, it is encouraged for those who are able to do so after SCI
- Consideration: reducing risk of falls and related possible fracture

Treadmill Training for Prevention

- **Weak evidence** demonstrating that treadmill training prevents BMD decline at the hip and knee regions

NMES and FES for Prevention

NMES and FES are suggested as an options for preventing BMD decline in the hip and knee region

- Most effective interventions should create a visibly strong contraction:
 - NMES against some resistance, such as isometric contraction, movement against gravity, or during loading (1B)
 - FES against some resistance during some functional task (1D)
- Clinical consideration: Cost of NMES/FES

Clinical Consideration: NMES and FES

- NMES should be delivered in weight-bearing standing, gradually achieving greater support from muscle contraction than the standing frame
- Progress as tolerated as muscle strength increases or fatigue decreases with training
- Physicians should assess BMD at sites that have the potential to be affected by the FES and NMES intervention and not at a remote site
- Exercise caution when providing FES/NMES in order to mitigate fracture risk
 - E-stim therapies should be prescribed and/or implemented only by clinicians with expertise in electrical stimulation and SCI

NMES/FES Parameters

- Pulse duration: 200 μ s or higher
- Frequency: 20-33 Hz
- Amplitude: up to 140 mA
- Treatment: at least 30 minutes, 3-5 times per week, for at least 1 year

Final Recommendation

- Minimum duration of 1 year for lower extremity muscle-activated and load-bearing rehabilitation therapy is needed before an effect on bone density is expected (1B)
- Further, to maintain effects on bone density, lower extremity muscle-activated and load-bearing rehabilitation therapy needs to be continued indefinitely (1B)
- Clinical Consideration: Adherence to NMES/FES

Case 2

- 58 y/o man with C7 complete tetraplegia for 30 years
- Requires set-up or assistance for ADLs and complex transfers but is independent with driving and manual wheelchair propulsion
- Working full-time and active on quad rugby team
- Reports increased shoulder pain with basic transfers and recent fatigue at the end of the day
- Comes in for routine check-up

Applicable recommendations

- Clinicians should assess for fracture risk at least on an annual basis (1B)
- Clinicians should evaluate risk factors for fractures any time there is a change in functional abilities (1B)
- Clinicians should routinely assess fall risk (1A)
- Hip, distal femur, and proximal tibia bone mineral density can help predict risk of fracture (1B)
 - Should be repeated 12 months after treatment initiated and every 1-2 years

Case 2

- Patient is found to have osteoporosis on bone mineral density
- He is interested in starting treatment for his osteoporosis

Treatment Recommendations - Osteoporosis

- Use shared decision making when selecting drug therapy (1C)
 - Avoid adverse effects
- Recommend treatment with alendronate, zoledronic acid, or denosumab in persons with SCI, low bone mass, and moderate-high fracture risk (1B)
 - Combined with adequate Calcium and Vitamin D supplementation
- Clinicians should reassess treatment if significant bone loss occurs for 2 consecutive years despite good adherence (2C)
 - Reassess treatment if a long bone fragility fracture occurs after 1 year of treatments despite good adherence (1D)

Long-term Treatment Recommendations - Osteoporosis

- Consider drug holiday in individuals with moderate fracture risk following 5 years of consecutive oral bisphosphonate therapy or 3 years of IV bisphosphonate therapy (2D)
- In individuals with high or very high risk for fractures, consider 7-10 year duration of oral bisphosphonate therapy or 6 annual doses of IV zoledronic acid (2D)
- Consider trialing alternative drug therapy if side effects or poor adherence preclude continued therapy (2D)
- Clinical consideration: consider Endocrinology consultation

Rehab Interventions for Treatment

Passive Standing

- **No evidence** that passive standing is effective for treatment of bone loss in chronic SCI
- To date, there are no adverse effects reported to be associated with passive standing, suggesting risks are low

Overground Walking

- **Weak evidence** with limitations in the methodology for demonstrating the effects of walking training on increasing BMD

Rehab Interventions for Treatment

Treadmill Training

- **Weak evidence** with limitations in the methodology for demonstrating the effects of treadmill training on increasing BMD

NMES and FES

- Lower extremity FES or NMES are suggested as an option for treating low BMD in the lower limbs.
 - The most effective interventions should:
 - NMES creates a visibly strong contraction against incrementally increasing resistance such as an isometric contraction, movement against gravity, or during weight bearing (1B)
 - FES creates a visibly strong contraction incrementally against resistance during some functional task (1D)

Case 3

- 45 y/o man with T12 paraplegia for 15 years, has a complex tib/fib fracture after a fall
 - Transfer from truck to manual wheelchair
- Presents to ER for evaluation
- Orthopedic surgery consulted
 - Need decision on operative management
 - Need decision on casting or bracing

Applicable Recommendations

- Long bone or fragility fractures should have an orthopedic consultation (1D)
- There should be shared decision making regarding surgical fixation vs conservative management (2D)
 - Risks and benefits
 - Patient values and preferences
 - Health status and medical comorbidities
 - Post-fracture attendant care resources
- Evaluate for venous thromboembolism even if chronic SCI (1C)
 - Provide prophylaxis with low molecular weight heparin (i.e. enoxaparin) or a direct oral anticoagulant (i.e. apixaban) as soon as possible (1C)
 - Continue until discharge from acute care/ rehabilitation (at least 2-4 weeks) (2D)

Applicable Recommendations

- Assess for leg edema and use multilayer compression wraps to mitigate edema in high risk individuals (1D)
- Monitor persons with injuries T6 and above for autonomic dysreflexia (1D)
 - Consider pharmacologic management if persistent AD symptoms (1D)
 - Consider transfer to monitored unit (1D)
 - Provide analgesia for nociceptive pain management in the first 3-5 days after the fracture and consider definitive fracture management (1D)

Conservative Treatment Recommendations

- Prescribe soft, custom-molded, immobilization devices (1D)
 - Bivalve the device
 - Provide heel and malleolar windows to prevent skin breakdown
- Clinicians should evaluate fracture risk after a fall with injury (1A)
 - Prior fracture will inform risk for future fracture
 - Patients with a fracture and diagnosis of osteoporosis should be considered moderate-high risk for fragility fracture
 - Consider osteoporosis treatment soon after diagnosis of a fragility fracture (2D)

Rehab Care Beyond Definitive Fracture Management

- For wheelchair users
 - Provide elevating leg rests or additional attendant care supports (1D)
 - Seating reassessment for wheelchair users with fracture-related changes (1D)
- For ambulatory individuals
 - Bracing reassessment for ambulatory individuals (2D)
- For all individuals with SCI
 - Comprehensive mobility assessment (1D)
 - Return to premorbid hip, knee, and ankle ROM after fracture healing (1D)
 - Decisions to progress weight-bearing and loading should be made with input from treatment team (surgeon, physiatrist, therapists) and the person with SCI (2D)

Prevention of Future Falls

- Patient should be offered falls prevention education, transfers and wheelchair skills upgrade, and balance training to reduce risk for future falls and build confidence to return to community participation (1D)
- Evaluate confidence in navigating home and community environments (2C)
- SCI-Specific Fall Prevention Programs (2D)
- Clinical considerations for wheelchair users:
 - Increase diameter of casters, increase dump, use seatbelts or chest straps, and taking time when performing physical tasks (e.g. transfers)
 - Advanced wheelchair skills training

SCI-Specific Fall Prevention Programs (2D)

SCI rehabilitation programs may consider establishing SCI-specific fall prevention programs accessible to individuals with SCI across the continuum of care.

This should include education regarding:

1. Fall prevention strategies
2. Techniques to reduce injury when a fall occurs
3. Psychological and physical fall recovery practices
4. Peer-to-peer education
5. Inclusion of SCI caregivers

Falls

- Falls are common and frequently result in fragility fractures after SCI
 - Ambulatory individuals: ~75% fall risk
 - Wheelchair users: 14%-35% experience injurious falls
- Mechanisms
 - Ambulatory individuals: perceived decreased muscular strength, environmental hazards, loss of balance, walking without a device
 - Wheelchair users: transferring or maneuvering over uneven terrain
- Who is most likely to experience an injurious fall (81%)?
 - Greater motor function, history of a fall, and inaccessible home entrance

The Impact of Falls

- Injuries
 - 10%-41% report minor injuries- bruises, scrapes, and muscle/ligament strain or sprain
 - Fractures reported after 18% of falls in wheelchair users
- Psychosocial
 - Altered self-image, concerns of falling, and avoidance or limitations in performing daily activities

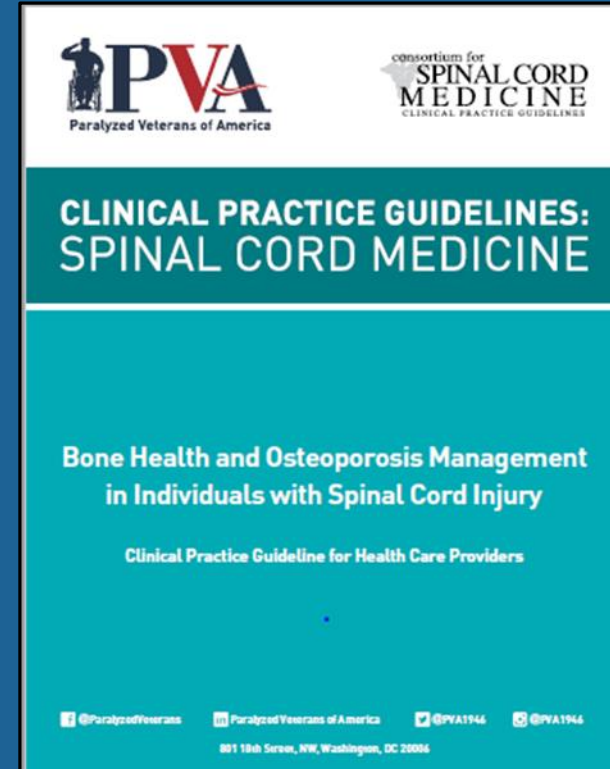
Bottom Line About Falls and Fractures

- We need to talk about falls and risk of falls to reduce fracture occurrence.
- Because of the various physical and psychological complications that individuals with SCI may face following a fracture, it is essential that risk factors be assessed throughout the individual's lifetime in both rehabilitation and community care settings.

Thank you & Questions

www.pva.org

Consortium for Spinal Cord Medicine.
Bone Health and Osteoporosis Management
In Individuals with Spinal Cord Injury:
Clinical Practice Guidelines. 2022
Access online at PVA.org



Summary of what you learned today

- Bone health
 - Screening recommendations
 - Labs / Radiologic studies
 - Supplementation
- Osteoporosis
 - Prevention
 - Diagnosis
 - Treatment
- Fractures
 - Risk mitigation
 - Treatment
- Fall
 - Assessment
 - Prevention