Disclaimer

The information provided is not intended as a substitute for the medical advice of a healthcare professional. It is intended for educational purposes and should not be used as the sole source of information or advice. Readers are encouraged to consult with a healthcare professional for medical advice and treatment.

Steven Conway DC, ESG
National Medical Park Project
Current FCPS Board of Directors
Past member of NECE Board of Directors
Past member of Wisconsin Board of Chiropractors
Second generation chiropractor

Re-imagined Compliance
Chiropractor
Problem is the Chiropractic Error Rate.
Chromatography

Problem is the
Chromatographic Error Report

Chromatography

Problem is the
Chromatographic Error Report

Chromatography

Problem is the
Chromatographic Error Report
The Future

Solution

OC4 solutions

2000 clinics in the US (750 clinics in the check-in line)

Increase in order enable and the ZPC

Problem is the Cataract Ectopic Ratio
Medicare Compliance

Do not document or encode services.

For new patients:
- Correctly identify all patients.  Use correct suffixes.
- DO NOT include Medicare/Medicaid patients in any performance measures.
- Do not include Medicare/Medicaid patients in any performance measures.
- Patients including exemptions, therapies or exemptions of Medicare can assist in providing free services to Medicare.

Please refer to the CoC's Patient Care Manual.

Medicare Compliance

Medicare Compliance

Medicare Compliance

Medicare Compliance
3 Phases of a Medicare Case

**Ending Phase:**
- Properly releasing the patient to end the episode of care.
- Filling out the necessary documentation.
- Providing the needed information to ensure that all the necessary paperwork is completed.
- Providing the patient with access to the entire case.

**Middle Phase:**
- Understanding the condition and developing the initial visit.

**Beginning Phase:**
- Understanding the condition and initial visit.

Future Audits will be based on...
Secondary complaints:
- Premenstrual symptoms
- Menses
- Menopause
- Dysmenorrhea
- Vaginal bleeding or spotting
- Nonspecific symptoms
- Abnormalities or symptoms on examination
- Symptoms of menopause
- Pelvic health history
- Family history for cancer
- Symptoms causing the patient to seek treatment

Initial Visit: History

Initial Visit Requirements:
- Date of initial treatment
- Treatment Plan
- Diagnosis
- Initial physical examination
- Evaluation of musculoskeletal/nervous system
- Description of the present illness
- History

Initial Visit Requirements:
- Information gathered by x-ray or physical exam is described
- The patient must have a substitution of the spine for the patient's condition that provides reasonable functional muscle and joint dysfunction.
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- The patient must have a substitution of the spine for the patient's condition that provides reasonable functional muscle and joint dysfunction.
Initial Visit: History

Supportive counseling choices for subsequent visits.
- Symptoms will be correlated to your DMS and medical conditions.
- Symptoms may correlate to a specific etiology.
- Symptoms need to be noncommunicable.
- Documentation will be documented.
- Treatment.

Symptoms causing patient to seek treatment.

Initial Visit: History

Secondary completion.
- Proactive consultation. Treatment. Medications and
- Identification of effective treatment.
- Radiation of symptoms.
- Control of symptoms. Fractures. Location and
- Quilty and comfort of symptom/prediction.
- Administration of trauma.
- Physical history.
- Family history if relevant.
- Symptoms causing the patient to seek treatment.

Initial Visit: History
Initial Visit: History

A correct treatment plan development:

- History of tumor - type of symptoms - past history

- Mechanism of Trimming

- Measuring of Trimming

- Mechanism of Trimming
Initial Visit: Examination

- History: Provide a detailed account of any symptoms, duration, and any relevant medical history.
- Physical examination: Include assessment of vital signs, general appearance, and specific areas of concern.
- Laboratory tests: Request any necessary tests as indicated by the examination.

Initial Visit: Present Illness

- Symptoms: Describe the current symptoms experienced by the patient.
- Medical history: Review any previous medical conditions and treatments.
- Family history: Obtain information about family medical history.

Initial Visit: Past Medical History

- Previous medical conditions: List any conditions treated in the past.
- Past surgical history: Include any past surgeries.
- Current medications: Provide a list of all current medications and dosages.

Initial Visit: Physical Examination

- Neurological examination: Assess for any neurological abnormalities.
- Orthopedic examination: Check for any orthopedic issues.
- Cardiovascular examination: Evaluate cardiovascular functions.

Initial Visit: Laboratory Tests

- Blood work: Conduct basic blood tests such as CBC, electrolytes, and liver function tests.
- Imaging studies: Request X-rays, CT scans, or MRIs as per the history and examination findings.
- Specialized tests: Order any specialized tests indicated by the initial assessment.
Treatment Plan

Initial Visit: Evaluation

- Exam to determine presence of malocclusion
- Evaluate if patient has a functional or structural deviation
- Determine the need for further examination
- Ensure all necessary components are present
- Address any issues that may require additional evaluation

Initial Visit: Diagnosis

- Initial Dx must be a substitution diagnosis and
- Efforts
- Universal agreement and LCDS harmonization
- NMs are used in the secondary dx codes.
- Diagnosis codes
- Must use the N99.0-10.99.05 segmental
- Found in the examination section.
- Correlate to the specific values.
- Subsections and

Initial Visit: Examination

- Examination values
correlate to the maxillodental
- Framework
- Evaluation of the maxillodental
- Framework system
- Correlate to the maxillodental
- Framework system
Initial Visit: Treatment Plan Goals

- Compare to worker's compensation goals.
- Goals that can be measured and verified with you.
- Use of meaningful goals vs. "let's see what is.
- Specific goals vs. Generic Goals.

Releasing Chiropractic "Micro"

- Complainants noticed on Oswestry by 20%.
- Improve patient's overall symptoms and pain.
- Goal of treatment will be to decrease.

List of commonly used chiropractic goals.

- Improve the % noted on Oswestry form.
- Increase range of motion.
- Increase range of motion.
- Increase function.
- Reduce pain.
New Model - START WITH THE GOAL FIRST!

Initial Visit: Treatment Plan

ExcessivePhysical

3 times per week for 16 weeks

Then you add a 6 week period

Then you add in the Maintenance period

Current model starts when visit frequency

Change the way you determine your

What goals should I include?

- No specific goal requirements are listed by
- Medicaid
- Medicare

- Include: Highly recommended, but NOT reimbursed goals

- Quarterly, measurable goals using numbers
- Goals associated with symptoms or other "G" activities of daily living (ADLs)
- Frogs
- Free loving
- Range of motion

- Increase ability to sleep from current 2 hours to 6
- Decrease current edema in the right foot to 2.5 cm to 0.5 cm
- Decrease this from 6 to 3

- Use Akt and other measurable goals
- Create the goal to the medication or treatment
- Start with a goal that can be measurable
- Determine the specific measurable goal

Initial Visit: Treatment Plan
Initial Visit: Treatment Plan

Next Focus on Frequency

Initial Visit: Treatment Plan

Next Focus on Duration
Your Visit:

Key Points:

- Measurable goals at each visit.
- Review and monitor your progress.
- Always review and monitor your progress.

Subsequent Visit:

- Next visit:
- Review and monitor your progress.
- Always review and monitor your progress.

Subsequent Visit:

- Next visit:
- Review and monitor your progress.
- Always review and monitor your progress.

Subsequent Visit:

- Next visit:
- Review and monitor your progress.
- Always review and monitor your progress.

Subsequent Visit:

- Next visit:
- Review and monitor your progress.
- Always review and monitor your progress.
Electronic Signatures

Signatures required.
Providers can submit the Attestation Form if
Signature Attestation documentation.

Signature for

Written or electronic. No stamps.

To be signed by the provider.

Signatures:
Levels of severity

CERT Summary

General

OCR unit (inspector) Office of Inspector
ZDC unit (zone program integrity coordinator)
RCR activities (correspondence)

CERT Review, Complainants' Form (Claim Review)
Compliance

If you are uncertain about the CERT findings, you may appeal the

Procedure, but only if you did not appeal.

CERT returns the identification of the company.

The company's response to the CERT findings must
be submitted in writing in the CERT's office.

CERT is responsible to ensure that these reviews are performed in

CERT

OEPR

OEPR

OEPR

OEPR

OEPR

OEPR

OEPR

OEPR
0IG Audits

Actions to Resubmit:

- Update the OIG submission with additional information and redactions as required.
- Submit all requested attachments.
- Provide a detailed response to the OIG's comments.
- Include a redacted version of any documents submitted.

0IG Audits

0IG Audits

0IG Audits

0IG Audits

0IG Audits
### Redetermination

**Redetermination**

<table>
<thead>
<tr>
<th>Explanation</th>
<th>Action</th>
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</thead>
<tbody>
<tr>
<td>A re-determination is requested for a reason within the 60 day period from the date the determination was made.</td>
<td>Response from the carrier must be within 10 days of receiving the re-determination request.</td>
</tr>
<tr>
<td>The notice of re-determination must be handled by the carrier and must include:</td>
<td></td>
</tr>
<tr>
<td>- A summary of the reasons for the re-determination (for summary re-determination).</td>
<td></td>
</tr>
<tr>
<td>- A copy of the determination.</td>
<td></td>
</tr>
<tr>
<td>- A copy of the notice of the determination.</td>
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</tbody>
</table>

### Initial Determination

**Initial Determination**

(The first denial)

<table>
<thead>
<tr>
<th>Explanation</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial determination is made by the payer's contractually designated agent in accordance with the medical policy.</td>
<td>The initial determination must be made within 15 days of receipt of the complete and correct claim.</td>
</tr>
<tr>
<td>The initial determination must include:</td>
<td></td>
</tr>
<tr>
<td>- A summary of the medical policy.</td>
<td></td>
</tr>
<tr>
<td>- A determination of coverage, or denial, based on the information provided and comparison to the medical policy.</td>
<td></td>
</tr>
<tr>
<td>- A copy of the claim submission, and any attachments that were considered in the determination.</td>
<td></td>
</tr>
<tr>
<td>- A statement that the initial determination is final unless the carrier's acquirer or another party designated in the carrier's contract has not agreed to a more timely determination.</td>
<td></td>
</tr>
</tbody>
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MEDICAL DOCUMENTATION ERRORS

AGENDA

- Most common Chiropractic errors
- Understanding informed consent
- Case review Stroke
- Case review low back
- Medical errors and common side effects
WHERE/WTHAT IS THE PRIMARY SOURCE OF CHIROPRACTIC ERRORS?

Initial visit
- History
- Patient's Health

Subsequent visits
- Treatment
- Progress notes

WHERE/WTHAT IS THE SECONDARY SOURCE OF CHIROPRACTIC ERRORS?

Initial visit
- History
- Patient's Health

Subsequent visits
- Treatment
- Progress notes

REVIEWING MALPRACTICE CLAIMS

- Informed consent is a key issue
- Intake form system
- Fulfilling all requirements
- If I would have been properly informed, I would never have consented to treatment.
- Lack of prior history documentation in the file
- No review of prior history before treatment
- Past history provided by the patient may be filtered
- Fear of disclosure would increase financial costs for examinations / diagnostics
MALPRACTICE CASE REVIEW

- Examination / Diagnosis
  - Failure to correctly examine / diagnosis (low back case today)
  - 20/20 hindsight is easy to find errors in documentation
  - X-ray issue / ACA guidelines
- Documentation
  - Poor documentation is difficult to overcome
- Closing issues
  - Progress Examinations
  - Lack of progress examinations makes it harder to defend continued treatment

MALPRACTICE CLAIM REVIEW

- Release
  - Treatment plans that have specific goals / objectives are key to defending the case
  - The “returning patient” vs the “brand new shiny patient”
- Procedures / Processing
- History / Examination decisions
- Informed consent issues

FREQUENCY OF CLOSED CHIROPRACTIC MALPRACTICE CLAIMS

<table>
<thead>
<tr>
<th></th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disc Problems</td>
<td>26.7</td>
</tr>
<tr>
<td>Fracture</td>
<td>13.8</td>
</tr>
<tr>
<td>Failure to Diagnose</td>
<td>13.1</td>
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<tr>
<td>Aggravation of Condition</td>
<td>7.1</td>
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<tr>
<td>Cerebrovascular Accidents</td>
<td>5.4</td>
</tr>
<tr>
<td>Burn</td>
<td>3.4</td>
</tr>
<tr>
<td>Therapy</td>
<td>3.0</td>
</tr>
</tbody>
</table>
Common Chiropractic Errors

- **Failure to diagnose and refer**
  fractures, pathology, arterial occlusions

- **Equipment related issues**
  improper equipment maintenance, contraindicated therapy choices, improper supervision of minors in treatment rooms, improper patient/equipment supervision

Common Chiropractic Errors

- **Improper treatment**
  high velocity techniques, contraindicated therapies, contraindications to adjustments

- **Erroneous recommendations**
  contraindicated recommendations with regard to medicines / supplements and or treatment including exercise, referrals and recommendations
Do you currently have valid informed consent?

- History of informed consent
- Definition of informed consent
- Do you have a valid informed consent?
- Elements of valid informed consent

Quick questions?

- Is a signed intake form a valid informed consent?
- Are you required to disclose stroke information during your informed consent?
- Do you know what is the "reasonable standard" for your state?
- Do you only need to do an informed consent once when they are a new patient?

Sard v Hardy (1977)

- A patient became pregnant despite a tubal ligation procedure.
- The patient claimed the doctor was negligent in failing to advise her that the procedure had a 2% failure rate and that there were alternative methods for sterilization and birth control.
- Court of Appeals agreed with her and established the physician's duty to obtain a patient's informed consent prior to providing any particular treatment.
- This duty was held to be separate and distinct from the duty of obtaining informed consent for a patient's treatment. (please refer to the text for the full context.)
**Sard v Hardy**

- There was no breach in the standard of care provided to the patient. The recommendation was reasonable and the procedures were carefully performed.
- However, there was a breach of the separate duty to obtain the patient's informed consent to the procedures as she was not informed of all of the alternatives or risks.
- The rationale is that a physician does not substitute their judgment, no matter how appropriate, for that of the patient.

**Sard v Hardy**

- The court held the following were required for informed consent:
  - 1. The nature of the patient's ailment or diagnosis
  - 2. The nature of the proposed treatment
  - 3. The probability of success and material risk, complications and outcomes
  - 4. Alternatives

**McQuitty v Spangler (2009)**

- Case involved a patient who gave birth to a child who sustained substantial neurological damage during delivery.
- The patient claimed the doctor did not provide sufficient information to permit her to have informed consent as to whether to continue carrying the child closer to term or to have a sooner Cesarean delivery.
- The doctor defense was that since he had the patient's initial informed consent to continue to carry the child and never proposed a Cesarean delivery, he had no duty to obtain her informed consent to that procedure.
McQuitty v Spangler (2009)

- The Court agreed with the patient which amplified the informed consent law. A doctor now has the duty to inform the patient of risks and available alternative treatments related to all material changes in their condition.
- Informed consent now requires provisions of all information material to a patient in determining their course of care. The information must be sufficient to permit the patient involvement in the healthcare choices and treatment alternatives pertinent to their condition.

Informed Consent

- When do you need to ask for consent?
- Consultation
- Examination
  - Ortho/ Neuro tests? (every tests?)
  - X-ray?
  - Invasive diagnostics
- Before treatment
- Same day treatment procedures
- One and done?

Hannemann Case

- Hannemann-the patient, filed a complaint against Boyson in Outagamie County Circuit Court, alleging that the defendant negligently provided chiropractic treatment to the plaintiff,
- Gary Hannemann, as a proximate consequence to which the plaintiff suffered serious and permanent injury. "As stated with more particularly in his scheduling conference statement, Hannemann alleged that "[t]he defendant negligently adjusted the plaintiff's cervical spine resulting in the plaintiff suffering a stroke with permanent disability."
HANNEMANN CASE

- During voir dire, Hannemann's attorney began arguing the theory that Boyson failed to provide informed consent by asking the potential jurors if they thought it was wrong for a doctor not to warn a patient about the possibility of harm before performing a procedure, even if it's a very remote risk that may result in serious injury or death.
- During opening statements, Hannemann's attorney concentrated on Boyson's alleged failure to discuss the risks inherent in performing a cervical adjustment with Hannemann and his failure to perform appropriate tests on Hannemann.

PLAINTIFF ARGUMENT

- What did the doctor not do?
  - He didn't recognize the problem and he didn't inform us that Saturday evening.
  - He didn't tell Gary Hannemann of the risk that he was about to run with another adjustment.
  - He did not tell Gary that there is an association between cervical adjustment and people who have strokes.
  - He didn't tell Gary that you had developed many neurological symptoms that may indicate you're in the process of having a neurovascular injury.
  - He didn't tell Gary that there are options, maybe you should go to a medical doctor, maybe we should do nothing.

What he did is he decided to proceed with an adjustment, that is exactly what he did. He didn't talk to Gary about the risks. He didn't do a complete neurological and orthopedic exam. He didn't tell Gary to get medical help.

FINAL DECISION

- A chiropractor has the duty to provide his patient with information necessary to enable the patient to make an informed decision about a procedure and alternative choices of treatments. If the chiropractor fails to perform this duty, he is negligent.
- To meet this duty to inform his patient, the chiropractor must provide his patient with the information a reasonable person in the patient's position would regard as significant when deciding to accept or reject the medical treatment.
- In answering this question, you should determine what a reasonable person in the patient's position would want to know in considering to or rejecting a chiropractic treatment.

However, the chiropractor's duty to inform does not require disclosure of: Information beyond what a reasonably well-qualified chiropractor in a similar classification would know; Extremely remote possibilities that might falsely or detrimentally alarm the patient.
• ANALYSIS

- Although liability for failure to obtain informed consent is
  premised on negligence principles, it is necessarily treated
  under the law as a separate and distinct form of malpractice. *A
  failure to diagnose is one form of medical malpractice. A failure
  to obtain informed consent is another discrete form of malpractice,
  requiring a consideration of additional and different factors.
- "The touchstone of the test [for informed consent] is what
  the reasonable person in the position of the patient would want
  to know."


• ANALYSIS

- We reject Hauserman's repeated assertions that informed consent to chiropractic is
  merely a sine qua non obligation that is satisfied by simply providing a form before
  beginning treatment.
- "The form may be evidence or documentation of the risks,
  disclosed to a patient, but the form itself is not informed
  consent.
- "Informed consent is predicated on such disclosures as will enable a reasonable person under
  the circumstances confronting the patient to exercise the patient's right to consent to, or to
  refuse the procedure proposed or to request an alternative treatment or method of
  diagnosis."
- In other words, informed consent is a duty to "make such disclosures as appear
  reasonably necessary under circumstances that reasonably enable a reasonable person
  under the circumstances confronting the patient to exercise the patient's right to consent to,
  or to refuse the procedure proposed or to request an alternative treatment or method of
  diagnosis."
- "Although the validity of the disclosure will be judged by the standards of a reasonable
  person under the circumstances confronting the patient, the standard for informed
  disclosure would be the same.
- "The scope and limits of the duty to disclose would be the same and would be highest in this
  respect."
- "While the rule may well be modified when applied to
  chiropractic, this would not appear incorrect."


• CONCLUSION

- In sum, we conclude that a chiropractor's duty of informed consent is
  to "make such disclosures as will enable a reasonable person under
  the circumstances confronting the patient to exercise the patient's
  right to consent to, or to refuse the procedure proposed or to request
  an alternative treatment or method of diagnosis."
- "We must "make such disclosures as appear reasonably necessary
  under circumstances then existing to enable a reasonable person
  under the same or similar circumstances confronting the patient at
  the time of disclosure to intelligently exercise his right to consent or
  to refuse the treatment procedure proposed."
CONCLUSION

- We conclude that although the practice of chiropractic and the practice of medicine are distinct health care professions, the obligations of the practitioners of both to disclose the risks of the treatment and risks they provide should be the same.
- While the actual disclosures will inevitably vary between doctors and chiropractors, the nature of the duty and limitations thereof should be the same. A patient of chiropractic has the same right as a patient of medical practice to be informed of the material risks of the proposed treatment or procedure so that he may make an informed decision whether to consent to the procedure or treatment. As such, we hold that the scope of a chiropractor's duty to obtain informed consent is the same as that of a medical doctor.

MALPRACTICE / INFORMED CONSENT

- 2 separate charges
- Malpractice difficult to win for plaintiff
- Informed consent became much easier to win

INFORMED CONSENT CASE

- Chiropractor, Dr. O.K. first met patient A who presented with symptoms of chronic low back pain that was recently acute.
- Patient was in her first trimester of pregnancy.
- Dr. K did not take x-rays or MRI due to pregnancy, but through examination did diagnosis a disc problem.
- Dr K did not have a normal policy to provide a written informed consent form.
INFORMED CONSENT CASE

- Dr. K perform high velocity/low amplitude spinal adjustments that demonstrated improvement in the patient's condition.
- After one of the treatments, her pain level increased and she went to the local ER where they diagnosed her with piriformis syndrome and sciatica.
- The next day she visited her MD for urinary retention. He had a UTI and indicated she could continue chiropractic care.
- She return to Dr. K and he checked to see if she could tolerate flexion distraction technique. It was not a positive experience as the patient screamed out with pain and left his office.

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INFORMED CONSENT CASE

- Patient returned to hospital the next day and after being evaluated was sent for surgery for cauda equine syndrome.
- The surgery left her with bowel and bladder dysfunction and loss of feeling in her sexual organs.
- Baby was delivered with no problems.

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INFORMED CONSENT CASE

- One year later the patient initiates a lawsuit against everyone.
- After much legal maneuvering only Dr. K and the first MD, who eventually was also dismissed leaving only Dr. K.
- Patient expert chiropractor claimed:
  - No informed consent
  - Did not fully evaluate her condition
  - Failed to refer in a timely manner preventing an earlier surgical option
  - Caused the cauda equine syndrome to worsen with the flexion distraction adjustment.

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**INFORMED CONSENT CASE**

- At trial, plaintiff’s chiropractic expert found:
  - Deviations from proper standard of care by failing to order MRI and by adjusting the lumbar region further damaging the disc
  - Deviated from standard of care by not performing a proper informed consent procedure and that specifically cauda equina syndrome could occur as a result of spinal manipulations.

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**INFORMED CONSENT CASE**

- Defense chiropractic expert testified:
  - DX and treatment plan were proper and within the standard of care.
  - "Standards of care do not require perfection"
- Jury findings:
  - Not negligent in treatment and did not cause her injury
  - Found negligent in the tort of lack of informed consent, directly proximately causing injury to the patient

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**SUMMARY OF CASES**

- Failure points could have been avoided
- Hanneman
  - Multiple gaps in care
  - Treatment outside normal hours
  - "brief" examinations
- Dr. OK case
  - NO informed consent procedures
OBTAINING INFORMED CONSENT

- Informed consent is a process for getting permission before conducting a healthcare intervention on a person.
- An informed consent can be said to have been given based upon a clear appreciation and understanding of the facts, implications and consequences of an action.
- You need to evaluate for any impairments in reasoning or judgment that would preclude the patient from properly understanding and consenting.
- Factors could include a high level of stress, intoxication, sleep deprivation, Alzheimer’s disease or other similar conditions.
- Children/ adults will need a parental informed consent to be signed.

OBTAINING INFORMED CONSENT

- Consent must be voluntary.
- DC must not unduly pressure or coerce the patient into consenting to a particular treatment or procedure, but must instead convey that the patient is free to choose among any recommended treatments and procedures, including no treatment or to revoke a prior consent without prejudice to the patient's access to future health care or other benefits.
- Killer nobbexation

OBTAINING INFORMED CONSENT

- Must be an ongoing process. It isn't a one and done type procedure.
- If condition changes, you should revisit the informed consent process.
ACA DEFINITION

- The American Chiropractic Association guidelines on Informed Consent recommend a DC:
  - Test informed consent in an ongoing discussion throughout the patient’s course of care.
  - Advise and describe the recommended course of treatment and discuss the benefits, risks, and available alternatives.
  - Determine if the patient reasonably understands the discussion.
  - Provide an opportunity to ask questions.
  - Note any records related to recommendations.
  - Document the elements of the informed consent in the patient’s record.

ICA Definition

- The International Chiropractic Association guidelines and Informed Consent form recommend:
  - Obtain a written informed consent signed by the patient and doctor.
  - Provide an opportunity to discuss the nature and purpose of proposed treatment and answer the patient’s questions.
  - Results are not guaranteed and a doctor must use professional judgement during the course of care.
  - Advice of possible complications, including stroke.

Valid Informed Consent

- Practitioner must:
  - Determine if the patient has decision-making capacity.
  - Provide information related to the six elements of an informed consent.
  - Properly document consent by patient.
DECISION MAKING CAPACITY

- A clinical determination made by the practitioner that a patient has the requisite capacities to make a well-informed decision. (This is not the same as “competency” which is determined by the court.)
- Four major components:
  - Understanding
  - Appreciating
  - Evaluating
  - Communicating
- The first two components represent the patient's ability to understand and appreciate the nature and expected consequences of such health care decision. The include explanation by the practitioner of the benefits and risks of the recommended treatment options, as well as any reasonable alternative options and things to consider.
- The latter two represent the ability to formulate a judgment and communicate a clear decision concerning health care.

SIX ELEMENTS

- For the patient's consent to be valid, the DC needs to review the following six elements:
  - The patient's diagnosis or condition and the proposed treatment, if any, or procedure
  - The potential risks and benefits of the proposed treatment, if any, or procedure
  - The nature of the treatment, if any, or procedure
  - The nature of the treatment, if any, or procedure
  - The nature of the treatment, if any, or procedure
  - The nature of the treatment, if any, or procedure

WISCONSIN INFORMED CONSENT LANGUAGE

- 446.08 Informed consent. Any chiropractor who treats a patient shall inform the patient about the availability of reasonable alternative modes of treatment and about the benefits and risks of these treatments. The reasonable chiropractor standard is the standard for informing a patient under this section. The reasonable chiropractor standard requires disclosure only of information that a reasonable chiropractor would know and disclose under the circumstances. The chiropractor's duty to inform the patient under this section does not require disclosure of any of the following:

1. Patient's personal or medical history.
2. Information that is not relevant to the treatment.
3. Information that is not likely to affect the patient's decision to consent to the treatment.
4. Information that is not relevant to the treatment.
5. Information that is not relevant to the treatment.
6. Information that is not relevant to the treatment.
6 ELEMENTS

- Element #1
  - The patient's diagnosis/condition and the proposed treatment, modality or procedures for correction.
  - Basically, a report of findings type communication with the patient signing a final document with the personal information included.

6 ELEMENTS

- Element #2
  - The relevant risks and benefits of the proposed treatment, modality or procedures
  - Risk:
    - the possible undesirable outcomes of a treatment or procedure, including known side effects, complications, serious social or psychological harms or other adverse outcomes.
    - Discussion of Stroke on every case
    - Full spine adjusters / Full spine examiners?

6 ELEMENTS

- Element #3
  - Alternative treatment or procedures that are available to the patient and the relative risk, benefits, and uncertainties related to each alternative;
Benits and Risks of Neck Pain Treatments

Neck pain will affect about 30% of the population at some point in their lives and is a common reason many individuals seek help from a health care professional. A particular episode of neck-related problems can be mildly irritating, or it could be seriously debilitating.

While recent scientific studies have found that there are useful treatments for many neck-related problems, no one treatment has been shown to be effective in all cases. Commonly used physical treatments for neck pain include spinal manipulation, mobilization, massage, and therapeutic exercises. Common pharmaceutical treatments include acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs), muscle relaxant medications, and narcotic (opiod) pain medications.

All of the commonly used neck pain treatments carry some risk. Most of these risks are mild, but some can be serious.

Physical Treatments: Manipulation, Mobilization, Massage and Exercises

Manipulation is a therapy in which a spinal manipulator or Chiropractor gently and quickly moves the spine into specific positions to create movement, shorten muscles, stretch the spine, and realign vertebrae. Misalignment techniques are similar, but is mostly performed more slowly.

Evidence from numerous clinical studies shows that both manipulation and mobilization of the cervical spine (neck) result in significant and lasting relief of neck pain and physical dysfunction, as well as prevention of functional disability. Manual therapy is safe in the hands of trained therapists. While there is a concern that manipulation may cause spinal injuries, studies have shown that spinal manipulation is safe and effective when performed by trained professionals.

This list of treatments is not exhaustive or inclusive of all the “likely effective” treatments for neck pain.

A variety of other approaches are commonly reported with alternate treatments. These include, but are not limited to, movement, massage, or chiropractic treatment of the cervical spine. The selection of these treatments and their combinations is controversial. However, any approach to reported cervical spine manipulation with a very high rate of success and with a low rate of serious adverse events may have merit and should be explored. The only sure cure for neck pain is surgical intervention, but this should be used as a last resort when all other treatments have failed.

The largest study performed to date looked at the medical records of 11 million people in the Canadian province of Ontario over a nine-year period and found that only 5% of patients who went to a doctor's chiropractor for neck pain were more likely to have a stroke following chiropractic visit than patients who went to their primary care medical physician for neck pain (1). This study concluded that any observed association between a stroke and a patient's visit to either a chiropractic physician or a family medical physician was not directly caused by any treatment performed. Instead, any association was likely due to patients with an existing vertebral artery dissection seeking care for symptoms such as neck pain or headache that sometimes take place before the stroke occurs. The likelihood of a person having one of these rare vertebral artery strokes is about 1 in 100,000 people and is similar among both chiropractic patients and the general population.
Pharmaceutical Treatments: Acetaminophen, NSAIDs, Muscle Relaxant Medications and Narcotics

Simple analgesics such as acetaminophen (paracetamol) are commonly used to treat non-infectious conditions. While generally safe at recommended doses, acetaminophen is the largest cause of drug overdoses in the United States because of the narrow range between therapeutic dose and toxic dose. Every year in the United States, acetaminophen overdoses are responsible for 5,000 emergency room visits, 2,600 hospitalizations, and 450 deaths due to acute liver failure.

NSAIDs are often used to treat acute conditions. Common side effects include nausea, vomiting, and abdominal pain. NSAIDs can be associated with a variety of outcomes, including acute kidney injury, gastrointestinal bleeding, and heart failure.

Our study published in The New England Journal of Medicine (5) estimated that at least 80,000 patients are hospitalized per year in the United States for serious gastrointestinal complications due to NSAID use. These authors also estimated that there are 10,000 NSAID-related deaths annually in the United States, mostly due to the death of patients with stomach ulcers. The impact of these deaths is not solely limited to the number of deaths but also includes morbidity and economic costs.

Muscle relaxant drugs including benzodiazepines such as Diazepam (Valium) are often used for treatment of neck pain. The most commonly reported side effects are drowsiness, fatigue, and muscle weakness. Less common side effects include confusion, depression, vertigo, constipation, blurred vision, and amnesia.

The use of narcotic (opioid) pain medications frequently leads to nausea, vomiting, constipation, and dizziness. These muscle relaxants and narcotic pain medications produce these effects that may impair walking or driving in about 1 in 3 patients.

Muscle relaxants and narcotics are associated with significant risks of abuse, addiction, dependence, withdrawal, seizures, potentially fatal injuries to the liver, and potentially fatal overdoses. Overdoses of opioid medications are responsible for more than 15,000 deaths per year, more than the number of deaths from tobacco-related diseases combined.

Comparative Effectiveness of Common Treatments

One recent article concluded that there is moderate-to-high-quality evidence that patients with some types of chronic neck pain have clinically important short-term and long-term improvements from a course of spinal manipulation or mobilization, but similar benefits were not seen from massage.

One recent study compared three groups of neck pain patients who were treated with 1) spinal manipulation, 2) an exercise program, or 3) medications, including NSAIDs, acetaminophen, or (in non-responsive patients) narcotic medications and muscle relaxants. This study found that the patients who were treated with either spinal manipulation or the exercise program had significantly greater relief of pain in the short term and in the long term (up to one year after treatment ceased).

The Bone and Joint Decade Task Force review concluded that there was "little helpful" for non-steroidal anti-inflammatory drugs, mobilization, and exercises. They concluded that there was "not enough evidence to make a recommendation" about the benefit of NSAIDs and other drugs.


Conclusion

The current scientific evidence indicates that all commonly recommended treatments for neck pain have limited evidence of effectiveness. Although some cause minimal risk or notable side effects, none have been found to be sufficiently safe or effective.

In general, the physical treatments (e.g., massage, manipulation, stretching, exercise, or other) have found good evidence of effectiveness and are generally accepted by most pain specialists. These treatments are generally considered safe and do not pose a significant risk of complications.

In conclusion, there is good epidemiologic evidence that the risk of having a neck injury is a factor in a patient's decision to seek treatment. A recent study found that a significant number of patients who have neck pain visit a primary care doctor (12). In addition, there is biologic evidence that the use of chiropractic care, which is often considered safe and effective, can significantly reduce the risk of cervical spine injuries. These findings underscore the need for further research to better understand the risks and benefits of chiropractic care, particularly in the context of neck pain.

However, it is important to note that neck pain is a complex issue and interventions should be guided by a multidisciplinary approach involving pharmacological, physical, and behavioral therapies. Further research is needed to better understand the underlying mechanisms of neck pain and to develop more effective and safe treatment strategies.
6 ELEMENTS

- Element #4
- The risk and benefits of not receiving or undergoing any treatment procedure

6 ELEMENTS

- Element #5
- The assessment of the patients understanding of the information provided (decision making capacity)

6 ELEMENTS

- Element #6
- The acceptance by the patient to undergo the recommended treatment, modality or procedure.
DOCUMENTATION

- Are written informed consent forms required?
- What should be included documentation in the patient's chart?

HOW TO RECORD

- Check your state statutes and rules to determine any requirements on how the patient is to be informed.
- Does the information need to be provided through written, oral or any combination?

DOCUMENTATION OF INFORMED CONSENT

- Recommended Minimal documentation:
  - "discussed findings with patient including..."
  - "discussed my recommendations for care including..."
  - "discussed the following risks and benefits including alternate treatment..."
  - "the patient appeared to understand and agreed to proceed with my recommended treatment plan"
DOCUMENTATION

- Make it routine to document the presence or absence of contraindications and red flags following exams/re-exams.
- Make it routine to document the patient’s immediate reaction to treatment.

DOCUMENTATION

- Red Flags
  - Potential herniated discs
  - Sudden onset of severe headaches or pain in the upper neck
  - Sudden difficulty speaking or slurred speech
  - Sudden onset of confusion or altered mental status
  - Sudden tingling on one side of the face or body (both)
  - Sudden onset of dizziness or unsteadiness, loss of balance or coordination or both
  - Sudden difficulty walking or standing upright
  - Sudden trouble with vision or sight
  - Loss of bowel or bladder control

DOCUMENTATION SUMMARY

- Document the patient encounter when obtaining informed consent in your notes.
- Patient initials for each element
- Patient sign informed consent document
- Continued documentation on each visit include the effects of the adjustment and if a new informed consent is necessary.
Standards of care

- Reasonable patient standard
- Reasonable physician standard
- Reasonable chiropractic standard (Wisconsin only)

Reasonable Patient standard

- Whether a reasonable patient would have considered the information sufficient to make an informed decision.
- The problem with Dr. Google.

Reasonable Physician standard

- A standard of disclosure of information used in the wording of informed consent documents, based on customary practice or what a reasonable practitioner in the medical community would disclose under the same/similar circumstances.
**Reasonable Chiropractic Standard**

- Only in Wisconsin!
- Based on what a reasonable chiropractor would disclose
- MD's can't testify against us

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**Wisconsin Law**

- New Wisconsin statute
- Reasonable chiropractic standard
- 6 exceptions

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**446.08 Informed consent.** Any chiropractor who treats a patient shall inform the patient about the availability of reasonable alternative modes of treatment and about the benefits and risks of these treatments. The reasonable chiropractic standard is the standard for informing a patient under this section. The reasonable chiropractic standard requires disclosure only of information that a reasonable chiropractor would have and disclose under the circumstances. The chiropractor's duty to inform the patient under this section does not require disclosure of any of the following:

1. Diagnosis that has been made by another chiropractor.
2. Information that the patient already knows or has been informed by the patient.
3. Information that the patient has been informed by another licensed health care provider.
4. Information that the patient has been informed by a licensed health care provider in a different jurisdiction or that the patient has trouble understanding the diagnosis or the treatment.
5. Information that the patient has been informed by a licensed health care provider in a different state or country who has made the diagnosis or the treatment.

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6 EXCEPTIONS

- (1) Detailed technical information that in all probability a patient would not understand.
- (2) Risks apparent or known to the patient.
- (3) Extremely remote possibilities that might falsely or detrimentally alarm the patient.
- (4) Information in emergencies where failure to provide treatment would be more harmful to the patient than treatment.
- (5) Information in cases where the patient is incapable of understanding.
- (6) Information about alternate modes of treatment for any condition the chiropractor has not included in his or her diagnosis at the time the chiropractor informs the patient.

PROCEDURES

- Sign informed consent form as part of the paper intake process
  - Generic form
  - No form, just provide ROF
  - Properly providing information and obtaining verbal and written consent prior to treating.
**Summary**

- Informed consent is not simply a form
- Procedures to obtain initial consent
- Not a one and done process. Need to continually monitor additional settings that will require new consent to be obtain.
- What information is required to achieve proper consent
- What about the Stroke issue

**Medical Malpractice Lawyers**

- Here are some examples of negligence resulting in misdiagnosis.
- Failing to listen to the patient: When patients tell their doctors that they aren’t feeling well, it is the responsibility of their doctors to listen and examine these symptoms. Should a doctor fail to examine a symptom and his or her patient gets sicker, the doctor can be liable for a misdiagnosis.
- Failing to recognize symptoms: Doctors are trained to make diagnoses based upon their patients’ symptoms. If a healthcare professional fails to make an accurate diagnosis, despite symptoms indicating a particular illness, he or she may be held liable for medical malpractice.
- Failing to examine medical history: Physicians have a responsibility to examine their patients’ personal and family medical histories. A physician may be considered negligent if he or she didn’t examine a patient’s medical history, the patient becomes sicker, and the illness would have been easily identifiable after examining the patient’s medical history.

**Medical Errors**

- According to a study that analyzed more than 360,000 medical claims between 2007 and 2013, the following health issues were the most commonly maldiagnosed:
  - Stroke
  - Heart attack
  - Spinal cord injury
  - Pulmonary embolism
  - Nerve tingel in the arm
  - Misdiagnosis
  - Too much surgery
  - Subtracted hormone
  - Septicemia
  - Lung cancer
  - Forth
  - Appendicitis
Medical Errors

- Medication Errors
  - Annual major medical error that affects public health in the United States is improper medication or dosage of these medications. It results in 100,000 people per year in 2015 alone and 125,000 to 200,000 were victims of medication error.
  - In the United States, between 7,000 and 10,000 patients die from medication errors every year.
  - The types of errors that fall under this category include:
    - Preparing the wrong medication.
    - Failing to include a necessary part of the prescription.
    - Failing to take the prescription at the wrong time of day.
    - Giving the improper dose of medication.
    - Failing to check whether the patient is allergic to that medication.
    - Failing to check whether there are other medications the patient takes that could interact with the prescribed drug.
    - Failing to record the prescription correctly.

What Causes Medical Errors?

- What are the factors that go into creating a medical error, and are they avoidable? Can we reduce the number of medical errors, and most importantly, the adverse effects of those errors on patients?

  - We notice a few of the most typical components that, in combination or alone, cause the vast majority of medical errors in the United States.
    - Lack of training
    - Assigning tasks to inappropriate staff
    - Time pressure or volume
    - Lack of adequate testing
    - Time sensitivity—the treatment or procedure must be done immediately
    - Complexity of the illness or health issue being treated
    - Age of the patient
    - New procedures

Summary

- Chiropractic errors can be reduced through proper compliance procedures and policies.