The Importance of Evidence Based Treatment Guidelines and the Screening for Serious Pathology

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WSC Global Spine Care Initiative

The Development and Evaluation of an Innovative, Integrated, Low-technology, Low-cost Model of Care to Improve the Management of Spinal Disorders in Underserved, Treatment Naïve, Vulnerable Populations with the Goal of Reducing the Associated Global Disability and Burden of Disease. The initiative uses evidence based medicine recommendations.
The World Through DALY

DALY
Disability Adjusted Life Years is a measure of overall disease burden, expressed as the cumulative number of years lost due to ill-health, disability or early death.

YLD = Years Lived with Disability
YLL = Years of Life Lost

Healthy life
Disease or Disability
Expected life years
Early death

(WHO 1996)
The World Through DALY

(80/100)  (WHO 2009)

(9/100)
The World Through Evidence Based Medicine for Lower Back Pain
Guideline History

- 1955  Reported clinical trials of excellence were 347
- 1970  Therapeutic Guidelines
- 1984  First low back pain guideline (Bigos et al)
- 1995  Evidence based medicine (Davidoff, Sackett, Haynes et al)
- 2000  *National Guideline Clearinghouse*
- 2002  Guidelines International Network (G-I-N) with 6700 guidelines, 48 countries from all continents
- 2010  50,000 new clinical trials a year
- 2010  500,000 existing clinical trials (Sackett 2010)
- 2013  we believe there are about 400 spine guidelines synthesized from clinical trials evidence
Guideline Evidence Example

- Medline and other sources: 31,878 citations
  - 30,675 irrelevant
  - 1,203 relevant
    - 651 (54%) not accepted
    - 552 (46%) accepted*
      - 249 epidemiology
      - 95 diagnosis
      - 70 prognosis
      - 170 intervention
      - 13 economic cost

(Haldeman et al 2008)
What is a Guideline?

• Medical treatment guidelines are written from a clinical perspective, to guide and provide the best clinical care possible.

• Medical guideline (also called a clinical guideline, clinical protocol or clinical practice guideline) is a document with the aim of guiding decisions and criteria regarding diagnosis, management, and treatment in specific areas of healthcare.

• Guidelines are evidence based if possible, if no evidence exist they are consensus based.
What is a Spine Guideline?

• Existing spine guidelines may include non-surgical and surgical treatment for the spine
• Some guidelines are for specific spine conditions other for non-specific spine conditions
• Guidelines ought to be updated every 2-3 years when new evidence is available
• Some spine guidelines have been implemented as state/government recommendations to improve care and curb costs
Recent Clinical Spine Guidelines

• Summarize and evaluate the highest quality evidence and most current data about prevention, diagnosis, prognosis, therapy including dosage of medications, risk/benefit and cost-effectiveness
• Identify all possible decision options and their outcomes in clinical care
• Contains algorithms for assessment and management
• Intend to standardize care and improve quality of care
• Provide balance between cost and medical parameters such as effectiveness, specificity and sensitivity
Who Releases Clinical Practice Guidelines?

- Government/states
- National Institutes
- Defense system
- Professional Associations
- Insurance companies
- Hospital entities
- Scientific Publications
- Networks
- Other
Content Spine Guidelines

- Background
- Scope
- Description of diseases
- Assessment of disease
- Principles of management
- Description of best evidence management
- When to refer
- Harms
- What not to do
Low back pain
Implementing NICE guidance

NICE clinical guideline 88
What NICE Guidelines cover

- Background
- Scope
- Key priorities for implementation
- Pharmacological therapies
- Non-pharmacological therapies
- Costs and savings
- Discussion
- A section on “Find out more”
Background

- Low back pain affects around one-third of the adult population each year
- Around 20% of people with low back pain will consult a physician in developed countries, few will consult in rural areas due to lack of access to clinicians
- Helping people to self-manage their low back pain and return to their normal activities is a key focus
Scope

• This guideline covers the early treatment and management of persistent or recurrent low back pain, defined as non-specific low back pain that has lasted for more than 6 weeks, but for less than 12 months.

• It does not cover the management of severe disabling low back pain that has lasted over 12 months.
What is non-specific low back pain?

- Non-specific low back pain is defined in the NICE guideline as:
  ‘tension, soreness and/or stiffness in the lower back region for which it isn’t possible to identify a specific cause of the pain’

- Specific causes of low back pain (not covered by the guideline) include malignancy, infection, fracture, and ankylosing spondylitis and other inflammatory disorders
Triage for Lower Back Pain

**Back Pain**

yes **Red Flags** no

- **Specific** 10%
- **Non-Specific** 90%
- **Disc-pathology** 5%

**Specific treatment**

**Maintain activity to multidisciplinary treatment**

**Expectancy to surgery**

(Nordin et al 2002)
Triage for Lower Back Pain

- Spinal disorders with serious or systemic pathology: congenital and developmental abnormalities, neoplasm, infection disorders, systemic inflammatory disorders and serious trauma (~2%)

- Spinal pain referred from non-spinal pathology: abdominal and pelvic pathologies may present as spinal pain (1-2%)

- Spinal pain with neurological deficits (~5-8%)

- Non-specific spinal pain (90%)

(Haldeman et al 2012)
Principles of Management

• Keep diagnosis under review at all times
  • AND
  • Promote self-management
  • AND
• Offer drug treatments as appropriate
  • AND
• Offer one of the treatment options listed on the next slide - consider offering another of these if improvement is not satisfactory
Non-specific Low Back Pain

• Provide people with reassurance and education to promote self-management
• Offer one of the following treatment options, taking patient preference into account:
  – an exercise program
  – a course of manual therapy
  – a course of acupuncture
If improvement is not satisfactory, consider offering another course of these treatments
Guideline Updates and Synthesis

• Evidence for Non-pharmacologic Therapies for Acute and Chronic Low Back Pain: A Review of the Society/American College of Physicians Clinical Practice Guideline (Chou and Hoyt 2007)

• Synthesis of recommendations for the assessment and management of low back pain from recent clinical practice guidelines (Dagenais et al 2010)
Guideline Updates and Synthesis

NICE Guidelines 2002 NSLBP

- Assessment recommendation sparse
  - History, clinical examination
  - No x-ray for nonspecific low back pain in acute stage

Synthesis Guidelines 2010 NSLBP

- Assessment emphasis triage explicit and detailed
  - History, clinical examination
  - Rule out serious pathology
  - Specific causes for low back pain
  - Neurological involvement
  - Identify risk factors for chronicity (such as perception of disability, fear of movement, catastrophizing)

(Dagenais et al 2010)
NICE Guidelines 2002 NSLBP

- Treatment <12 months
  - Patient education and reassurance
  - Exercise
  - Manual therapy
  - Acupuncture
  - Acetaminophen first
  - NSAID or short term opioids
- Repeat if not successful

Synthesis Guidelines 2010 NSLBP

- Treatment Acute
  - Patient education and reassurance
  - Short term acetaminophen or NSAID or
  - Spinal manipulation
- Treatment Chronic >6 weeks
  - Same as above and
  - Back exercise
  - Cognitive behavioral therapy
  - Possibly short term opioids

(Dagenais et al 2010)
Predicting Persistent Low Back Pain

The most helpful components for predicting persistent disabling low back pain were maladaptive pain coping behaviors, non-organic signs, functional impairment, general health status, and presence of psychiatric comorbidities. (Chou and Shekelle 2010)

Clinical Take Home Message

Mal-adaptive pain behaviors and co-morbidity may affect prognosis and outcome if not managed
Treatment Effect (Pain and Function)

• Treatment effect is moderate for acute non-specific low back pain due to the natural history of low back pain
• Treatment effect is moderate to good for chronic non-specific low back pain
Therapies Proven Ineffective

- Bed rest
- Laser therapy
- Interferential therapy
- Therapeutic ultrasound
- Transcutaneous Electrical Nerve Stimulation (TENS)
- Lumbar supports
- Traction
Injections NSLBP

Do not offer injections of therapeutic substances into the back for non-specific low back pain

(NICE, Chou et al 2006)
X-ray and Imaging NSLBP

- Do not offer routine X-ray of the lumbar spine for acute NSLBP
- Refer to imaging if suspicion of
  - Malignancy
  - Trauma
  - Neurological involvement
  - Age <18 or >50 years
- Imaging for referral for an opinion for epidural steroid injections or surgery
Synthesis of 10 Low Back Pain Guidelines
Assessment Recommendation

1) Ruling out serious spinal pathology, specific causes for low back pain and neurological involvement (Red Flags)

2) Identify risk for chronicity measuring the severity of symptoms, functional limitations through the history, physical and neurological examination (Yellow Flags)

(Dagenais et al 2010)
Synthesis of 10 Low Back Pain Guidelines
Management Recommendation

• Acute low back pain
  – Reassurance, education, maintain activity, short term use of acetaminophen or non steroid anti inflammatory drugs, short term spinal manipulation therapy

• Chronic low back pain
  – Back exercises, cognitive behavioral therapy, short term opioid analgesics

• Low back pain with neurological involvement
  – similar as above for acute and chronic
  – if surgery add imaging (MRI or CT) to select appropriate candidates who are willing to undergo epidural steroid injections and/or surgery

(Dagenais et al 2010)
Why Are Spine Guidelines Important?

- Guidelines are evidence based from international studies
- Standardize care over geographical areas and regions
- Eliminate ineffective care
- Promote effective care
- Reduce cost
- Reward patient and clinician
- Takes into account patient preference
- Promotes active lifestyle and self management through education i.e. empower the patient
Message To Take Home

• Guidelines are very helpful for effective care and to reduce the burden of cost
• Guidelines are evidence based where evidence exist
• Guidelines for spine care are relatively new (low back pain since 1984, for neck pain since 2010)
• There are no specific guidelines for spine care in underserved rural or urban areas
• Guidelines need to be culturally adapted to be accepted
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Thank You