OptumHealth℠
Care Solutions
Physical Health

## Highlights

***Positive answers to key historical questions commonly referred to as "red flags" are very sensitive in identifying the possibility of serious spinal pathology as the cause of low-back pain.***

***Understanding the most common causes of chiropractic malpractice law-suits can provide insight into common problem areas and where to focus risk management policies and procedures to reduce risk.***

***Currently, there are no valid or reliable methods or standards to use in identifying and evaluating biomechanical alignment and the application of chiropractic manipulation.***

***…no one has been able to demonstrate that using x-ray to detect subluxations to manipulate achieves better outcomes than those who use non-radiographic methods for assessing which levels to manipulate.***

***Cell Radiation Sensitivity - Scale of Least Radiosensitive (Mature Red Blood Cells) to Most Radio-sensitive (Lymphocytes).***

# Chiropractic and X-ray

Chiropractors commonly use x-ray as a diagnostic aid. Despite the risks and limitations of plain film radiography, the current application of this service varies greatly by provider and geographic region. Routinely x-raying all patients assumes all of the different causes of low-back pain are of similar consequence and that x-ray is the gold standard imaging tool for low-back pain. This is an unsupported assumption that ignores the natural history of most causes of low-back pain and the high prevalence of abnormal findings on x-ray in the asymptomatic population. New research continues to demonstrate more clearly the boundaries of usefulness and appropriateness of this diagnostic aid.

## Patient Selection

Prior to taking an x-ray on any given patient, the clinician should establish a need or benefit for taking the x-ray. Ask yourself

- Does having the information from a radiograph improve the outcome of treatment?
- Does the benefit clearly outweigh the risks of ionizing radiation, or affect patient management in a significant way that could not be possible without it?

Traditionally, the rationale for taking initial x-rays has been to:

- Identify serious underlying pathology such as tumor, fracture, infection
- Identify contraindications to manipulation
- Perform a biomechanical analysis
- Identify subluxations
- Avoid Malpractice claims

Recent advances in chiropractic literature help provide guide-lines for optimal use of x-rays for these purposes. The following guidelines are intended to facilitate an evidence-based approach to clinical decision-making. It is not OptumHealth Care Solution, Inc. (OptumHealth)'s intent to prohibit necessary or appropriate imaging application(s).

## Identify Serious Underlying Pathology (Tumor, Fracture, Infection)

New research has greatly improved our ability to identify patients presenting with low-back pain that may have serious underlying pathology. Ironically, in this day of high technology, simple key historical and examination findings are some of the most sensitive and specific tools for identifying serious spinal pathology. Positive answers to key historical questions commonly referred to as "red flags" are very sensitive in identifying the possibility of serious spinal pathology as the cause of low-back pain. We must remember that serious underlying pathology is rare; therefore, the use of clinical red flags can aid in increasing the likelihood of finding serious pathology and also help avoid unnecessary exposure to ionizing radiation. Some estimates of serious pathology are as follows: [2]

***Recent research has evaluated the effectiveness of red flags on over 900 patients; they found that screening for red flags identified all patients with serious spinal***

- 4% of back pain is due to osteoporotic compression fractures
- 0.7% of back pain is due to metastatic disease
- 0.01% of back pain is due to spinal infection

We always must consider the sensitivity (the probability that a patient who actually has pathology will be diagnosed as having the pathology i.e. true positive result) of x-ray as a diagnostic tool. X-ray has low sensitivity to:

***Remember you need at least 30-50% bone destruction before any bone changes will be visible on plain film x-ray. In addition, if you still have a high degree of suspicion of underlying pathology that is not evident on plain film x-ray further advanced imaging may be warranted especially in the presence of red flags.***

- Spinal stenosis (especially lateral recess stenosis)
- Metastatic disease (early)
- Herniated discs
- Infection (early stages)
- Intraspinal neoplasms

Therefore, certain major spinal pathologies may not be evident on plain x-ray until the disease has progressed to a more advanced stage and a different imaging procedure would be warranted.

## Identify Contraindications to Manipulation

Identifying contraindications to manipulation is a core element of the initial chiropractic assessment. There are generally well-accepted contraindications to manipulation. Contraindications not identified by red flag screening (those other than tumor, fracture, infection) are typically suggested by history and past medical history. When the history suggests a possible contraindication, a more thorough work up should proceed using the most appropriate diagnostic tools. A common concern voiced by providers relates to risk management / malpractice issues and the need for routine radiographic assessment. Data regarding the most common causes of chiropractic malpractice lawsuits provide insight into high-risk areas.[3] The three most common reasons for malpractice in order of occurrence are:

1. Disc problems
2. Fracture from manipulation
3. Failure to diagnose

The authors concluded "The main focus for the prevention of complications resulting from chiropractic treatment is the recognition of well-known and established indicators or red flag signs and symptoms, which may require careful assessment and reassessment, changes in treatment plan, or other appropriate

actions such as emergency care for referral to another health care specialist. Ignoring these red flag indicators increases the likelihood of patient harm."

Using plain film radiography in patients with uncomplicated low-back pain for detecting and monitoring degenerative changes and intervertebral foramina encroachment is not supported by current evidence.[4] The most common feature seen on x-ray is degenerative changes. Many patients without low-back pain have been shown to have degenerative changes and intervertebral foramina encroachment and in those patients with low-back pain, the severity and location of the degenerative changes correlate poorly with symptoms.[8] Degenerative changes are seen more commonly with increasing age for both those with and without a history of low-back problems and by themselves are not supported as a cause of back pain. Because of this variability, the presence and/or severity of degenerative changes is unreliable for assessing prognosis or being able to predict future episodes of low-back pain. In addition, the presence and monitoring of degenerative changes will unlikely alter treatment except in patient with severe unstable degenerative spondylolisthesis or severe degenerative spinal stenosis, in which more advanced imaging would likely be more useful.[5]

## Perform a Biomechanical Analysis and Identify Subluxations

One of the most contested issues within our profession is the routine use of x-rays to perform spinal analysis and identify subluxations. It would seem appropriate to review our initial question again:

- Does having the information from a radiograph improve the outcome of treatment in a significant way that could not be possible without it?

Those who answer yes to this question routinely cite two reasons for needing to take spinal x-rays. First, to perform a postural/biomechanical analysis and, second to detect subluxations. Chiropractic literature can help provide a greater understanding regarding these two issues.

### 1. Perform a postural/biomechanical analysis:

In order to perform a postural/biomechanical analysis we must understand what optimal posture is. To date, there is no valid or reliable method or data to identify or evaluate posture/biomechanical alignment.[6] Additionally, there is no information that supports any relationship to postural and biomechanical abnormalities with symptoms or future risk of symptoms.[7,8] In other words, many of the findings we report on our x-rays are equally present in individuals with no symptoms.[9] Based on this information it is not possible to support taking routine x-rays for patients with low-back, thoracic, or neck pain to perform postural or biomechanical analysis. In addition the models of an ideal spine do not take into consideration natural and normal asymmetries within the body. With more valid and reliable outcome measures available to assess chiropractic treatment effects, reliance on the radiograph for biomechanical information has come under increasing criticism.[16]

However, there are circumstances in which radiographic structural and biomechanical information is not only useful, but crucial to patient diagnosis and treatment. Scoliosis and intersegmental instability or hypermobility whether due to trauma, arthropathy, or congenital anomaly are examples.[16]

### 2. Detect subluxations:

Similar challenges are experienced when trying to validate the routine use of x-ray to detect subluxations. Some of these challenges include the lack of any valid, reliable method or data to identify or evaluate for the presence of subluxations.[9] This is further complicated by the fact that there is no way to associate symptoms or future risk of symptoms with x-ray findings.[10] Most important, no one has

been able to demonstrate that using x-ray to detect subluxations to manipulate achieves better outcomes than those who use non-radiographic methods for assessing which levels to manipulate.

## Avoid Malpractice claims

An article published in the Journal of Manipulative and Physiological Therapeutics reviewed all malpractice claims for 1991 through 1995 from the National Chiropractic Mutual Insurance Company (NCMIC). The author presented the most common causes of chiropractic malpractice claims and identified risk management/preventative methods to help reduce the risk of occurrence. The most common causes of chiropractic malpractice in order of occurrence of are:

1. Disc problems -- 26.7%
2. Fractures -- 13.8%
3. Failure to diagnose -- 13.1%
4. Aggravation of prior condition -- 7.1%
5. Cerebral vascular accidents -- 5.4%
6. Burn -- 3.4%
7. Therapy -- 3.0%

Although there are numerous reasons for malpractice lawsuits, this review will give primary emphasis to the most common three causes, which make up the majority of all claims.

### Disc problems

Disc Problems are by far the most prevalent cause of malpractice suits against chiropractors. The majority of problems arise from side posture adjusting in the lumbar spine. Although the literature is clear, treatment of disc herniation by side posture adjusting is both safe and effective, caution should be used with excessive use of force or rotation in patients with suspected or confirmed disc problems. Remember, plain film radiography is insensitive to detecting disc bulging or herniation.

### Fractures

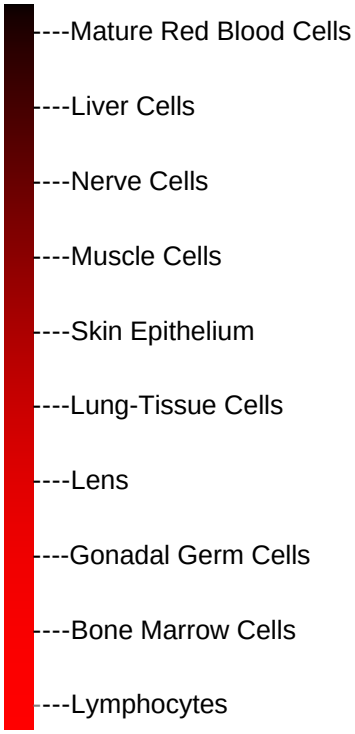
The Second Most Common Cause of malpractice suits against chiropractors resulted from fractures following manipulation. The most common site of fracture occurred in the ribs. The authors point out that practitioners need to be aware of and control the force generated through their manipulative thrusts. Careful attention must be paid to patients who are more susceptible to fractures (i.e. elderly, patients on specific medications)

## Failure to diagnose

The Third Most Common Cause of Malpractice Suits against Chiropractors is related to a failure to diagnose. This most commonly consisted of failure to diagnose the presence of cancer or fractures. Scott Haldeman, D.C. M.D. writes:

*"The main focus for the prevention of complications resulting from chiropractic treatment is the recognition of well-known and established indicators or red flag signs and symptoms, which may require careful assessment and reassessment, changes in treatment plan, or other appropriate actions such as emergency care for referral to another health care specialist. Ignoring these red flag indicators increases the likelihood of patient harm."*

**LEAST RADIOSENSITIVE**




**MOST RADIOSENSITIVE**

**An interesting randomized control study measured the effect of radiography on outcome measures in patients with acute low-back pain. The study contained 421 patients randomly selected from 1995-1999. The intervention group in addition to receiving the usual care also received a low-back x-ray. The control group received the usual care from their doctor without low-back x-ray. Outcome measures used were changes in scores of the Roland-Morris back disability index, visual analog scale (VAS), health status scale, duration of low-back pain, duration of sick leave, and drug use. These outcomes were measured prior to randomization and at the 3-month and 9-month follow-up periods.**

**At the 3-month follow-up the group that had the x-ray tended to report more pain, lower overall perceived health status, borderline higher Roland-Morris Disability (greater limitation of activities), and higher VAS scores.**

**By 9-month follow-up there was no difference between the groups in terms of persistent low-back pain and the group that had the x-ray still showed borderline higher Roland-Morris scores. The authors suggested that the radiographs gave the patients a reason to believe they were unwell, which caused them to report having more pain and disability[13].**

## Risks of Ionizing Radiation

Because of the close proximity of the reproductive organs, lumbar spine radiographs result in one of the highest cumulative doses of radiation to the gonads.[11] It's this exposure that increases the risk of cell mutation and cancer induction in this highly susceptible tissue. In spinal displacement analysis techniques some estimates place exposure levels more than 1000 times greater than the radiation dose associated with chest radiographs.[12] When we speak of cell mutation and cancer induction, estimates put the risk of contracting cancer at 0.1% for every 1000 mrem (10 mSv).

This may seem like a small number but, according to the National Cancer Institute, the overall lifetime risk of cancer is about 30-40%. According to the International Commission on Radiology Protection (ICRP), 5 malignancies are induced per 1 million persons exposed to lumbar spine radiographs.[13] In Britain, the National Radiation Protection Board estimates that 19 lives are lost each year because of unnecessary lumbar spine radiographs.[14] The Department of Health and Human Services recently released its eleventh edition of the Report on Carcinogens, adding x-rays to the growing list of cancer-causing agents.[18] In summary, there is no known safe level of radiation exposure. Therefore, we must use this diagnostic tool judiciously.

***The amount of dosage received from airline flights at 35000 feet is ~ 0.6 mrem/hour. A typical coast-to-coast flight is 3mrem (US DOT, FAA AC No: 120-52; 1990). Compare that to an average lateral lumbar x-ray, which is 1100 mrem***.

### Cell Radiation Sensitivity

All cells are not equally sensitive to radiation damage. In general, cells, which divide rapidly and/or are relatively non-specialized tend to show effects at lower doses of radiation. These would include bone marrow and gonadal germ cells. Looking at the list above you can see the greatest concern is to hematopoietic tissue and the induction of leukemia.

### Average Annual Dose to the General Population

The annual effective dose of ionizing radiation to people in the United States is estimated at 150-300 mrem/yr (1.5-3 mSv/yr). Most of this comes from background radiation, which is mostly from Radon gas and its decay products. However, Radon varies tremendously depending on geographic region. Next to

Radon, in terms of artificial sources, the second largest contribution of dose comes from diagnostic x-ray. Lumbar spine x-ray accounts for one of the procedures that accounts for more than half the total effective dose for diagnostic radiation. *(NCRP Report number 93).*

**Biological Effects of Ionizing Radiation**

Ionizing radiation is so named because its initial interaction with matter causes the ejection (ionization) of an orbital electron from an atom. This produces free radicals within the cell (mostly from water molecules). When these free radicals interact with other cell materials, damage can result. Possible outcomes of this interaction are (1) Immediate cell death, (2) Damage with complete cell repair and normal function (how well cell repair mechanisms work depends on the kind of cell, type and dose of radiation, and state of the individual) or, (3) The cell is damaged, repairs the damage, and operates abnormally (precursor to cancer).

Direct Effects: Biological damage may be a result of direct interaction with the DNA molecule causing breakage of DNA chains (breaks electron bonds that hold the DNA molecule together), removal of bases that may result in somatic mutations that may show up years later or genetic mutations (due to damaged chromosomes recombining abnormally) that show up several generations later.

Indirect Effects: Biological damage of the cell wall and cell death caused by a chain of chemical reactions through free radicals (most commonly a water molecule). Approximately 98% of damage is due to this effect.

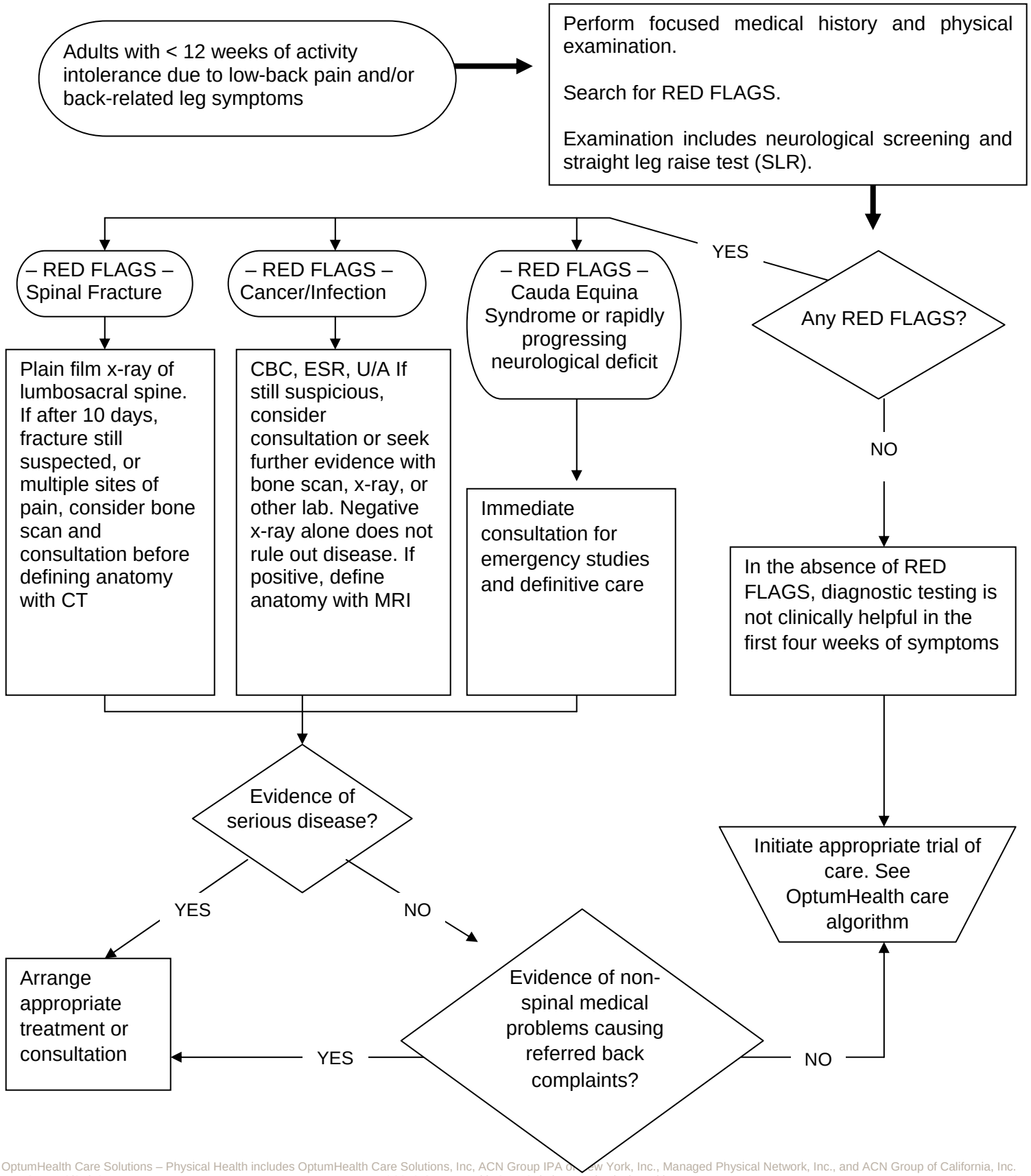
The greatest concern is that there is no known threshold to which no harmful effect will occur for small-accumulated doses of radiation. Therefore, we can never say that there is a safe dose. Current estimates of cancer risk caused by radiation are based on previous population studies exposed to very high doses (eg. Hiroshima). Rothkamm et al looked at the effect on the DNA when exposed to very low x-ray doses. This study used cultures from human lung and skin cells and were exposed to varying doses of x-ray radiation, while control cultures were given sham radiation. DNA damage in cultures of human cells induced by very low doses of radiation remained unrepaired for multiple days, up to two weeks longer than damage from higher doses. The study concluded that low-dose radiation may do more long lasting cell damage than high-dose radiation. The authors suggest this may be due to the body not recognizing the damage caused by low radiation doses, and therefore not repairing it. [17]

## Current International Guidelines on Plain Film Radiography

This section provides summaries and links to published guidelines as they relate to plain film radiography.

| Country | Patient Population | Plain Film Radiography | Source |
|---|---|---|---|
| United States | Acute | Only in cases with Red Flags | AHCPR, Public Health Service, US Dept. of HHS, 1994 |
| Netherlands | Acute/Chronic | Not useful in nonspecific LBP | Dutch Guideline for the Management of Occupational Physicians of Employees with Low Back Pain. 1999 |
| Israel | Acute/Recurrent/ Chronic | Optional after 5-6 weeks | The Israeli Low Back Pain Guideline Group. 1996 |
| New Zealand | Acute | Only in cases with Red Flags | NZ Acute Low Back Pain Guide www.nhc.govt.nz 1997 |
| Finland | Acute/Subacute /Chronic | Not useful in nonspecific acute LBP | Clinical Practice Guidelines of The Finnish Medical Assoc. Duodecim. Diseases of the Low Back. 1999 |
| Australia | Acute | Not useful in acute LBP; use only in case of Red Flags | National Health and Medical Research Council. 2000 www.health.gov.au:80/nhmrc |
| UK | Acute | Not useful in nonspecific LBP | Royal College of General Practitioners. 1996 and 1999 |
| Switzerland | Acute/Chronic | In case of Red Flags after 4 wks | Not available in English |
| Germany | Acute/Chronic | Not indicated in nonspecific LBP | German Medical Society. 1997 |
| Denmark | Acute/Chronic | Only in case of suspicion of serious pathologic change or after 4 weeks duration of pain | Danish Institute for Health Technology Assessment. 1999 |
| Sweden | Acute/Chronic | Ordinary radiographic exams in the absence of red flags have no diagnostic or therapeutic value | The Swedish Council on Technology Assessment in Health Care. 2000 |
| Adapted from: Koes BW, et al. Clinical Guidelines for the Management of Low Back Pain in primary Care – An International Comparison. Spine. 2001; 26(22):2504-2514 | | | |

# Red Flag Algorithm



## Clinical Guidelines

Evidence-based clinical guidelines were developed to assist practitioners in making appropriate evidence-based[15] decisions in patient management. Since 1994, national clinical guidelines on low-back pain have been issued in at least 12 different countries. Some were sponsored by Governments and others by professional associations. The development of clinical red flags in the guidelines are designed to increase true-positive findings on radiographs and to assist the practitioner in decision-making to avoid unnecessary radiographs that do not reveal significant findings that would affect patient outcomes. In general, clinical guidelines in all countries give similar advice on the use of radiographs. For acute low-back pain the United States Guidelines AHCPR (Agency for Health Care Policy and Research) findings are:

1. The use of lumbar x-rays to screen for degenerative changes, congenital anomalies, spondylolisthesis or scoliosis rarely adds useful clinical information.
2. 1/2500 x-rays detect something not suspected from the history or examination.
3. Patient selection should be based on the presence of red flags, which suggest underlying pathology.

Recommendations of the ACCR (American Chiropractic College of Radiology) are very similar to the position adopted by the ACA (American Chiropractic Association) Council on Diagnostic Imaging in that routine radiography of any patient should not be performed without due regard for clinical need. This statement is based on the recognition that exposure to unnecessary ionizing radiation represents an unwarranted health risk.

## Summary

1. There is a significant body of research that discourages the routine use of x-ray to evaluate for serious spinal pathology and contraindications to manipulation.
2. A history and past medical review with an emphasis on evaluating for red flags will clearly improve the necessity for x-ray use.
3. There is no support for the routine use of x-ray to perform biomechanical analysis and subluxation identification given the insufficient and contradictory literature. Furthermore, there is no evidence linking these assessment techniques with better short or long-term health benefits for patients.

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