

内容として、文献検索、科学的論文の取り寄せ、Delphi 過程に必要なものの配布、結果の集計とコンピュータ入力、検討会議の一般的手伝い、などである。

規準作りの過程

各委員会は参照する臨床的状況を選択する。これには、良く遭遇する状況、手技のバラツキ、相対的費用、副作用と致死率の可能性、治療改善の可能性、などが加味された。各質問は出来る限り明確にされ、良く吟味され、その結果、しばしば臨床的状況は幾つかの亜形に細分化されることになる。臨床的状況とその亜形が一度決定されると、充査読された医学雑誌から文献を探し出し、重要な至適論文が選別され集積される。検討委員医会の1-2名の指導者が各臨床状況について、最新の文献に基づく証拠表(evidence table)の作成責任者となる。これらの表は各臨床的状況に特異的解説を作成するための基礎に利用される。

既存の科学的研究によるデータは通常メタアナリシスには不十分であり、適切な規準作りには、専門医委員会でのコンセンサスを得ることが必要である。ACRはコンセンサスを得るために修正Delphi法を採用した。各委員会で専門家の意見を集約するため、質問票を配布する方法で一連の調査が行われた。根拠表(evidence table)と代表的な指導者による解説共に、これらの質問票は各委員に配布される。他の委員の影響を受けることなく、質問票は各委員の職業的状況に応じて回答する。質問票への答え方は1-9の点数付けとし、最も適切な画像診断法や治療法を9として、最も意味のないものを1とした。調査結果が集計され、匿名で表として示され、再度配布された。最大3回の回覧が行われ、最も多くの委員が投票した点数に集約される。80%以上の同意が得られたものをコンセンサスとする。この修正Delphi法は各委員が他の委員の影響なく採点でき、経済的で、理解しやすく、比較的採決が単純である。もしDelphi法でコンセンサスが得られない場合、委員会を招集し、委員会のコンセンサスを得る方法が行われる。各テストと方法の利点と欠点が論じられ、出来る限りコンセンサスを得る様にする。医療は変化し進歩するため、新しいあるいは極めて科学的に優れた結果が公表された場合、適切な規準も3年後に委員会で再評価する。

至適規準の適用

臨床的ガイドラインは大部分の患者に適用できる。ACR 至適規準のより特徴的なことは、放射線診断医、主治医、患者に対して、画像診断、治療法の初回決定に役立つ様になっていることである。患者の臨床的状況の複雑さと重症度が至適画像診断法選択と治療に影響する。さらに、使用可能な機器や経験豊かな医師の存在が至適画像診断と治療の選択に影響する。特定の検査あるいは治療の至適な利用に関する最終決定は、患者を取り巻く各種の状況を勘案して、放射線科医と主治医によってされるべきことである。

この規準は第三者補償のためのガイドラインを目的としていない。FDA によ臨床試験と位置づけられた画像診断は考慮していないが、対策委員会は新しい機器と適応に関する研究は推進されるべきであると考えている。

市場原理が医師と供給者団体に影響を与え、代価に見合う医療を行うことになるが、質の確保が重要である。放射線診療の管理はこの変化では重要な因子である。ACR 至適規準は後ろ向き、前向き考察により管理の基礎として利用できる。

まとめ

この本「ACRの画像診断と治療に対する至適規準」は、ACRの専門家委員会が最初の至適規準として作成したものを掲載している。委員会はさらに規準を作成し続け、完成したのから順に配布されて行くであろう。この規準作りの系統的過程は、科学的解析と広範なコンセンサス法に基盤をおいて、放射線診断法の信頼できるガイドラインを作成していく、と考えている。最終的結果が代価にみあう効果的な高品質放射線診療となることを祈っている。

Lung Cancer Work Group

ROL-1. Staging of Non-Small cell Lung Carcinoma.....	ROL-1.1
Variant 1; 52-year-old man with a 4cm peripheral right lung lesion with no ROL-1.1
Variant 2; 52-year-old man with a 4cm peripheral right lung lesion with no. ROL-1.2
Variant 3; 52-year-old man with a 4cm peripheral right lung lesion with no ROL-1.3
Variant 4; 52-year-old man with a 4cm peripheral right lung lesion with no ROL-1.4
Variant 5; 60-year-old women who is found to have a 3 cm peripheral mass ROL-1.5
Variant 6; 60-year-old women who is found to have a 3 cm peripheral mass ROL-1.6
Variant 7; 60-year-old women who is found to have a 3 cm peripheral mass ROL-1.7
Variant 8; 52-year-old man with a 4cm peripheral right lung lesion with normal ROL-1.8
Summary of Literature Review	ROL-1.9
ROL-2. Postoperative Radiotherapy in Non-Small Cell Lung Cancer.....	ROL-2.1
Squamous Cell Lung Cancer, Negative Margins Post Resection	
Variant 1; T2N1(hilar) no mediastinal surgical staging ROL-2.1
Variant 2; T2N1(hilar) no mediastinal surgical staging ROL-2.2
Variant 3; T2N2 limited sampling of clinically positive nodes ROL-2.3
Variant 4; T2N2 with careful mediastinal staging highest node negative ROL-2.4
Variant 5; T2N2 with careful mediastinal staging highest node positive ROL-2.5
Adeno and Large Cell Lung Cancer, Negative Surgical Margins Post Resection	
Variant 6; T2N1(hilar) no mediastinal surgical staging ROL-2.6
Variant 7; T2N1(hilar) careful mediastinal staging ROL-2.7
Variant 8; T2N2 limited sampling of clinically positive nodes ROL-2.8
Variant 9; T2N2 with careful mediastinal staging highest node negative ROL-2.9
Variant 10; T2N2 with careful mediastinal staging highest node positive ROL-2.10
Non-Small Cell Lung Cancer, Negative Margins Post-Resection	
Variant 11; T1-2N0 no mediastinal surgical staging ROL-2.11
Variant 12; T1-2N0 with careful mediastinal staging ROL-2.12
Variant 13a; T3N0 with chest wall invasion, without mediastinal node staging ROL-2.13
Variant 13b; T3N0 with chest wall invasion, with mediastinal node staging ROL-2.14
T1-3N0 Non-Small cell Lung Cancer	
Variant 14a; T1-3N0 non-small cell lung cancer with positive margins ROL-2.15
Variant 14b; T1-3N0 non-small cell lung cancer with positive margins ROL-2.16
Squamous Cell Lung Cancer, Negative Surgical Margins Post Resection	
Variant 15; T2N2 limited sampling of clinically positive nodes, FEV1=700ml ROL-2.17
Variant 16; T2N2 limited sampling of clinically positive nodes, FEV1=1000ml ROL-2.18
Summary of Literature Review	ROL-2.19
ROL-3. Non-Small Cell Lung Carcinoma, Non-Surgical, Aggressive Treatment.....	ROL-3
Variant 1; T1N3M0 55-year-old female with palpable supraclavicular lymph ROL-3.1
Variant 2; T3N3M0 60-year-old male with hoarseness due to paralyzed ROL-3.2
Variant 3; T3N3M0 60-year-old male with postobstructive pneumonia ROL-3.3
Variant 4; T4N3M0 60-year-old male with a left shoulder pain radiating ROL-3.4
Variant 5; T4N3M0 60-year-old male with a few weeks history of superior ROL-3.5
Variant 6; T4N3M0 60-year-old male with hemoptysis and chest pain ROL-3.6
Variant 7; T4N3M0 58-year-old female with a palpable supraclavicular ROL-3.7
Variant 8; T1N0M0 70-year-old man with long history of heavy smoking ROL-3.8
Summary of Literature Review	ROL-3.9
ROL-4. Neoadjuvant Therapy for Marginally Resectable, Non-Small Cell Lung Carcinoma ROL-4.1
Variant 1; T2N2M0 ROL-4.1
Summary of Literature Review	ROL-4.2
ROL-5. Non-Aggressive, Non-Surgical Treatment of Inoperative Non-Small Cell Lung Cancer ROL-5.1

Variant 1;	70-year-old female with FEV-1 of 900 ml, coronary artery disease	ROL-5.1
Variant 2;	66-year-old male with Stage IIIB squamous cell carcinoma. Bulky	ROL-5.2
Variant 3;	66-year-old male with Stage IIIB squamous cell carcinoma. Bulky	ROL-5.3
Variant 4;	57-year-old male with hemoptosis, Stage IIIA squamous cell	ROL-5.4
Variant 5;	84-year-old female with Stage IIIA adenocarcinoma, 2cm largest	ROL-5.5
Variant 6;	55-year-old male with Stage IV NSCLCA, metastasis to bone	ROL-5.6
Variant 7;	62-year-old female with widely spread Stage IV NSCLCA, KPS 80	ROL-5.7
Variant 8;	68-year-old male with recurrent mediastinal and primary NSCLCA	ROL-5.8
Summary of Literature Review			ROL-5.9
ROL-6. Follow-up of Non-Small Cell Lung Cancer		 ROL-6.1
Variant 1;	62-year-old male, 3 months postoperative of StagII squamous	ROL-6.1
Variant 2;	78-year-old female, never smoked, postoperative 33 months	ROL-6.2
Variant 3;	50-year-old female, never smoked, with incidentally found	ROL-6.3
Variant 4;	52-year-old male, heavy smoker, had wedged resection of	ROL-6.4
Variant 5;	65-year-old male, treated with neoadjuvant chemotherapy	ROL-6.5
Summary of Literature Review			ROL-6.6

米国放射線医学会 画像診断と治療決定の至適な基準
(ROL-1.1)

臨床的病態: 非小細胞肺癌の臨床進行診断

症例 1: 52才、男性、胸部単純写真上右肺の辺縁に4cm大の腫瘤影。生検で扁平上皮癌。患者は骨の痛みや中枢神経の症状はない。

検査法	至適点数	コメント
胸部の病巣診断		
胸部単純写真	9	
縦隔鏡	4	検査結果で治療法が変わる場合のみ適応。
MRI-胸部	2	
食道内超音波検査	2	
胸腔穿刺	2	
全身の病巣分布		
CT-腹部 (胸部 CT の一環として)	9	
CT-腹部 (別個の検査として)	2	
CT-骨盤部	2	
CT-頭部	2	頭部の検査では MRI の方が優れている。
MRI-腹部 (胸部 MRI の一環として)	2	
MRI-腹部 (別個の検査として)	2	
MRI-骨盤部	2	
MRI-頭部	2	
骨シンチグラフィ	2	
Ga シンチグラフィ	2	
モノクローナル抗体シンチ	2	

Appropriateness Criteria Scale
1 2 3 4 5 6 7 8 9
1=適応最低 9=適応最大

* これらの検査の中、幾つかは現在も研究として行われている。現状ではそれらを広く一般的に行う意義は認められていない。

米国放射線医学会 画像診断と治療決定の至適な基準
(ROL-1.2)

臨床的病態: 非小細胞肺癌の臨床進行診断

症例 2: 52才、男性、胸部単純写真上右肺の辺縁に4cm大の腫瘤影。生検で 大細胞癌。患者は骨の痛みや中枢神経の症状はない。

検査法	至適点数	コメント
胸部の病巣診断		
胸部単純写真	9	
縦隔鏡	8	
MRI-胸部	2	
食道内超音波検査	2	
胸腔穿刺	2	
全身の病巣分布		
CT-腹部 (胸部 CT の一環として)	9	
MRI-頭部	7	
骨シンチグラフィ	6	
CT-腹部 (別個の検査として)	2	
CT-骨盤部	2	
CT-頭部	2	
MRI-腹部 (胸部 MRI の一環として)	2	
MRI-腹部 (別個の検査として)	2	
MRI-骨盤部	2	
Ga シンチグラフィ	2	
モノクローナル抗体シンチ	2	

Appropriateness Criteria Scale

2 2 3 4 5 6 7 8 9
1=適応最低 9=適応最大

米国放射線医学会 画像診断と治療決定の至適な基準
(ROL-1.3)

臨床的病態: 非小細胞肺癌の臨床進行診断

症例 3: 52才、男性、胸部単純写真上右肺の辺縁に4cm大の腫瘤影。生検で扁平上皮癌。患者は胸部と下背部の痛みがある。中枢神経の症状はない。

検査法	至適点数	コメント
胸部の病巣診断		
胸部単純写真	9	
縦隔鏡	4	
MRI-胸部	2	
食道内超音波検査	2	
胸腔穿刺	2	
全身の病巣分布		
CT-腹部 (胸部 CT の一環として)	9	
骨シンチグラフィ	9	
CT-腹部 (別個の検査として)	2	
CT-骨盤部	2	
CT-頭部	2	
MRI-腹部 (胸部 MRI の一環として)	2	
MRI-腹部 (別個の検査として)	2	
MRI-骨盤部	2	
MRI-頭部	2	
Ga シンチグラフィ	2	
モノクローナル抗体シンチ	2	

Appropriateness Criteria Scale
3 2 3 4 5 6 7 8 9
1=適応最低 9=適応最大

米国放射線医学会 画像診断と治療決定の至適な基準
(ROL-1.4)

臨床的病態: 非小細胞肺癌の臨床進行診断

症例 4: 52才、男性、胸部単純写真上右肺の辺縁に4cm大の腫瘤影。胸部単純写真では縦隔の拡張はない。生検で扁平上皮癌。患者は頭痛を訴え、性格の変化を認めている。骨の痛みはない。

検査法	至適点数	コメント
胸部の病巣診断		
胸部単純写真	9	
縦隔鏡	4	
MRI-胸部	2	
食道内超音波検査	2	
胸腔穿刺	2	
全身の病巣分布		
CT-腹部 (胸部CTの一環として)	9	
MRI-頭部	9	
骨シンチグラフィ	9	
CT-腹部 (別個の検査として)	2	
CT-骨盤部	2	
CT-頭部	2	
MRI-腹部 (胸部MRIの一環として)	2	
MRI-腹部 (別個の検査として)	2	
MRI-骨盤部	2	
Ga シンチグラフィ	2	
モノクローナル抗体シンチ	2	

Appropriateness Criteria Scale

4 2 3 4 5 6 7 8 9
1=適応最低 9=適応最大

米国放射線医学会 画像診断と治療決定の至適な基準
(ROL-1.5)

臨床的病態: 非小細胞肺癌の臨床進行診断

症例 5: 60才、女性、胸部単純写真上左肺辺縁に3cm大の腫瘤影。同側の肺門に腫瘤がある。気管支鏡と生検で腺癌。患者は骨の痛みや中枢神経系の症状はない。

検査法	至適点数	コメント
胸部の病巣診断		
胸部単純写真	9	
縦隔鏡	8	
MRI-胸部	2	
食道内超音波検査	2	
胸腔穿刺	2	
全身の病巣分布		
CT-腹部 (胸部 CT の一環として)	9	
MRI-頭部	8	
骨シンチグラフィ	8	
CT-腹部 (別個の検査として)	2	
CT-骨盤部	2	
CT-頭部	2	
MRI-腹部 (胸部 MRI の一環として)	2	
MRI-腹部 (別個の検査として)	2	
Ga シンチグラフィ	2	
モノクローナル抗体シンチ	2	
MRI-骨盤部	1	

Appropriateness Criteria Scale
5 2 3 4 5 6 7 8 9
1=適応最低 9=適応最大

米国放射線医学会 画像診断と治療決定の至適な基準
(ROL-1.8)

臨床的病態: 非小細胞肺癌の臨床進行診断

症例 8: 52才、男性、胸部単純写真上右肺の辺縁に4cm大の腫瘤影。肺門部は正常であるが、大動脈弓部にリンパ節腫大が疑われる。生検では扁平上皮癌。患者は骨の痛みや中枢神経系の症状はない。

検査法	至適点数	コメント
胸部の病巣診断		
胸部単純写真	9	
縦隔鏡	8	
MRI-胸部	2	
食道内超音波検査	2	
胸腔穿刺	2	
全身の病巣分布		
CT-腹部 (胸部 CT の一環として)	9	
MRI-頭部	8	
骨シンチグラフィ	8	
CT-腹部 (別個の検査として)	2	
CT-骨盤部	2	
CT-頭部	2	
MRI-腹部 (胸部 MRI の一環として)	2	
MRI-腹部 (別個の検査として)	2	
Ga シンチグラフィ	2	
モノクローナル抗体シンチ	2	
MRI-骨盤部	2	

Appropriateness Criteria Scale

6 2 3 4 5 6 7 8 9
1=適応最低 9=適応最大

米国放射線医学会 画像診断と治療決定の至適な基準
(ROL-2.1)

臨床的病態: 扁平上皮癌。手術を行い術後照射。断端陰性。

症例 1: T2N1 (肺門部)。縦隔部位の手術による検索は行っていない。

治療法	至適点数	コメント
縦隔部位の術後照射	8	
使用線量		
50.4 Gy/ 28 分画	8	
54 Gy/ 30 分画	8	
45Gy/ 25 分画	7	
59.4 Gy/ 33 分画	3	
30 Gy/ 10 分画	3	
40 Gy/ 20 分画	2	
70.2 Gy/ 39 分画	2	
69.6 Gy/ 59 分画(1日2回法)	2	
縦隔の術後照射+化学療法		
照射前化学療法	2	
化学放射線同時療法	2	
照射後化学療法	2	
放射線治療法		
コンピュータ治療計画	8	二次元治療計画
CT-治療計画	8	腫瘍体積決定に CT を用いる
3D 治療計画	3	この場合、3D 治療計画の役割は今後の課題で有用性は不明。
Radiotherapy Technique		
多照射野法	8	
複雑なブロック挿入	8	
前後/後前 単独	2	

Appropriateness Criteria Scale
7 2 3 4 5 6 7 8 9
1=適応最低 9=適応最大

米国放射線医学会 画像診断と治療決定の至適な基準
(ROL-2.2)

臨床的病態: 扁平上皮癌。手術を行い術後照射。断端陰性。

症例 2: T2N1 (肺門部)。縦隔部位の手術による十分な検索を行った。

治療法	至適点数	コメント
縦隔部位の術後照射	意見の一致無し	治療で局所再発は減少するが、生存率の改善にはつながらない。
使用線量		
50.4 Gy/ 28 分画	8	
50 Gy/ 25 分画	8	
54 Gy/ 30 分画	7	
45Gy/ 25 分画	3	
59.4 Gy/ 33 分画	3	
30 Gy/ 10 分画	2	
40 Gy/ 20 分画	2	
70.2 Gy/ 39 分画	2	
69.6 Gy/ 59 分画(1日2回法)	2	
縦隔の術後照射+化学療法		
照射前化学療法	2	
化学放射線同時療法	2	
照射後化学療法	2	
放射線治療法		
コンピュータ治療計画	8	二次元治療計画
CT-治療計画	8	腫瘍体積決定に CT を用いる
3D 治療計画	3	この場合、3D 治療計画の役割は今後の課題で有用性は不明。
Radiotherapy Technique		
多照射野法	8	
複雑なブロック挿入	8	
前後/後前 単独	2	

Appropriateness Criteria Scale
8 2 3 4 5 6 7 8 9
1=適応最低 9=適応最大

米国放射線医学会 画像診断と治療決定の至適な基準
(ROL-2.3)

臨床的病態: 扁平上皮癌。手術を行い術後照射。断端陰性。

症例 3: T2N2 (肺門部)。臨床的に陽性と思われる縦隔部位のリンパ節のサンプリングのみを行った。

治療法	至適点数	コメント
縦隔部位の術後照射	8	
使用線量		
54 Gy/ 30 分画	8	
59.4 Gy/ 33 分画	8	
50.4 Gy/ 28 分画	3	
50 Gy/ 25 分画	3	
30 Gy/ 10 分画	2	
40 Gy/ 20 分画	2	
45Gy/ 25 分画	2	
70.2 Gy/ 39 分画	2	
69.6 Gy/ 59 分画(1日2回法)	2	
縦隔の術後照射+化学療法		
照射前化学療法	意見の一致無し	患者は切除不能と同等と考えられ、化療と放射線の併用の適応である。
化学放射線同時療法	意見の一致無し	患者は切除不能と同等と考えられ、化療と放射線の併用の適応である。
照射後化学療法	2	
放射線治療法		
コンピュータ治療計画	8	二次元治療計画
CT-治療計画	8	腫瘍体積決定に CT を用いる
3D 治療計画	3	この場合、3D 治療計画の役割は今後の課題で有用性は不明。
Radiotherapy Technique		
多照射野法	8	
複雑なブロック挿入	8	
前後/後前 単独	2	

Appropriateness Criteria Scale
9 2 3 4 5 6 7 8 9
1=適応最低 9=適応最大

米国放射線医学会 画像診断と治療決定の至適な基準
(ROL-2.4)

臨床的病態: 扁平上皮癌。手術を行い術後照射。断端陰性。リンパ節転移無し。

症例 4: T2N2。縦隔部位の注意深い検索が行われ、最上位のリンパ節転移はなかった。

治療法	至適点数	コメント
縦隔部位の術後照射	8	
使用線量		
50.4 Gy/ 28 分画	8	
54 Gy/ 30 分画	8	
59.4 Gy/ 33 分画	8	
30 Gy/ 10 分画	5	
40 Gy/ 20 分画	2	
45Gy/ 25 分画	2	
70.2 Gy/ 39 分画	2	
69.6 Gy/ 59 分画(1日2回法)	2	
縦隔の術後照射+化学療法		
照射前化学療法	意見の一致無し	患者は切除不能と同等と考えられ、化療と放射線の併用の適応である。
化学放射線同時療法	意見の一致無し	患者は切除不能と同等と考えられ、化療と放射線の併用の適応である。
照射後化学療法	2	
放射線治療法		
コンピュータ治療計画	8	二次元治療計画
CT-治療計画	8	腫瘍体積決定にCTを用いる
3D 治療計画	3	この場合、3D 治療計画の役割は今後の課題で有用性は不明。
Radiotherapy Technique		
多照射野法	8	
複雑なブロック挿入	8	
前後/後前 単独	2	

Appropriateness Criteria Scale

10 2 3 4 5 6 7 8 9
1=適応最低 9=適応最大

米国放射線医学会 画像診断と治療決定の至適な基準
(ROL-2.5)

臨床的病態: 扁平上皮癌。手術を行い術後照射。断端陰性。リンパ節転移無し。

症例 5: T2N2。縦隔部位の注意深い手術的検索が行われ、最上位のリンパ節に転移があった。

治療法	至適点数	コメント
縦隔部位の術後照射	8	
使用線量		
54 Gy/ 30 分画	8	
59.4 Gy/ 33 分画	8	
50.4 Gy/ 28 分画	2	
50.Gy/ 25 分画	2	
30 Gy/ 10 分画	2	
40 Gy/ 20 分画	2	
45Gy/ 25 分画	2	
70.2 Gy/ 39 分画	2	
69.6 Gy/ 59 分画(1日2回法)	2	
縦隔の術後照射+化学療法		
照射前化学療法	2	
化学放射線同時療法	2	
照射後化学療法	2	
放射線治療法		
コンピュータ治療計画	8	二次元治療計画
CT-治療計画	8	腫瘍体積決定にCTを用いる
3D 治療計画	3	この場合、3D 治療計画の役割は今後の課題で有用性は不明。
Radiotherapy Technique		
多照射野法	8	
複雑なブロック挿入	8	
前後/後前 単独	2	

Appropriateness Criteria Scale
1 2 3 4 5 6 7 8 9
1=適応最低 9=適応最大

AMERICAN COLLEGE OF RADIOLOGY (一部抜粋・原文)

APPROPRIATENESS CRITERIA FOR IMAGING AND TREATMENT DECISIONS

Background

In 1993, the leadership of the American College of Radiology (ACR) determined that in the changing health care environment a premium would be placed on the efficient use of resources including appropriate use of radiologic services. Additionally, ACR leadership concluded that there was an immediate need for nationally accepted, scientifically based appropriateness criteria to assist radiologists and referring physicians in making appropriate imaging decisions for given patient clinical conditions and that a system needed to be developed for the creation of these criteria.

The ACR had received multiple inquiries from radiologists, hospitals, and payers concerning the availability of such criteria. These contacts emphasized the need for the discipline of radiology to take a leadership role in criteria development. The ACR Task Force on Appropriateness Criteria was created for this purpose. It was recognized from the beginning that setting criteria would require use of broad-based consensus techniques because data from existing scientific outcome and technology assessment studies are usually insufficient for this purpose. It was also recognized that the input of physicians from other medical specialties would be invaluable to the effort. This was the background that led to the current structure and process of the Task Force.

The Principles of Setting Guidelines

In establishing these criteria, the ACR Task Force incorporated attributes for developing acceptable medical practice guidelines used by the Agency for Healthcare Policy and Research (AHCPR) as developed by the Institute of Medicine. These eight attributes were followed to the degree possible by the ACR consensus panels. These attributes are:

- (1) **Validity:** Guidelines are valid if they lead to better outcomes. Validity assessment should be based on the quality of the scientific evidence and the method of evidence evaluation.
- (2) **Reliability/Reproducibility:** Another set of experts should be able to produce similar guidelines when using the same methodology to evaluate the same scientific evidence.
- (3) **Clinical Applicability:** Guidelines should include an explicit description of the applicable patient population.
- (4) **Clinical Flexibility:** Guidelines must specify known or expected exceptions.
- (5) **Clarity:** Guidelines must be unambiguous with clearly defined terms. They should be presented in a logical manner and be easy to follow.
- (6) **Multidisciplinary Process:** Affected provider groups should have representation in the guideline development process.
- (7) **Scheduled Review:** all guidelines should undergo scheduled review to determine whether revision is indicated based on current scientific evidence.
- (8) **Documentation:** The development procedure, the participants, the evidence, and the methods of analysis should be documented.

The AHCPR is explicit in stating its intent that scientific evidence should be used as much as possible but that judgment and group consensus will be necessary in the development of appropriateness criteria.

Task Force Structure

The ACR Appropriateness Task Force is led by the Task Force Chair who oversees the activities of ten consensus panels, eight diagnostic, and two therapeutic. The diagnostic panels are organized along organ system lines with exceptions for panels on pediatric and women's imaging. There are separate treatment decision panels for radiation oncology and interventional radiology. Each consensus panel is chaired by an individual with leadership capabilities and national recognition of expertise in the area of focus.

Together, panel leaders and the chair of the Task Force act as a Steering Committee. The Steering Committee develops policy and provides direction for the Task Force. Responsibilities include

management of the overall criteria development process, and time table conformance. Consultants to the Steering Committee provide expertise as needed, for example providing advice in the development of consensus techniques and handling legal implications associated with the setting of national criteria.

Each panel chair is responsible for selecting panel participants. Broad representation is imperative and radiologists with diverse geographical representation are included from academic and private practice settings. Members have expertise in applicable imaging modalities. Panel participants were nominated by Specialty Commissions of the American College of Radiology and nationally recognized radiology scientific organizations. The ACR recognized the importance of input in the development of the appropriateness criteria. Major scientific societies representing medical specialty organizations outside of radiology have been contacted, and based on their recommendations, non-radiologist participants have been invited to participate. As of this writing, panelists from fourteen non-radiology specialty organizations are participating, with more being added to the listing on an ongoing basis.

Almost 150 physician representatives are involved in the criteria development process, with over 100 criteria under development at any given point in time. The funding for the process is assumed entirely by the American College of Radiology. ACR staff provide support to the Task Force. Support functions include literature searches, acquisition of scientific articles, dissemination of materials for the Delphi process, collation of results and computer entry, and general assistance of the panel participants.

Process of Criteria Development

Each panel selects clinical conditions to be addressed based on the prevalence of the condition, the variability of practice, the relative cost, the potential for morbidity or mortality, and the potential for improved care. Each question is clarified and refined to be as specific as possible and frequently clinical conditions are broken down into a number of variants. Once the clinical condition and its variants have been defined, literature searches of peer-reviewed medical journals are conducted and the major applicable articles are identified and collected. One or two topic leaders within a panel assume the responsibility of developing an evidence table for each clinical condition, based on the analysis of the current literature. These tables serve as the basis for developing a narrative specific to each clinical condition.

Since data available from existing scientific studies are usually insufficient for meta analysis, broad-based consensus techniques are needed for reaching agreement in the formulation of the appropriateness criteria. The ACR uses a modified Delphi technique to arrive at a consensus level. Serial surveys are conducted by distributing questionnaires to consolidate expert opinions within each panel. These questionnaires are distributed to the participants along with the evidence table and narrative as developed by the topic leader(s). Questionnaires are filled out by participants in their own professional setting without the influence of the other panel members. Voting is conducted using a scoring system from 1-9, indicating the most to the least appropriate imaging examination or therapeutic procedure. The survey results are collected, tabulated in anonymous fashion, and redistributed after each round. A maximum of three rounds are conducted and opinions are unified to the highest degree possible. Eighty percent agreement is considered a consensus. This modified Delphi technique enables individual, unbiased expression, is economical, easy to understand, and relatively simple to conduct.

If consensus cannot be reached by the Delphi technique, the panel is convened and group consensus techniques are utilized. The strengths and weaknesses of each test or procedure are discussed and consensus reached whenever possible.

Because the practice of medicine is dynamic and ever evolving, the appropriateness criteria are to be reviewed by the panels after three years, if not sooner, depending on introduction of new and highly significant scientific evidence.

Use of Appropriateness Criteria

Clinical practice guidelines are meant to apply to the majority of patients. More specifically, the ACR appropriateness criteria are intended to guide radiologists, referring physicians, and patients in making initial decisions about diagnostic imaging and therapeutic techniques. The complexity and severity of a patient's clinical condition dictates the selection of appropriate imaging procedures

and treatments. Additionally, the availability of equipment or trained personnel may influence the selection of appropriate imaging procedures or treatments. The ultimate decision regarding the appropriate use of any specific examination or treatment is one that is made by the radiologist and the referring physician in light of all the circumstances presented in an individual situation.

These criteria are not designed as a guide for third-party reimbursement. Imaging techniques classified as investigational by the Federal Drug Administration have not been considered and the Task Force believes that the study of new equipment and applications should be encouraged.

Market forces are influencing physicians and provider organizations to practice cost-effective medicine while still maintaining quality. Utilization management of radiology services is a significant component of this change. The ACR appropriateness criteria can be used as a basis for utilization management by retrospective or prospective review.

Summary

This document, ACR Appropriateness Criteria for Imaging and Treatment Decisions, contains the first appropriateness criteria as developed by the ACR expert panels. The panels continue to develop additional criteria and more will be distributed as they are finalized. It is believed that this systematic process of criteria development will provide credible guidelines for radiology decision making based on scientific analysis and broad-based consensus techniques. It is hoped that the end result will be the cost-effective practice of high-quality radiology.

Lung Cancer Work Group

ROL-1. Staging of Non-Small cell Lung Carcinoma.....	ROL-1.1
Variant 1; 52-year-old man with a 4cm peripheral right lung lesion with no ROL-1.1
Variant 2; 52-year-old man with a 4cm peripheral right lung lesion with no. ROL-1.2
Variant 3; 52-year-old man with a 4cm peripheral right lung lesion with no ROL-1.3
Variant 4; 52-year-old man with a 4cm peripheral right lung lesion with no ROL-1.4
Variant 5; 60-year-old women who is found to have a 3 cm peripheral mass ROL-1.5
Variant 6; 60-year-old women who is found to have a 3 cm peripheral mass ROL-1.6
Variant 7; 60-year-old women who is found to have a 3 cm peripheral mass ROL-1.7
Variant 8; 52-year-old man with a 4cm peripheral right lung lesion with normal ROL-1.8
Summary of Literature Review	ROL-1.9
ROL-2. Postoperative Radiotherapy in Non-Small Cell Lung Cancer.....	ROL-2.1
Squamous Cell Lung Cancer, Negative Margins Post Resection	
Variant 1; T2N1(hilar) no mediastinal surgical staging ROL-2.1
Variant 2; T2N1(hilar) no mediastinal surgical staging ROL-2.2
Variant 3; T2N2 limited sampling of clinically positive nodes ROL-2.3
Variant 4; T2N2 with careful mediastinal staging highest node negative ROL-2.4
Variant 5; T2N2 with careful mediastinal staging highest node positive ROL-2.5
Adeno and Large Cell Lung Cancer, Negative Surgical Margins Post Resection	
Variant 6; T2N1(hilar) no mediastinal surgical staging ROL-2.6
Variant 7; T2N1(hilar) careful mediastinal staging ROL-2.7
Variant 8; T2N2 limited sampling of clinically positive nodes ROL-2.8
Variant 9; T2N2 with careful mediastinal staging highest node negative ROL-2.9
Variant 10; T2N2 with careful mediastinal staging highest node positive ROL-2.10
Non-Small Cell Lung Cancer, Negative Margins Post-Resection	
Variant 11; T1-2N0 no mediastinal surgical staging ROL-2.11
Variant 12; T1-2N0 with careful mediastinal staging ROL-2.12
Variant 13a; T3N0 with chest wall invasion, without mediastinal node staging ROL-2.13
Variant 13b; T3N0 with chest wall invasion, with mediastinal node staging ROL-2.14
T1-3N0 Non-Small cell Lung Cancer	
Variant 14a; T1-3N0 non-small cell lung cancer with positive margins ROL-2.15
Variant 14b; T1-3N0 non-small cell lung cancer with positive margins ROL-2.16
Squamous Cell Lung Cancer, Negative Surgical Margins Post Resection	
Variant 15; T2N2 limited sampling of clinically positive nodes, FEV1=700ml ROL-2.17
Variant 16; T2N2 limited sampling of clinically positive nodes, FEV1=1000ml ROL-2.18
Summary of Literature Review	ROL-2.19
ROL-3. Non-Small Cell Lung Carcinoma, Non-Surgical, Aggressive Treatment.....	ROL-3
Variant 1; T1N3M0 55-year-old female with palpable supraclavicular lymph ROL-3.1
Variant 2; T3N3M0 60-year-old male with hoarseness due to paralyzed ROL-3.2
Variant 3; T3N3M0 60-year-old male with postobstructive pneumonia ROL-3.3
Variant 4; T4N3M0 60-year-old male with a left shoulder pain radiating ROL-3.4
Variant 5; T4N3M0 60-year-old male with a few weeks history of superior ROL-3.5
Variant 6; T4N3M0 60-year-old male with hemoptysis and chest pain ROL-3.6
Variant 7; T4N3M0 58-year-old female with a palpable supraclavicular ROL-3.7
Variant 8; T1N0M0 70-year-old man with long history of heavy smoking ROL-3.8
Summary of Literature Review	ROL-3.9
ROL-4. Neoadjuvant Therapy for Marginally Resectable, Non-Small Cell Lung Carcinoma ROL-4.1
Variant 1; T2N2M0 ROL-4.1
Summary of Literature Review	ROL-4.2
ROL-5. Non-Aggressive, Non-Surgical Treatment of Inoperative Non-Small Cell Lung Cancer ROL-5.1

Variant 1;	70-year-old female with FEV-1 of 900 ml, coronary artery disease	ROL-5.1
Variant 2;	66-year-old male with Stage IIIB squamous cell carcinoma. Bulky	ROL-5.2
Variant 3;	66-year-old male with Stage IIIB squamous cell carcinoma. Bulky	ROL-5.3
Variant 4;	57-year-old male with hemoptosis, Stage IIIA squamous cell	ROL-5.4
Variant 5;	84-year-old female with Stage IIIA adenocarcinoma, 2cm largest	ROL-5.5
Variant 6;	55-year-old male with Stage IV NSCLCA, metastasis to bone	ROL-5.6
Variant 7;	62-year-old female with widely spread Stage IV NSCLCA, KPS 80	ROL-5.7
Variant 8;	68-year-old male with recurrent mediastinal and primary NSCLCA	ROL-5.8
Summary of Literature Review			ROL-5.9
ROL-6. Follow-up of Non-Small Cell Lung Cancer		 ROL-6.1
Variant 1;	62-year-old male, 3 months postoperative of Stage II squamous	ROL-6.1
Variant 2;	78-year-old female, never smoked, postoperative 33 months	ROL-6.2
Variant 3;	50-year-old female, never smoked, with incidentally found	ROL-6.3
Variant 4;	52-year-old male, heavy smoker, had wedge resection of	ROL-6.4
Variant 5;	65-year-old male, treated with neoadjuvant chemotherapy	ROL-6.5
Summary of Literature Review			ROL-6.6

AMERICAN SOCIETY OF RADIOLOGY
 APPROPRIATENESS CRITERIA
 (ROL-1.1)

Clinical Condition: Staging of Non-Small Cell Lung Cancer

Variant 1: 52-year-old man with 4cm peripheral right lung lesion with no mediastinal widening on chest X-ray. Fine needle biopsy shows squamous cell carcinoma. The patient has no bone pain or CNS symptoms.

Treatment	Appropriateness Rating	Comments
Thoracic staging		
CT-chest	9	
Mediastinoscopy	4	Only appropriate if the procedure influence the choice of therapy
MRI-Chest	2	
Transesophageal sonography	2	
Thoracentesis	2	
Staging for Systemic Disease		
CT-abdomen (as part of chest CT)	9	
CT-abdomen (separate study)	2	
CT-pelvis	2	
CT-brain	2	MRI is a better imaging exam. for the brain
MRI-abdomen (as part of chest MRI)	2	
MRI-abdomen(separate study)	2	
MRI-pelvis	2	
MRI-brain	2	
Bone scan	2	
Gallium scan	2	
Monoclonal antibody scintigraphy	2	

Appropriateness Criteria Scale
 1 2 3 4 5 6 7 8 9
 1=least appropriate 9=Most appropriate

* A number of the listed tests and procedures should continue to be a studied under a research setting. Even their general use may not be deemed appropriate at this time.