

Leitlinienreport

Interdisziplinäre Leitlinie der Qualität S3 zur Früherkennung, Diagnose und Therapie der verschiedenen Stadien des Prostatakarzinoms

2. Aktualisierung Version 3.1 – Oktober 2014

AWMF-Register-Nummer (043-022OL)

Leitlinienreport

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1. Informationen zu dieser Leitlinie

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1. Aktualisierung: Monika Nothacker, Thomas Langer, Susanne Weinbrenner, Günter Ollenschläger

2. Aktualisierung: Susanne Schorr, Carmen Khan

Ärztliches Zentrum für Qualität in der Medizin (ÄZQ), Gemeinsame Einrichtung von Bundesärztekammer und Kassenärztlicher Bundesvereinigung

1.2. Herausgeber

Leitlinienprogramm Onkologie der Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e.V. (AWMF), Deutschen Krebsgesellschaft e.V. (DKG) und Deutschen Krebshilfe e.V. (DKH).

1.3. Federführende Fachgesellschaft

Deutsche Gesellschaft für Urologie e. V. (DGU)



1.4. Finanzierung der Leitlinie

Diese Leitlinie wurde von der Deutschen Krebshilfe im Rahmen des Leitlinienprogramms Onkologie gefördert.

1.5. Kontakt

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1.6. Bisherige Änderungen an der Version 3

Oktober 2014, Version 3.1: Die ausstehende Zustimmung der Deutschen Gesellschaft für Allgemeinmedizin und Familienmedizin (DEGAM) ist erfolgt und wurde in den Leitliniendokumenten ergänzt.

1.7. Zitierweise des Leitlinienreports

Leitlinienprogramm Onkologie (Deutsche Krebsgesellschaft, Deutsche Krebshilfe, AWMF): Interdisziplinäre Leitlinie der Qualität S3 zur Früherkennung, Diagnose und Therapie der verschiedenen Stadien des Prostatakarzinoms, Leitlinienreport 3.1, 2014, AWMF Registernummer: 034/022OL, <http://leitlinienprogramm-onkologie.de/Leitlinien.7.0.html> (Zugriff am: TT.MM.JJJJ)

1.8. Weitere Dokumente zur Leitlinie

Die Lang- und Kurzversion der S3-Leitlinie zur "Früherkennung, Diagnose und Therapie der verschiedenen Stadien des Prostatakarzinoms", ist über die folgenden Seiten zugänglich

- AWMF (<http://www.awmf.org/leitlinien/aktuelle-leitlinien.html>)
- Leitlinienprogramm Onkologie (<http://www.leitlinienprogramm-onkologie.de/OL/leitlinien.html>)
- Deutsche Krebsgesellschaft (http://www.krebsgesellschaft.de/wub_1levidenzbasiert_120884.html)
- Deutsche Krebshilfe (<http://www.krebshilfe.de/>)
- <http://www.arztbibliothek.de>
- Guidelines International Network (<http://www.gin.net>)

Neben der Langversion gibt es folgende ergänzende Dokumente:

- Leitlinienreport zur Leitlinie
- Dokument mit Evidenztabelle zur Leitlinie
- Kurzfassung der Leitlinie
- Patientenleitlinie "Früherkennung von Prostatakrebs"
- Patientenleitlinie: "Prostatakrebs 1 - Lokal begrenztes Prostatakarzinom"
- Patientenleitlinie "Prostatakrebs 2 - Lokal fortgeschrittenes und metastasiertes Prostatakarzinom"
- Englische Übersetzung (geplant)

1.9. Verwendete Abkürzungen

Abkürzung	Erläuterung
AS	Active Surveillance (Aktive Überwachung)
AUA	American Urological Association
AWMF	Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften
ÄZQ	Ärztliches Zentrum für Qualität in der Medizin
BT	Brachytherapie
BPS	Bundesverband Prostatakrebs Selbsthilfe
CT	Computertomographie
DGU	Deutsche Gesellschaft für Urologie
DNA	Deoxyribonucleic acid, Desoxyribonukleinsäure
DRU	Digital-Rektale Untersuchung
EAU	European Association of Urology
EBRT	External Beam Radiotherapy = Perkutane Strahlentherapie
ECOG	Eastern Cooperative Oncology Group
fPSA	freies Prostata-spezifisches-Antigen
GS	Gleason-Score
GIN	Guideline International Network
Gy	Kurzbezeichnung für die Maßeinheit der Energiedosis
HDR	High-Dose-Rate
HIFU	Hochintensive Fokussierte Ultraschall
HT	Hormontherapie
HTA	Health Technology Assessment
Kryo	Kryotherapie
LDR	Low-Dose-Rate
LoE	Level of Evidence
MRT	Magnetresonanztomographie
NICE	National Institute of Clinical Excellence
OL	Onkologisches Leitlinienprogramm
PCa	Prostatakarzinom
PCA3	Prostate Cancer Gene 3
PET/CT	Positronen-Emissions-Tomographie/Computertomographie
PSA	Prostata-spezifisches-Antigen
PSADT	PSA-Doubling-Time
QOL	Quality Of Life
RCT	Randomized Controlled Trial
RPE	Radikale Prostatektomie
RT	Strahlentherapie, Radiotherapie
SIGN	Scottish Intercollegiate Guidelines Network
TED	Tele-Dialog
TRUS	Transrektale Ultraschalluntersuchung
TURP	Transurethrale Resektion der Prostata
WW	Watchful Waiting
Z. n.	Zustand nach

2. Geltungsbereich und Zweck der Leitlinie

2.1. Adressaten

Die interdisziplinäre Leitlinie der Qualität S3 zur Früherkennung, Diagnose und Therapie der verschiedenen Stadien des Prostatakarzinoms richtet sich an alle Betroffenen und alle Berufsgruppen, die mit der Prävention und Früherkennung von Prostatakarzinom befasst sind sowie alle Berufsgruppen, die Patienten mit Verdacht auf bzw. mit nachgewiesenem Prostatakarzinom jeglichen Stadiums behandeln, sowie deren Angehörige betreuen. Weitere Adressaten dieser Leitlinie sind übergeordnete Organisationen (z. B. Krankenkassen und Einrichtungen der ärztlichen Selbstverwaltung) und die interessierte Fachöffentlichkeit.

2.2. Zielsetzung

Die interdisziplinäre Leitlinie der Qualität S3 zur Früherkennung, Diagnose und Therapie der verschiedenen Stadien des Prostatakarzinoms ist ein evidenz- und konsensbasiertes Instrument, um Früherkennung, Diagnostik und Therapie des Prostatakarzinoms zu verbessern.

Männer und Ärzte sollen durch die Leitlinie bei der Entscheidung über Früherkennungsmaßnahmen unterstützt werden. Die Leitlinie soll dazu beitragen, eine angemessene Gesundheitsversorgung bei der Früherkennung sicherzustellen.

Es ist weiterhin die Aufgabe der Leitlinie, dem Patienten (mit Verdacht auf Prostatakarzinom oder nachgewiesenem Prostatakarzinom) angemessene, wissenschaftlich begründete und aktuelle Verfahren in der Diagnostik, Therapie und Rehabilitation anzubieten. Dies gilt sowohl für die lokal begrenzte oder lokal fortgeschrittene Erkrankung als auch bei Vorliegen eines Rezidivs oder von Fernmetastasen.

Die Leitlinie soll neben dem Beitrag für eine angemessene Gesundheitsversorgung auch die Basis für eine individuell zugeschnittene, qualitativ hochwertige Therapie bieten. Mittel- und langfristig sollen so die Morbidität und Mortalität von Patienten mit Prostatakarzinom gesenkt und die Lebensqualität erhöht werden.

3. Zusammensetzung der Leitliniengruppe

3.1. Autoren-Steuergruppe der Leitlinie

Manfred Wirth (Vorsitzender), Lothar Weißbach (stellvertretender Vorsitzender), Rolf Ackermann (bis 2009), Winfried Alberti (bis 2009), Clemens Albrecht (bis 2009), Bernt Göckel-Beining, Michael Fröhner, Wolfgang Hinkelbein (bis 2013), Kurt Miller, Herbert Rübben, Michael Stöckle (seit Aktualisierung 2011), Frederik Wenz (seit Aktualisierung 2011), Thomas Wiegel, Johannes Wolff, Bernhard Wörmann

3.2. Beteiligte Autoren und Mitglieder der Leitliniengruppe

Die bei der Erstellung der Leitlinie 2009 beteiligten Personen die bei der 1. Aktualisierung 2011 sowie die bei der 2. Aktualisierung 2013/2014 beteiligten Personen können Tabelle 1 entnommen werden.

Tabelle 1: Mitglieder der Leitliniengruppe 2006-2014

Name	Organisation	Zeitraum
Ackermann, Prof. Dr. med. Rolf	DGU	2006-2009
Alberti, Prof. Dr. med. Winfried	DEGRO	2006-2009
Albrecht, Dr. med. Clemens	DEGRO/ BDVST	2006-2014
Beyersdorff, PD Dr. med. Dirk	DRG	2006-2009
Blana, PD Dr. med. Andreas	DGU	2011-2014
Böhmer, PD Dr. med. Dirk	DEGRO	2006-2014
Börgermann, Dr. med. Christof	DGU	2006-2014
Borchers, Dr. med. Holger	DGU	2006-2009
Burchardt, Prof. Dr. med. Martin	DGU	2006-2014
Deger, Prof. Dr. med. Serdar	DGU	2006-2009
Doehn, Prof. Dr. med. Christian	DGU	2006-2014
Donner-Banzhoff, Prof. Dr. Norbert	DEGAM	2013-2014
Ebermayer, Dr. med. Johann	DGU	2006-2009
Ebert, Prof. Dr. med. Thomas	DGU	2006-2009
Egidi, Dr. med. Günther	DEGAM	2013-2014
Enders, Dipl. Ing. Paul	BPS	2006-2014
Fichtner, Prof. Dr. med. Jan	DGU	2006-2009
Fiebrandt, Hanns-Jörg	BPS	2006-2014
Fornara, Univ.-Prof. Dr. med. Paolo	DGU	2006-2014
Fröhner, PD Dr. med. Michael	DGU	2006-2014
Galalae, PD Dr. med. Razvan-Mircea	DEGRO	2006-2009
Ganswindt, PD Dr. med. Ute	DEGRO	2013-2014
Göckel-Beining, Dr. med. Bernt	BDU	2006-2014
Goldner, Dr. med. Gregor	DGU	2006-2009
Graefen, Prof. Dr. med. Markus	DGU	2006-2014
Grimm, Prof. Dr. med. habil. Marc-Oliver	DGU	2006-2014
Grün, Dr. med. Arne	DEGRO	2006-2009

Name	Organisation	Zeitraum
Hampel, PD Dr. med. Christian	DGU	2006-2009
Hakenberg, Prof. Dr. med. Oliver	DGU	2006-2014
Hammerer, Prof. Dr. med. Peter	DGU	2006-2009
Hartmann, Prof. Dr. med. Arndt	DGP/BDP	2013-2014
Hautmann, Prof. Dr. med. Richard	DGU	2006-2009
Heidenreich, Prof. Dr. med. Axel	DGU	2006-2014
Henkel, Dr. med. Thomas-Oliver	DGU	2006-2014
Hinkelbein, Prof. Dr. med. Wolfgang	DEGRO	2006-2014
Höcht, Prof. Dr. med. Stefan	DEGRO	2006-2014
Hölscher, Dr. med. Tobias	DEGRO	2006-2014
Hoffmann, Prof. Dr. med. Wolfgang	BVDST	2013-2014
Jakse, Prof. Dr. med. Gerhard	DGU	2006-2009
Jocham, Prof. Dr. med. Dieter	DGU	2006-2009
Jünemann, Prof. Dr. med. Klaus-Peter	DGU	2006-2009
Kahl, Dr. med. Philip	DGP	2006-2009
Kaufmann, Dr. med. Sascha	DGU	2006-2009
Klein, Tobias	KOK	2013-2014
Kotzerke, Prof. Dr. med. habil. Jörg	DGN	2013-2014
Krause, Prof. Dr. med. Bernd	DGN	2011-2014
Kristiansen, Prof. Dr. med. Glen	DGP/BDP	2013-2014
Küfer, PD Dr. med. Rainer	DGU	2006-2009
Lein, Prof. Dr. med. Michael	DGU	2011-2014
Loch, Prof. Dr. med. Tillmann	DGU	2013-2014
Loertzer, Prof. Dr. med. Hagen	DGU	2006-2014
Luboldt, PD Dr. med. Hans-Joachim	DGU	2006-2014
Lümmen, Prof. Dr. med. Gerd	DGU	2006-2014
Machtens, Dr. med. Stefan	DGU	2006-2014
Martin, Dr. med. Thomas	DEGRO	2006-2014
Miller, Prof. Dr. med. Kurt	DGU	2006-2014
Moser, Dr. med. Lutz	DEGRO	2006-2014
Mueller-Lisse, Prof. Dr. med. Ullrich G.	DRG	2006-2014
Otto, Prof. Dr. med. Ullrich	DGU	2006-2014
Palmedo, Prof. Dr. med. Holger	DGN	2006-2014
Pummer, Univ.-Prof. Dr. med. Karl	DGU	2006-2014
Rohde, Dr. med. Volker	DGU	2006-2014
Roth, Prof. Dr. med. Wilfried	DGP/BDP	2013-2014
Rübber, Prof. Dr. med. Dr. h.c. Herbert	DGU	2006-2014
Schmitz-Dräger, Prof. Dr. med. Bernd Jürgen	DGU	2006-2014
Schostak, Prof. Dr. med. Martin	DGU	2006-2014
Schrader, Prof. Dr. med. Mark	DGU	2006-2014
Schulz, Prof. Dr. rer. nat. Wolfgang Arthur	DGU	2006-2009
Sedlmayer, Prim. Univ.-Prof. Dr. Felix	DEGRO	2006-2014
Semjonow, Prof. Dr. med. Axel	DGU	2006-2014
Steuber, PD Dr. Thomas	DGU	2006-2009, 2013-2014

Name	Organisation	Zeitraum
Stöckle, Prof. Dr. med. Michael	DGU	2011-2014
Tedsen, Dr. med. Sönke	DGU	2006-2009
Thomas, Dr. med. Christian	DGU	2006-2009
Thüroff, Prof. Dr. med. Joachim W.	DGU	2006-2009
Vögeli, Prof. Dr. med. Thomas-Alexander	DGU	2011-2014
Volkmer, Dr. med. Jens-Peter	DGU	2006-2009
Wagner, Dr. med. Sigrid	DGU	2009-2014
Walden, Dr. med. Oliver	DGU	2006-2009
Wedding, PD Dr. med. Ulrich	DGG	2013-2014
Weißbach, Prof. Dr. med. Lothar	DGU	2006-2014
Wenz, Prof. Dr. med. Frederik	DEGRO	2006-2014
Wernert, Prof. Dr. med. Nicolas*	DGP	2006-2014
Wetterauer, Prof. Dr. med. Ulrich	DGU	2006-2009
Wiedemann, PD Dr. med. Andreas	DGG	2013-2014
Wiegel, Prof. Dr. med. Thomas	DEGRO	2006-2014
Wirth, Prof. Dr. med. Dr. h.c. Manfred P.	DGU	2006-2014
Wörmann, Prof. Dr. Bernhardt	DGHO	2006-2014
Wolff, Prof. Dr. med. Johannes M.	DGU	2006-2014
Zacharias, Dipl. Ing. Jens-Peter	BPS	2006-2014
Zastrow, Dr. med. Stefan	DGU	2013-2014
Zips, Prof. Dr. med. Daniel	DEGRO	2013-2014

Abkürzungen: BDP = Bundesverband Deutscher Pathologen e.V., BDU = Berufsverband der Deutschen Urologen, BPS = Bundesverband Prostatakrebs Selbsthilfe, BVDST = Berufsverband Deutscher Strahlentherapeuten, DEGAM = Deutsche Gesellschaft für Allgemeinmedizin und Familienmedizin, DEGRO = Deutsche Gesellschaft für Radioonkologie, DGG = Deutsche Gesellschaft für Geriatrie, DGHO = Deutsche Gesellschaft für Hämatologie und Onkologie, DGN = Deutsche Gesellschaft für Nuklearmedizin, DGP = Deutsche Gesellschaft für Pathologie, DGU = Deutsche Gesellschaft für Urologie, DRG = Deutsche Röntgengesellschaft, KOK = Konferenz Onkologischer Kranken- und Kinderkrankenpflege.

* Bei der 2. Aktualisierung 2014 als Beratendes Mitglied der Leitliniengruppe

Für die 2. Aktualisierung 2014 waren folgende Experten lediglich als Vertreter für die Konsensuskonferenz benannt: Grün, Dr. med. Arne (DEGRO), Hinkelbein, Prof. Dr. med. Wolfgang (DEGRO), Carl, Ernst-Günther (BPS), Dietz, Josef (BPS).

3.3. Fachgesellschaften

Deutsche Gesellschaft für Urologie (DGU), Berufsverband der Deutschen Urologen (BDU), Berufsverband Deutscher Strahlentherapeuten (BVDST), Deutsche Gesellschaft für Radioonkologie (DEGRO), Deutsche Gesellschaft für Hämatologie und Onkologie (DGHO), Deutsche Gesellschaft für Pathologie (DGP), Bundesverband Deutscher Pathologen e.V. (BDP), Deutsche Gesellschaft für Nuklearmedizin (DGN), Deutsche Röntgengesellschaft (DRG), Bundesverband Prostatakrebs Selbsthilfe (BPS), Deutsche Krebsgesellschaft (DKG), Deutsche Gesellschaft für Geriatrie (DGG), (Deutsche Gesellschaft für Allgemeinmedizin und Familienmedizin (DEGAM), Konferenz Onkologischer Kranken- und Kinderkrankenpflege (KOK).

3.4. Andere Institutionen

Redaktion, Koordination, Moderation und Gestaltung

Ärztliches Zentrum für Qualität in der Medizin ÄZQ, Gemeinsame Einrichtung von Bundesärztekammer und Kassenärztlicher Bundesvereinigung.

- Erststellung (Christoph Röllig, Christina Niederstadt, Monika Lelgemann, Achim Wöckel, Monika Nothacker, Marga Cox, Susanne Weinbrenner, Günter Ollenschläger)
- 1. Aktualisierung (Monika Nothacker, Thomas Langer, Susanne Weinbrenner, Günter Ollenschläger)
- 2. Aktualisierung (Susanne Schorr, Carmen Khan)

Methodische Begleitung

1. Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften, AWMF (Ina Kopp, Monika Nothacker (nur 2. Aktualisierung))
2. Leitlinienprogramm Onkologie, OL (Markus Follmann, Thomas Langer (nur 2. Aktualisierung))

Beteiligte externe Experten:

Erststellung (2006–2009, Version 1.0):

- Behre, Prof. Dr. med. Hermann M.; Kapitel 2.2.2. Testosteronsubstitution
- Koller, Prof. Dr. med. Michael; Kapitel 8.1.2. Psychosoziale Unterstützung

1. Aktualisierung (2011, Version 2.0):

- Dubben, PD Dr. rer. nat Hans-Herrmann.; Kapitel 3.1. PSA und DRU in Früherkennung/Screening

2. Aktualisierung (2014, Version 3.0):

- Böcking, Prof. Dr. med. Alfred; Kapitel 4.3 Pathomorphologische Untersuchungen
- Seitz, Prof. Dr. med. Gerhard; Kapitel 4.3 Pathomorphologische Untersuchungen

3.5. Patientenbeteiligung

An der Erstellung der Leitlinien waren Vertreter der Patientenorganisation ‚Bundesverband Prostatakrebs Selbsthilfe e.V. (BPS)‘ direkt beteiligt. Vertreter des BPS (siehe Tabelle 1) waren an den Arbeitsgruppen beteiligt und bei den Konsensuskonferenzen stimmberechtigt.

4. Fragestellungen und Gliederung

Die Grundstruktur der Leitlinie basiert auf der Einteilung in Hauptkomplexe, die mit den folgenden Kapiteln der vorliegenden Leitlinie korrespondieren:

- Kapitel 2: Epidemiologie, Risikofaktoren, Prävention und Ernährung
- Kapitel 3: Früherkennung, Screening und Biopsie
- Kapitel 4: Diagnostik und Stadieneinteilung
- Kapitel 5: Therapie des nichtmetastasierten Prostatakarzinoms
- Kapitel 6: Diagnostik und Therapie des rezidivierten oder metastasierten Prostatakarzinoms
- Kapitel 7: Rehabilitation und Nachsorge
- Kapitel 8: Psychosoziale Aspekte und Lebensqualität

Zur Bearbeitung der verschiedenen Aspekte dieser Hauptkomplexe formulierte das Leitliniengremium zu Beginn des Erstellungsprozesses der Leitlinie Schlüsselfragen. Die aufgestellten Schlüsselfragen wurden in einem formalisierten Konsensusverfahren durch die gesamte Leitliniengruppe gebilligt. An den konsentierten Schlüsselfragen orientierte sich die Literaturrecherche und spätere Formulierung von Empfehlungen und Statements. Die Schlüsselfragen sind in Kapitel 12.1 aufgelistet. Bei der 1. Aktualisierung 2011 erfolgte eine Priorisierung der zu bearbeitenden Themen bzw. Kapitel durch die Steuergruppe. Hierbei wurden neue Schlüsselfragen ergänzt (siehe Kapitel 5.1.2). Bei der 2. Aktualisierung 2014 erfolgte eine Priorisierung der zu bearbeitenden Themen bzw. Kapitel durch die Steuergruppe. Hierbei wurden neue Schlüsselfragen ergänzt (siehe Kapitel 5.1.3).

5. Methodik

5.1. Evidenzbasierung

5.1.1. Erstellung der Leitlinie 2006-2009

Die Evidenzbasis für die S3-Leitlinie wurde durch die folgenden systematischen Recherchen vom ÄZQ festgelegt:

5.1.1.1. Berücksichtigung evidenzbasierter Leitlinien

Die Suche nach Leitlinien erfolgte im August 2006 über die Datenbank des Guidelines International Network (G-I-N), den Guideline Finder des britischen National Health Service sowie die Pubmed-Suchoberfläche der National Library of Medicine. Leitlinien in anderen Sprachen als deutsch oder englisch wurden nur im Falle Frankreichs und der Niederlande zugelassen, da hier eine orientierende Lektüre möglich war und teilweise auch englische Übersetzungen oder Zusammenfassungen vorhanden sind. Der Recherchezeitraum wurde primär für Publikationen ab 2002 festgelegt. Eine Aktualisierung der Recherche erfolgte im Juni 2008. Die EAU-Leitlinie 2009 wurde zusätzlich berücksichtigt.

Zusätzlich wurden gezielt die Webseiten folgender Organisationen gesichtet:

- Frankreich (ANAES);
- Niederlande (NEDERLANDS HUISARTSEN GENOOTSCHAP);
- England (NICE);
- Irland (Royal College of Surgeons in Ireland (RCSI));
- Europa (EAU – European Association of Urology);
- USA (NCCN – National Comprehensive Cancer Network);
- Kanada (Cancer Care Ontario);
- Australien (National Health and Medical Research Council);
- Neuseeland (New Zealand Guidelines Group).

Leitlinien wurden berücksichtigt, wenn sie die folgenden Kriterien einer evidenzbasierten Leitlinie erfüllten:

- Systematische Recherche nach Primär- bzw. Sekundärliteratur
- Bei der Mehrheit der Empfehlungen sind die zugrunde liegende Primär- / Sekundärliteratur hinterlegt.
- Bei der Mehrheit der Empfehlungen ist eine Evidenz- und / oder Empfehlungseinstufung (Level of Evidence [LoE] und / oder Grade of Recommendation [GoR]) angegeben.

Eine Ausnahme hinsichtlich der methodischen Mindestanforderungen wurde wegen ihrer internationalen Bedeutung für die EAU-Leitlinie gemacht.

Folgende Leitlinien wurden in der Folge als Quelleitlinien herangezogen:

- “Guideline for the Management of Clinically Localized Prostate Cancer: 2007 Update” (2007) der AUA (American Urological Association) [1];
- Clinical practice guidelines: evidence based information and recommendations for the management of localized prostate cancer (2002) der Australian National Networking Party on Management of localised prostate cancer [2];

- “Guidelines on Prostate Cancer” (2007+2009) der EAU (European Urological Association) [3; 4];
- “Prostate Cancer. Nationwide-Guideline” (2007) der DUA (Dutch Urological Association) [5];
- “Prostate Cancer. Diagnosis and Treatment” (2008) des NICE (National Institut of Clinical Excellence) [6].

Die Schlüsselempfehlungen der genannten Leitlinien wurden extrahiert und sind Bestandteil der Evidenztabelle zu dieser Leitlinie.

5.1.1.2. Systematische Recherche nach aggregierter Evidenz (Übersichtsarbeiten, Metaanalysen und Health Technology Assessment (HTA)- Berichte)

Die systematische Recherche erfolgte in:

- den Datenbanken der Cochrane Library;
- Pubmed (unter Verwendung eines Suchfilters für systematisch recherchierte aggregierte Evidenz).
- Vorliegende systematische Übersichtsarbeiten/Metaanalysen/HTA-Berichte wurden in den Evidenztabelle gesondert ausgewiesen und den extrahierten Einzelpublikationen vorangestellt.

5.1.1.3. Systematische Recherche nach Einzelpublikationen (bevorzugt RCT's)

Aufbauend auf den Ergebnissen der identifizierten aggregierten Evidenzquellen wurden systematische, themenbezogene Recherchen nach Einzelstudien in folgenden Datenbanken durchgeführt:

- Pubmed (inklusive Daten der ehem. Cancerlit-Datenbank und "In-process-Citations"); Sprache Deutsch oder Englisch, Erscheinungsjahr ab 2002 bzw. bei Themen ohne gute aufbereitete Evidenz auch ab 2000. Wichtige, in aufbereiteter Evidenz zitierte Studien wurden zusätzlich dann im Original eingesehen, wenn sie nach 1990 publiziert worden waren und dies für die Bewertung der aufbereiteten Quelle (Leitlinie, Review, HTA) hilfreich oder notwendig war.
- Cochrane Clinical Trials Database (thematische Suche nach "Prostatakarzinom"; keine Einschränkungen während der Recherche) und manuelle Sichtung und Zuordnung zu einzelnen Themenblöcken.

Das Ergebnis der Literatursuche wurde zentral beim ÄZQ erfasst und in eine Online-Datenbank eingespeist. Die Ergebnislisten wurden an die Fachexperten verschickt und per Internet zugänglich gemacht. Von den Methodikerinnen und Methodikern des ÄZQ wurde ggf. unter Einbeziehung der Fachexperten methodisch hochwertige Literatur identifiziert, die vom ÄZQ nach EbM-Kriterien bewertet und den Experten als Grundlage für die Formulierung von Empfehlungen zur Verfügung gestellt wurde. Die spezifischen Suchstrategien erfolgten themenbezogen und wurden zusammen mit dem Recherchezeitraum den Evidenztabelle zu den einzelnen Themen vorangestellt. Die Trefferzahl vor Titel/Abstract Sichtung ist angegeben oder kann auf Anfrage beim ÄZQ eingesehen werden.

Themenübergreifend wurden die folgenden Suchfilter eingesetzt:

a) Methodische Filter

Strategie zur Identifikation systematischer Reviews und Metanalysen:

```
((Prostat*[ti] AND ((Prostate Cancer[mh] OR prostatic neoplasms[majr]) AND (cancer*[tiab] OR neoplas*[tiab] OR growth[tiab] OR malign*[tiab] OR tumor[tiab] OR tumour[tiab] OR carcino*[tiab] OR adenocarcino*[tiab]))) NOT benign*[ti] NOT prostatitis[ti])
```

```
AND ("review"[pt] OR "review"[ti] OR "review academic" OR "systematic review" OR "Meta-Analysis"[mh] OR "Meta-Analysis"[pt] OR "meta analysis" OR metaanaly*)
```

```
OR systematic[sb]
```

Strategie zur Identifikation randomisiert kontrollierter Studien:

```
(Prostat*[ti] AND ((Prostate Cancer[mh] OR prostatic neoplasms[majr]) AND (cancer*[tiab] OR neoplas*[tiab] OR growth[tiab] OR malign*[tiab] OR tumor[tiab] OR tumour[tiab] OR carcino*[tiab] OR adenocarcino*[tiab]))) NOT benign*[ti] NOT prostatitis[ti])
```

```
AND ((clinical[tiab] AND trial[tiab]) OR ("clinical trials"[mh] OR random*[tiab] OR "random allocation"[mh] OR quantitativ*[tiab] OR quality[tiab] OR qualitativ*[tiab] OR systematic*[tiab] OR stringent[tiab] OR strict[tiab] OR rigorous[tiab] OR controlled[tiab] OR placebo[ti] OR (double[ti] AND blind*[ti])))
```

b) Übergreifende Suchstrategie zur Identifizierung des Prostatakarzinoms

Die Suchstrategie zu den Themenbereichen und Schlüsselthemen wurde modular aufgestellt. Die Strategien enthielten einen Themenblock „Prostatakarzinom“ (PCa), weitere Strategiemodule wurden je nach Fragestellung kombiniert. Die Ergebnisqualität wurde nach jedem Suchprozess durch Vergleich mit Literaturlisten aus Schlüsselpublikationen sowie durch Bildung von Differenzmengen mit und ohne Anwendung der Filter für die Studienqualität geprüft. Bei nicht ausreichend sensitiver Suche wurden die benutzten Filter für die Studienqualität entfernt und die Suchen erneut durchgeführt.

Strategie-Block „Modul zur Identifikation von Publikationen zum Thema Prostatakarzinom“:

```
(Prostat*[ti] AND ((Prostate Cancer[mh] OR prostatic neoplasms[majr]) AND (cancer*[tiab] OR neoplas*[tiab] OR growth[tiab] OR malign*[tiab] OR tumor[tiab] OR tumour[tiab] OR carcino*[tiab] OR adenocarcino*[tiab]))) NOT benign*[ti]
```

```
NOT prostatitis[ti]
```

Das Modul wurde bezüglich des gesuchten Stadiums des Prostatakarzinoms angepasst oder, falls nicht erforderlich, in der vorliegenden, übergreifenden Form verwendet.

5.1.1.4. **Auswahl und Bewertung der Evidenz**

Die vollständigen Ergebnisse der systematischen Recherchen wurden den Experten als Listen mit bibliographischen Angaben und Abstrakts online über eine Internetplattform zur Verfügung gestellt.

Zielgruppe

Für die Themen Risikofaktoren, Prävention und Ernährung sowie Früherkennung war die Zielgruppe auf Männer beschränkt. Abhängig von den weiteren Schlüsselfragen war die Zielgruppe Männer, die an einem lokal begrenzten, lokal fortgeschrittenen, rezidierten oder metastasierten Prostatakarzinom leiden.

Eingeschlossene Studientypen

Zur Beantwortung der Fragestellung Nutzen und Schaden der einzelnen Verfahren sind grundsätzlich randomisierte kontrollierte Studien mit den Endpunkten Morbidität, Mortalität und Lebensqualität geeignet. Nur in solchen Studien kann gezeigt werden, ob ein relevanter klinischer Nutzen erreicht werden kann oder wie die Effektivität eines Verfahrens im Vergleich zu anderen zu beurteilen ist. Deshalb erfolgte im ersten Schritt grundsätzlich eine Suche nach randomisiert kontrollierten Studien oder Quellen aggregierter Evidenz (HTA-Berichte, systematische Reviews und Metaanalysen) in denen entsprechende randomisierte prospektive Studien selektiert und gewichtet vorliegen. Wenn orientierende Vorrecherchen ergaben, dass bei den einzelnen diagnostischen oder therapeutischen Verfahren keine oder nur wenige randomisiert kontrollierte Studien zu der fokussierten Fragestellung vorlagen, wurde im nächsten Schritt nach prospektiven Kohortenstudien gesucht. Auch retrospektive Kohortenstudien wurden in die Auswertung bei schwacher oder Fehlen von prospektiver Evidenz miteinbezogen. Im Weiteren wurden auch Fallserien eingeschlossen, vorzugsweise bei Anwendung einer klinisch und methodische sinnvollen Stratifizierung und multivariaten Analyse.

Die in den Recherchen identifizierte Literatur wurde durch die Methodikerinnen und Methodiker des ÄZQ einem Titel- und Abstraktscreening unterzogen. Die ausgewählten Abstrakts wurden im Volltext bestellt und nach erneuter Sichtung und Kommentierung durch Mitarbeiter des ÄZQ ggf. unter inhaltlicher Beteiligung der Fachexperten eingeschlossen, wenn die Volltexte als relevant und methodisch geeignet bewertet wurden. Die eingeschlossenen Studien wurden in Evidenztabellen extrahiert. Die formal methodische Bewertung der Evidenz erfolgte nach den Kriterien des Scottish Intercollegiate Guidelines Network (SIGN) (siehe Tabelle 2).

Tabelle 2: Schema der Evidenzgraduierung des Scottish Intercollegiate Guidelines Network (SIGN)

Grad	Beschreibung Evidenzgraduierung 2006-2011	Beschreibung Evidenzgraduierung 2013-2014
1++	Qualitativ hochwertige Metaanalysen, systematische Übersichten von RCTs, oder RCTs mit sehr geringem Risiko systematischer Fehler (Bias)	
1+	Gut durchgeführte Metaanalysen, Systematische Übersichten <u>von RCTs</u> , oder RCTs mit geringem Risiko systematischer Fehler (Bias)	Gut durchgeführte Metaanalysen, Systematische Übersichten, oder RCTs mit geringem Risiko systematischer Fehler (Bias)
1-	Metaanalysen, Systematische Übersichten <u>von RCTs</u> , oder RCTs mit hohem Risiko systematischer Fehler (Bias)	Metaanalysen, Systematische Übersichten, oder RCTs mit hohem Risiko systematischer Fehler (Bias)
2++	Qualitativ hochwertige systematische Übersichten von Fall-Kontroll- oder Kohortenstudien oder Qualitativ hochwertige Fall-Kontroll- oder Kohortenstudien mit sehr niedrigem Risiko systematischer Verzerrungen (Confounding, Bias, „Chance“) und hoher Wahrscheinlichkeit, dass die Beziehung ursächlich ist	
2+	Gut durchgeführte Fall-Kontroll-Studien oder Kohortenstudien mit niedrigem Risiko systematischer Verzerrungen (Confounding, Bias, „Chance“) und moderater Wahrscheinlichkeit, dass die Beziehung ursächlich ist	
2-	Fall-Kontroll-Studien oder Kohortenstudien mit einem hohen Risiko systematischer Verzerrungen (Confounding, Bias, „Chance“) und signifikantem Risiko, dass die Beziehung nicht ursächlich ist	
3	Nicht-analytische Studien, z. B. Fallberichte, Fallserien	
4	Expertenmeinung	

Anmerkung: Ein Evidenzlevel 2+ -3 wurde auch vergeben bei Fallserien, bei denen multivariate Analysen vorlagen.

Die eingeschlossenen Studien wurden als Evidenzgrundlage für die Empfehlungen mit den Experten der Arbeitsgruppen besprochen. In einer folgenden Gegenprüfung wurden die Aussagen der Arbeitsgruppen mit den Inhalten der Studien und der gesamten Evidenzlage von den Methodikerinnen und Methodikern (ÄZQ) abgeglichen und Optimierungsvorschläge für die Konsensuskonferenz erarbeitet. Die Evidenztabelle mit den extrahierten Angaben der berücksichtigten Studien sind in einem gesonderten Dokument veröffentlicht worden (z. B. unter www.leitlinienprogramm-onkologie.de oder www.awmf-online.de).

5.1.1.5. **Erstellung von Kapiteln für die keine systematische Literaturrecherche nach Primärliteratur erfolgte**

Aus Gründen einer effizienten Ressourcenallokation wurden folgende Kapitel auf Basis von Leitlinien, Konsensuspapieren und ergänzenden Literaturangaben der jeweiligen Autoren erstellt:

4.2 Pathomorphologische Diagnostik;

5.1 Therapieplanung und Aufklärung;

6.1 Definition und Diagnostik des Tumorrezidivs;

6.7 Supportiv- und Palliativtherapie;

7.2.1 Nachsorge nach lokaler, kurativ intendierter Therapie;

7.2.3 Follow-up unter Hormontherapie.

5.1.2. **Erstellung der ersten modularen Aktualisierung 2011**

5.1.2.1. **Themen der Aktualisierung**

Die erste Aktualisierung der Leitlinie erfolgte modular, d.h. es wurden nicht alle Kapitel der Leitlinie im ersten Schritt überarbeitet. Das Gesamtkonzept für die Aktualisierung der Prostatakarzinomleitlinie ist das einer „living guideline“ mit einer geplanten modularen Überarbeitung in etwa jährlichen Abständen. Der für die erste Überarbeitung identifizierte Aktualisierungsbedarf bestand zum einen aus Themen, die bei der Erstellung der Leitlinie nicht bearbeitet werden konnten und dort bereits benannt wurden, sowie aus Themen, die während der öffentlichen Konsultationsphase eingebracht wurden. Zum anderen wurden Themen berücksichtigt, die sich aus einer Befragung der Autorengruppen und der Patientenvertreter ergaben. Die Steuergruppe nahm eine Priorisierung von 18 Einzelrecherchen aus einer Liste von insgesamt 24 Themen vor. Es erfolgten 11 Aktualisierungsrecherchen und 5 Recherchen zu neuen Themen, die im Folgenden genannt sind. 2 Themen (neue Marker und DNA-Zytometrie) konnten aus Kapazitätsgründen nicht bearbeitet werden.

Aktualisierungsrecherchen:

- Nutzen und Schaden der Früherkennung/des Screening
- MRT und TRUS zu Primärdiagnostik und Staging
- Stellenwert des Active Surveillance
- Radikale Prostatektomie bei Operation bei Patienten mit hohem Risikoprofil bzw. lokal fortgeschrittenem Prostatakarzinom
- LDR-Brachytherapie bei Patienten mit mittleren/hohem Risikoprofil
- Perkutane Strahlentherapie bei Patienten mit hohem Risikoprofil bzw. lokal fortgeschrittenem Prostatakarzinom
- Perkutanen Strahlentherapie mit Dosisescalation beim lokal begrenzten Prostatakarzinom
- HIFU zur Primär- und Rezidivtherapie
- Prävention und Behandlung von Knochenmetastasen
- Therapie des androgenunabhängigen oder kastrationsresistenten Prostatakarzinoms

Recherchen zu Themen, die erstmalig in der Leitlinie bearbeitet wurden:

- Elastographie und Histoscanning zu Primärdiagnostik und Staging
- PET/CT zu Primärdiagnostik und Staging
- Kombination der LDR-Brachytherapie mit perkutaner Strahlentherapie bzw. mit adjuvanter hormonablativer Therapie
- Nutzen der Protonentherapie

5.1.2.2. **Berücksichtigung evidenzbasierter Leitlinien**

Auf eine erneute systematische Leitlinienrecherche wurde nach Rücksprache mit den Mitgliedern der Steuergruppe verzichtet, da keine wesentlichen neuen evidenzbasierten Leitlinien zu erwarten waren. Es wurde beschlossen, die aktuellen Versionen der bisherigen Quell-Leitlinien zu nutzen. Ergänzend zu den Literaturrecherchen wurden dementsprechend die Empfehlungen der Leitlinien der European Association of Urology (EAU) von 2011 [7; 8], des National Institute of Clinical Excellence (NICE) von 2008 [6] und der 2009 revidierten Leitlinie der American Urological Association (AUA) [1] extrahiert und berücksichtigt. Eine erneute methodische Bewertung der Leitlinien wurde nicht vorgenommen. Die EAU-Leitlinie wurde nicht aufgrund ihrer Methodik, sondern aufgrund ihrer internationalen Bedeutung berücksichtigt.

5.1.2.3. **Systematische Recherche nach aggregierter Evidenz und Einzelstudien**

Zu allen Fragestellungen erfolgte eine spezifische systematische Literaturrecherche in den Datenbanken Medline (Pubmed) und den Datenbanken der Cochrane Library. Für erstmals bearbeitete Fragestellungen erfolgte die Recherche ab dem Jahr 2000. Für alle aktualisierten Fragestellungen wurde ab dem Datum der letzten Recherche der 1. Auflage gesucht. Es wurden außerdem Studien berücksichtigt, die in Referenzlisten bekannter Studien oder durch Hinweise aus der Leitliniengruppe identifiziert wurden.

5.1.2.4. **Auswahl und Bewertung der Evidenz**

Die Auswahl der Studien zu den einzelnen Fragestellungen erfolgte durch Methodikerinnen und Methodiker (Monika Nothacker, Thomas Langer) des ÄZQ nach vorab definierten Ein- und Ausschlusskriterien. Die eingeschlossenen Studien wurden in Evidenztabelle extrahiert und nach dem Evidenzklassen-System des Scottish Intercollegiate Guidelines Network (SIGN) (siehe Tabelle 2) bewertet.

Eine formale methodische Bewertung der berücksichtigten Leitlinien wurde nicht durchgeführt, da eine Adaptation bereits bestehender Leitlinienempfehlungen nicht vorgesehen war.

Die spezifischen Fragestellungen, Ein- und Ausschlusskriterien sowie die Recherchestrategien und Trefferangaben und die ein- und ausgeschlossenen Publikationen können dem Kapitel 12.2 entnommen werden. Die Evidenztabelle mit den extrahierten Angaben der berücksichtigten Studien sind in einem gesonderten Dokument veröffentlicht worden (z. B. unter www.leitlinienprogramm-onkologie.de oder www.awmf-online.de).

5.1.3. Erstellung der zweiten modularen Aktualisierung 2014

5.1.3.1. Themen der Aktualisierung

Die zweite Aktualisierung der Leitlinie erfolgte modular. Angesichts des Aufwands einer Aktualisierung erschien eine 2-jährliche Aktualisierung an Stelle der ursprünglich jährlich geplanten Aktualisierung als eine praktikable Vorgehensweise. Überarbeitet wurden die Themen, die von der Steuergruppe priorisiert wurden. Die Steuergruppe nahm eine Priorisierung von 10 Einzelrecherchen vor. Es erfolgten 8 Aktualisierungsrecherchen und 2 Recherchen zu neuen Themen, die im Folgenden genannt sind. Ein Thema (intermittierende Hormontherapie) konnte aus Kapazitätsgründen nicht bearbeitet werden.

Aktualisierungsrecherchen:

- Früherkennung hinsichtlich risikoadaptierter Zeitabstände, Altersbeginn der Früherkennung
- Stellenwert des PET/CT bzw. PET/MRT beim PSA-Rezidiv nach radikaler Prostatektomie bzw. Strahlentherapie
- Stellenwert der DNA-Zytometrie
- Stellenwert immunhistochemischer Zusatzuntersuchungen
- Behandlung des Low-Risk-Karzinom
- Systemtherapie des kastrationsresistenten Prostatakarzinoms
- Behandlung ossärer Metastasen

Recherchen zu Themen, die erstmalig in der Leitlinie bearbeitet wurden:

- Stellenwert von Komorbiditätsklassifikationen als Unterstützung bei der Therapieentscheidung beim frühen Prostatakarzinom
- Geriatrisches Assessment vor Chemotherapie

5.1.3.2. Berücksichtigung evidenzbasierter Leitlinien

Auf eine erneute systematische Leitlinienrecherche wurde verzichtet, da keine wesentlichen neuen evidenzbasierten Leitlinien zu erwarten waren. Es wurde stattdessen systematisch nach (fokussierten oder modularen) Updates der bisher verwendeten Quell-Leitlinien gesucht (Stand 19.06.2013):

- Guideline for the Management of Clinically Localized Prostate Cancer: 2009 Hrsg: American Urological Association (AUA) –Reviewed and validity confirmed 2011[1]

Die Leitlinie ist unverändert gültig, es wurden zwei ausgegliederte Module, die Inhalte der Schlüsselfragen behandeln, identifiziert:

- Carter HB, Albertsen PC, Barry MJ, Etzioni R, Freedland SJ, Greene KL, Holmberg L, Kantoff P, Konety BR, Murad MH, Penson DF, Zietman AL. Early Detection of Prostate Cancer: AUA Guideline. *Journal of Urology* 2013; [1]
- Cookson MS, Roth BJ, Dahm P, Engstrom C, Freedland SJ, Hussain M, Lin DW, Lowrance WT, Murad MH, Oh WK, Penson DF, Kibel AS. Castration-Resistant Prostate Cancer: AUA Guideline. *Journal of Urology* 2013; [9]

- Clinical practice guidelines: evidence based information and recommendations for the management of localized prostate cancer (2002) Hrsg: Australian National Networking Party on Management of localized prostate cancer [2]

Die Leitlinie wurde im Jahr 2013 außer Kraft gesetzt, es wurden keine (fokussierte oder modulare) Updates identifiziert.

- Guidelines on Prostate Cancer (2013) Hrsg: European Urological Association (EAU) [10]

Die Leitlinie wurde mehrfach (jährlich) fokussiert aktualisiert unter anderem auch zu Schlüsselfragen der 2. Aktualisierung.

- Prostate Cancer. Nationwide-Guideline (2007) Hrsg: Dutch Urological Association (DUA) [5]

Die Leitlinie ist unverändert gültig und wird momentan überarbeitet.

- Prostate Cancer. Diagnosis and Treatment (2008) Hrsg: National Institute for Health and Care Excellence (NICE).[6]

Die Leitlinie ist weiterhin gültig und wird momentan überarbeitet. Sie wurde im Januar 2014 publiziert.

Die Schlüsselempfehlungen von aktualisierten Quelleitlinien wurden extrahiert und sind Bestandteil der Evidenztabelle zu dieser Leitlinie.

Zusätzlich wurden per Handsuche nach Referenzleitlinien zu spezifischen Schlüsselfragen gesucht.

5.1.3.3. Systematische Recherche nach aggregierter Evidenz und Einzelstudien

Zu allen Fragestellungen erfolgte eine spezifische systematische Literaturrecherche in den Datenbanken Medline (Pubmed) und den Datenbanken der Cochrane Library. Für erstmals bearbeitete Fragestellungen erfolgte die Recherche ab dem Jahr 2003. Für alle aktualisierten Fragestellungen wurde ab dem Datum der letzten Recherche gesucht. Es wurden außerdem Studien berücksichtigt, die in Referenzlisten bekannter Studien oder durch Hinweise aus der Leitliniengruppe identifiziert wurden.

5.1.3.4. Auswahl und Bewertung der Evidenz

Die Auswahl der Studien zu den einzelnen Fragestellungen erfolgte durch Methodikerinnen (Susanne Schorr, Carmen Khan, Corinna Schäfer) des ÄZQ nach vorab definierten Ein- und Ausschlusskriterien. Die eingeschlossenen Studien wurden in Evidenztabelle extrahiert und nach dem Evidenzklassen-System des Scottish Intercollegiate Guidelines Network (SIGN) bewertet. Dabei kam die im April 2013 von SIGN modifizierte Version zur Anwendung (siehe Tabelle 2).

Eine formale komplette methodische Bewertung der Quelleitlinien wurde nicht durchgeführt, da eine Adaptation bereits bestehender Leitlinienempfehlungen nicht vorgesehen war. Die Quelleitlinien wurden genauso wie weitere über die Literaturrecherche identifizierte Leitlinien jedoch bezüglich methodischer Exaktheit und Umgang mit Interessenkonflikten kritisch bewertet. Die EAU-Leitlinie wurde nicht aufgrund ihrer Methodik, sondern aufgrund ihrer internationalen Bedeutung berücksichtigt. Weitere per Handsuche identifizierte mögliche Referenzleitlinien wurden mit DELBI bewertet.

Die spezifischen Fragestellungen, Ein- und Ausschlusskriterien sowie die Recherche-strategien und Trefferangaben und die ein- und ausgeschlossenen Publikationen können dem Kapitel 12.4 entnommen werden. Die Evidenztabelle mit den extrahierten Angaben der berücksichtigten Studien und Leitlinien sind in einem gesonderten Dokument veröffentlicht worden (z. B. unter www.leitlinienprogramm-onkologie.de oder www.awmf-online.de).

5.2. Formulierung der Empfehlung und formale Konsensusfindung

In der Leitlinie sind die wesentlichsten Aussagen in gesonderten Kästen unter Angaben der zugrundeliegenden Evidenz, der jeweiligen Evidenzklasse, des Empfehlungsgrades und der Konsensstärke sowie des Erstellungs- bzw. Aktualisierungsdatums dargestellt. Die Kernaussagen sind entweder als handlungsleitende Empfehlungen oder Statements formuliert. Als Statements werden Darlegungen oder Erläuterungen von spezifischen Sachverhalten oder Fragestellungen ohne unmittelbare Handlungsaufforderung bezeichnet.

Die Verabschiedung von Empfehlungen und Statements sowie die Festlegung der Empfehlungsgrade erfolgten bei der Erstellung der Leitlinie und bei den Aktualisierungen vorwiegend im Rahmen von Konsensuskonferenzen unter Verwendung formaler Konsensusverfahren. Empfehlungen die nicht in den Konsensuskonferenzen abschließend abgestimmt werden konnten, wurden schriftlich durch die Leitlinienautoren konsentiert. Bei den Konsensuskonferenzen erfolgte jeweils eine Einführung zum Stand der Leitlinienbearbeitung durch einen Methodiker des ÄZQ und die Teilnehmer wurden in die Technik der strukturierten Konsensusfindung eingewiesen. Die Konsensuskonferenzen waren gegliedert in themenbezogene Gruppenarbeit und eine nachfolgende Plenumsitzung.

Tabelle 3: Konsensuskonferenzen und behandelte Themen

Konsensuskonferenz n	Datum	Themen
1. Konferenz (Erstellung)	31.10. 2005	<ul style="list-style-type: none"> • Initiierungstreffen der gesamten Leitliniengruppe und der AWMF, Besprechung der methodischen Vorgehensweise.
2. Konferenz (Erstellung)	20.09. 2007	<ul style="list-style-type: none"> • Stellenwert des Watchful Waiting/Active Surveillance beim lokal begrenzten PCa • Stellenwert der primären Hormontherapie beim lokal begrenzten PCa • Stellenwert anderer Verfahren (Kryotherapie, HIFU-Therapie, Hyperthermie) zur Primärtherapie des lokal begrenzten PCa
3. Konferenz (Erstellung)	2./3.04. 2008	<ul style="list-style-type: none"> • Stellenwert der radikalen Prostatektomie bei lokal begrenztem PCa • Stellenwert der Lymphadenektomie bei lokal begrenztem PCa • Stellenwert der adjuvanten/neoadjuvanten Therapie bei lokal begrenztem PCa

Konsensuskonferenzen	Datum	Themen
		<ul style="list-style-type: none"> • Stellenwert der perkutanen Strahlentherapie bei lokal begrenztem PCa • Stellenwert der LDR-Brachytherapie bei lokal begrenztem PCa • Therapie der Harnstauung bei kastrationsresistentem PCa • Testosteronsubstitution im Zusammenhang mit dem PCa
4. Konferenz (Erstellung)	28.08. 2008	<ul style="list-style-type: none"> • Früherkennung und Biopsie • Diagnostik und Stadieneinteilung • Therapieplanung des nichtmetastasierten PCa • Watchful Waiting und primäre Hormontherapie • Radikale Prostatektomie beim lokal fortgeschrittenen PCa • Stellenwert der HDR-Brachytherapie beim lokal begrenzten und lokal fortgeschrittenen PCa
5. Konferenz (Erstellung)	23.01. 2009	<ul style="list-style-type: none"> • Perkutane Strahlentherapie beim lokal fortgeschrittenen PCa • Lymphadenektomie beim lokal fortgeschrittenen PCa • (neo-) adjuvante Hormontherapie beim lokal fortgeschrittenen PCa • Andere lokale Verfahren (Kryo, HIFU, Hyperth.) beim lokal fortgeschrittenen PCa • Hormontherapie beim metastasierten PCa • Therapie des kastrationsresistenten PCa • Rehabilitation nach kurativer Therapie • Lebensqualität und psychosoziale Aspekte
6. Konferenz (Erstellung)	4./5.06. 2009	<ul style="list-style-type: none"> • Pathomorphologische Diagnostik • adjuvante Strahlentherapie des nichtmetastasierten PCa • Behandlung des lymphknotenpositiven PCa • Supportiv- und Palliativtherapie • Nachsorge/Verlaufskontrolle: Wann und wie? • Definition und Diagnostik des Tumorrezidivs/Bildgebung im Verlauf des metastasierten PCa • Behandlung des PSA-Rezidivs nach RPE und des PSA-Progresses nach Strahlentherapie • Therapie von Knochenmetastasen
7. Konferenz (1. Konferenz der 1. Aktualisierung)	30./31. 05. 2011	<ul style="list-style-type: none"> • Früherkennung • Diagnostik • Active Surveillance • Radikale Prostatektomie (bei Patienten mit hohem Risiko oder lokal fortgeschrittenem Prostatakarzinom) • Perkutane Strahlentherapie (bei Patienten mit hohem

Konsensuskonferenzen	Datum	Themen
		<ul style="list-style-type: none"> Risiko oder lokal fortgeschrittenem Prostatakarzinom) <ul style="list-style-type: none"> HIFU
8. Konferenz (2. Konferenz der 1. Aktualisierung)	28.06. 2011	<ul style="list-style-type: none"> Diagnostik und Staging Active Surveillance Perkutane Strahlentherapie und hormonablativ Therapie LDR-Brachytherapie Behandlung des kastrationsresistenten Prostatakarzinoms Knochenmetastasen Früherkennung
9. Konferenz (1. Konferenz der 2. Aktualisierung)	08.09. 2013	<ul style="list-style-type: none"> Früherkennung PET/CT, MRT beim PSA-Rezidiv DNA-Zytometrie Immunhistochemische Zusatzuntersuchungen Komorbiditätsklassifikationen beim frühen Prostatakarzinom Behandlung des Low-Risk-Karzinoms Geriatrisches Assessment vor Chemotherapie Systemtherapie des kastrationsresistenten Prostatakarzinoms Behandlung ossäre Metastasen

5.2.1. Themenbezogene Gruppenarbeit

Arbeitsgruppen mit je etwa 15- bis 20 Mitgliedern arbeiteten zunächst parallel themenbezogen. In den Gruppen wurden die von den Kapitel-Autoren in Kleingruppen erarbeiteten Empfehlungen und Statements nach den Regeln des nominalen Gruppenprozesses (siehe unten) diskutiert, gegebenenfalls modifiziert und (vor-) abgestimmt. Die (vor-)abgestimmten Empfehlungen dienten als Vorlage für die Plenumsabstimmung.

Die Sitzungen der Arbeitsgruppen bei der Erstellung wurden von Frau Prof. Dr. I. Kopp (AWMF), Frau Dr. M. Nothacker (ÄZQ), Herrn Prof. Dr. G. Ollenschläger (ÄZQ) und Frau Dr. S. Weinbrenner (ÄZQ) moderiert. Bei der 1. Aktualisierung moderierten Dr. M. Nothacker und Dr. S. Weinbrenner (beide ÄZQ) und Dr. M. Follmann (DKG) die Sitzungen der Arbeitsgruppen. Bei der 2. Aktualisierung moderierte M. Nothacker (AWMF) die Arbeitsgruppe 1 (DNA-Zytometrie, immunhistochemische Zusatzuntersuchungen, Behandlung des Low-Risk-Karzinoms, geriatrisches Assessment vor Chemotherapie), I.Kopp die Arbeitsgruppe 2 (Früherkennung, Komorbiditätsklassifikationen beim frühen Prostatakarzinom) und C. Khan (ÄZQ) die Arbeitsgruppe 3 (PET/CT, MRT beim PSA-Rezidiv, Systemtherapie des kastrationsresistenten Prostatakarzinoms, Behandlung ossärer Metastasen).

In den Arbeitsgruppen wurde der folgende Ablauf des nominalen Gruppenprozesses befolgt (gemäß Leitlinienmanual von AWMF und ÄZQ [11; 12]):

- stille Generierung von Änderungsvorschlägen;
- Registrierung der Ideen im Einzel- Umlaufverfahren;
- Reihendiskussion;
- Vorabstimmung;
- Debattieren und Diskutieren;
- endgültige (Vor-)Abstimmung.

Wurde im Rahmen der Abstimmung in den Arbeitsgruppen kein Konsens erreicht, konnte in der Plenumsrunde auch ein fortbestehender Dissens dargestellt werden.

Definition des Konsens: Gemäß dem Regelwerk der AWMF wird die Konsensusstärke wie folgt definiert:

Starker Konsens	> 95 % der Teilnehmer
Konsens	> 75-95 % der Teilnehmer
Mehrheitliche Zustimmung	> 50-75 % der Teilnehmer
Kein Konsens	< 50 % der Teilnehmer

5.2.2. Plenumsitzung mit endgültiger Verabschiedung der Empfehlungen

Im zweiten Teil wurden die zuvor in den Arbeitsgruppen abgestimmten Empfehlungsvorschläge dem gesamten Expertengremium vorgestellt. Die definitive Abstimmung erfolgte im Plenum in Form einer strukturierten Konsensuskonferenz in Anlehnung an die vom amerikanischen National Institut of Health entwickelte Methode [13]:

- Vorstellung der Empfehlungsvorschläge vor dem Plenum;
- Gelegenheit zu Rückfragen, zur Klärung der Evidenzgrundlage durch das Plenum;
- Vorabstimmung über die Empfehlungen und ihre Graduierung;
- bei fehlendem Konsens Diskussion;
- endgültige Abstimmung.

Für das Abstimmungsverfahren wurde ein TED-System eingesetzt, um die Voten der einzelnen Teilnehmer zu schützen (Anonymisierung).

5.2.2.1. Abstimmung im Delphi-Verfahren im Nachgang der 2. Konsensuskonferenz der 2. Aktualisierung 2014 (methodisch betreut durch die AWMF)

Es wurde vom Vorsitzenden der Steuergruppe (Prof. Wirth) festgelegt, dass die nicht in der Konsensuskonferenz konsentierten Empfehlungen der Kapitel 5.1 Therapieplanung und Aufklärung und 5.2 Active Surveillance in einem dreistufigen Verfahren nochmals bearbeitet werden sollen. Für die Entscheidung waren drei Ursachen maßgeblich:

- 1.) In der Konsensuskonferenz hatten zum Zeitpunkt der Abstimmung bereits viele Experten die Konferenz verlassen müssen. Mangels Repräsentativität konnten daher die Empfehlungen nicht konsentiert werden.
- 2.) Die Diskussionen innerhalb der Kleingruppenarbeit der AG 1 am Vormittag der Konsensuskonferenz wurden aufgrund von Zeitdruck als nicht ausreichend von der Moderatorin der AWMF erachtet.
- 3.) Auch im Vorfeld der Konsensuskonferenz war trotz intensiver Bemühungen kein ausreichender Austausch in der ursprünglich festgelegten Kleingruppe organisierbar.

Das dreistufige Verfahren sah vor, dass diese Empfehlungen zunächst in einer Kleingruppe, dann in der AG 1 der Konsensuskonferenz und anschließend im Delphi-Konsensusverfahren von der Gesamtgruppe abgestimmt werden sollten. Als Stufe 1 wurden die Empfehlungen unter der methodischen Leitung von Frau Nothacker in einer Kleingruppe erneut bearbeitet und in einer Telefonkonferenz am 20.09.2013 diskutiert. Teilnehmer der Kleingruppe waren die Experten Börgermann, Göckel-Beining, Hakenberg, Kristiansen, Schostak, Stöckle, Wirth, Wörmann. Als Stufe 2 wurden die Empfehlungen an die AG 1 der Konsensuskonferenz zur Vorabstimmung im Delphi-Verfahren gesendet. Stufe 3 stellte die Abstimmung der Empfehlungen in der Gesamtgruppe zur finalen Konsentierung dar. An der Abstimmung haben sich 53 Experten (84 %) beteiligt. Alle Empfehlungen wurden mit über 75 % Zustimmung in der ersten Runde final konsentiert.

5.2.3. Empfehlungen und deren Graduierung

Empfehlungen sind thematisch bezogene handlungsleitende Kernsätze der Leitlinie. Die OL-Methodik sieht eine Vergabe von Empfehlungsgraden durch die Leitlinien-Autoren im Rahmen eines formalen Konsensusverfahrens vor. Dementsprechend wurde ein durch die AWMF moderierter, mehrteiliger Nominaler Gruppenprozess durchgeführt. Die Empfehlungsgrade drücken den Grad der Sicherheit aus, dass der erwartbare Nutzen der Intervention den möglichen Schaden aufwiegt (Netto-Nutzen) und die erwartbaren positiven Effekte ein für die Patienten relevantes Ausmaß erreichen. Im Fall von Negativempfehlungen (soll nicht) wird entsprechend die Sicherheit über einen fehlenden Nutzen bzw. möglichen Schaden ausgedrückt.

Bei der Graduierung der Empfehlungen werden neben den Ergebnissen der zugrunde liegenden Studien, die klinische Relevanz der in den Studien untersuchten Effektivitätsmaße, die beobachteten Effektstärken, die Konsistenz der Studienergebnisse; die Anwendbarkeit der Studienergebnisse auf die Patientenzielgruppe, die Umsetzbarkeit im ärztlichen Alltag oder ethische Verpflichtungen sowie Patientenpräferenzen berücksichtigt.

Empfehlungsgrad	Beschreibung	Ausdrucksweise
A	Starke Empfehlung	soll
B	Empfehlung	sollte
0	Empfehlung offen	kann

5.2.4. Statements

Als Statements werden Darlegungen oder Erläuterungen von spezifischen Sachverhalten oder Fragestellungen ohne unmittelbare Handlungsaufforderung bezeichnet. Sie werden entsprechend der Vorgehensweise bei den Empfehlungen im Rahmen eines formalen Konsensusverfahrens verabschiedet und können entweder auf Studienergebnissen oder auf Expertenmeinungen beruhen.

5.2.5. Expertenkonsens (EK)

Als Expertenkonsens (EK) werden Empfehlungen bezeichnet, zu denen keine Recherche nach Literatur durchgeführt wurde. In der Regel adressieren diese Empfehlungen Vorgehensweisen der guten klinischen Praxis, zu denen keine wissenschaftlichen Studien notwendig sind bzw. erwartet werden können. Der Begriff ‚Expertenkonsens‘ ersetzt

den in den bisherigen Versionen der Leitlinie genutzten Begriff ‚Good Clinical Practice‘ (GCP).

6. Qualitätsindikatoren

6.1. 1. Aktualisierung 2011

Die Ableitung der Qualitätsindikatoren aus starken Empfehlungen (Empfehlungsgrad A) und ggf. handlungsrelevanten Statements mit hochwertiger Evidenz (LoE 1) erfolgte bis März 2012. Im Dezember 2011 wurde eine Liste mit 93 potentiell messbaren Indikatorenvorschlägen erstellt. Von den insgesamt 128 starken Empfehlungen und Statements mit LoE 1 waren zuvor 35 durch die beteiligten Methodiker primär als nicht messbar eingeschätzt worden oder es waren Empfehlungen zu pathomorphologischen Untersuchungen. Letztere wurden zurückgestellt.

Die 93 potentiell messbaren Indikatorenvorschläge wurden zu einer Vorabstimmung in die Arbeitsgruppen gegeben. Die Arbeitsgruppenmitglieder gaben ihre Einschätzung zu den von ihnen bearbeiteten Themen hinsichtlich der Bedeutung der Empfehlungen/Statements für das Versorgungssystem ab (Kriterium: „Bedeutung für die Versorgungsqualität“ der NVL-Methodik für die Erstellung von Leitlinien, siehe Langfassung). 54 potentiellen Qualitätsindikatoren wurde von den Arbeitsgruppenmitgliedern eine hohe Bedeutung beigemessen. Diese sind in der Langfassung tabellarisch zusammengefasst. Eine weitere Bewertung dieser Vorschläge steht aus und wird bei der nächsten Aktualisierung angestrebt. Als Ziel sollen etwa 10 Indikatoren entwickelt werden.

6.2. 2. Aktualisierung 2014 (methodisch betreut durch das OL-Office)

Im Rahmen des Leitlinienprogramms Onkologie werden Qualitätsindikatoren in einem standardisierten Prozeß aus den Empfehlungen bzw. spezifischen Zielen einer Leitlinie abgeleitet. Die detaillierte Beschreibung der Methodik findet sich auf der Homepage des Onkologischen Leitlinienprogramms (<http://leitlinienprogramm-onkologie.de/Informationen-zur-Methodik.53.0.html>).

Die Generierung der Vorschläge für Qualitätsindikatoren wurde in folgenden Schritten durchgeführt:

1. Bestandsaufnahme:
 - a. Zusammenstellung der in Deutschland bestehenden Dokumentationsgrundlagen (Basisdatensatz der klinischen Krebsregister (Quelle: <http://www.tumorzentren.de/onkol-basisdatensatz.html>))
 - b. Recherche national und international bereits bestehender Qualitätsindikatoren mit folgender Suchstrategie, siehe Anhang 12.5.
2. Vorbereitung Anwesenheitstreffen (Erstellung einer Primärliste potentieller QI): Soweit möglich, wurden im Vorfeld des Anwesenheitstreffens (siehe 3.) aus den starken Empfehlungen der Leitlinie potentielle Indikatoren mit Definition von Zähler und Nenner abgeleitet. Die Liste wurde den Mitgliedern der AG im Vorfeld des Anwesenheitstreffens zugesandt.
3. Anwesenheitstreffen (Diskussion und primäre Sichtung): Das Treffen der AG QI, die aus Mitgliedern der Leitliniengruppe, Vertretern der klinischen Krebsregister, des Zertifizierungssystems und des OL bestand, fand am 19.03.2014 statt. In dem Treffen wurden den Teilnehmern der Prozeßablauf der QI-Erstellung sowie das Bewertungsinstrument des OL erläutert. Die unter 2. generierte Zusammenstellung

aus den Empfehlungen der Leitlinie wurde diskutiert und entschieden, ob aus der jeweiligen Empfehlung ein potentieller QI generiert werden könne. Das gleiche Vorgehen wurde für die bestehenden nationalen/internationalen QI angewandt. Folgende Ausschlußkriterien kamen bei diesem ersten Screening zur Anwendung:

Gründe für einen Ausschluß der Empfehlung aus der Liste der potentiellen QI:

- a. Empfehlung ist nicht operationalisierbar (Meßbarkeit nicht gegeben)
 - b. Fehlender Hinweis auf Verbesserungspotential
 - c. Sonstiges (mit Freitexteingabe in Liste der Empfehlungen)
4. Bewertung: Das vorselektierte Set der 19 potentiellen QI wurde mit dem Bewertungsinstrument des Leitlinienprogramms Onkologie mittels eines standardisierten Bogens durch das interdisziplinäre Gremium der Leitliniengruppe bewertet (in Anlehnung an: [14]). Als angenommen galten Indikatoren mit mind. 75% Zustimmung zu den Kriterien 1- 4 (d.h. 1.-3. Kriterium: „Trifft eher zu“ und „Trifft zu“ und 4. Kriterium: „Nein, kein Risiko für Fehlsteuerung“). Die Auswertung dieser Abstimmungen erfolgte durch einen Methodiker, der nicht am QI Entwicklungsprozess teilgenommen hatte.

Tabelle 4: Kriterien für potentielle Qualitätsindikatoren

	1 Trifft nicht zu	2 Trifft eher nicht zu	3 Trifft eher zu	4 Trifft zu
1. Kriterium: Bedeutung des Indikators für das Versorgungssystem: hat die durch den Indikator gemessene Maßnahme aufgrund einer hohen Fallzahl, einer großen Versorgungsvariabilität, einer bekannten Unter- oder Überversorgung eine wichtige Bedeutung? Kann dadurch z.B. die Morbidität oder auch Letalität bzw. die Lebensqualität verbessert werden? Trägt der Einsatz des Indikators wesentlich zur Abbildung von guter Qualität bei?				
2. Kriterium: Klarheit der Definition: Ist der mögliche Indikator klar und eindeutig bezüglich Nenner und Zähler definiert bzw. können benötigte Definitionen eindeutig aus der Leitlinie entnommen werden? Nur bei klarer Definition ist eine Messbarkeit gegeben.				
3. Kriterium: Beeinflussbarkeit der Indikatorausprägung: kann der bewertete Aspekt vom Leistungserbringer beeinflusst werden?				
	Ja		Nein	

	1 Trifft nicht zu	2 Trifft eher nicht zu	3 Trifft eher zu	4 Trifft zu
4. Kriterium: Risiken zur Fehlsteuerung: Hier wurde bewertet, ob durch den Indikator ein Risiko zur Fehlsteuerung gesetzt wird, das nicht ausgeglichen werden kann durch einen Gegenindikator oder andere Informationen.				

Darüber hinaus haben die Experten die potentiellen Indikatoren nach folgenden Kriterien bewertet:

- a. Risikoadjustierung (gilt der Indikator für alle Patienten oder nur für eine Gruppe?)
 - b. Implementationsbarrieren (gibt es schwerwiegende Hindernisse bspw. struktureller oder finanzieller Natur für eine Umsetzung?)
 - c. Datenverfügbarkeit (werden die geforderten Daten derzeit noch nicht erhoben, sehen Sie Schwierigkeiten bei der Datenerfassung?)
5. Finale Telefonkonferenz: Nach der schriftlichen Bewertung erfolgte eine moderierte Telefonkonferenz (30.07.2014) in der die Ergebnisse der Bewertung diskutiert und das finale Set der QI (= 11 QI) konsentiert wurden. Das Set der konsentierten Vorschläge für Qualitätsindikatoren findet sich in der Lang- und Kurzversion der Leitlinie. Die Primärliste der potentiellen Qualitätsindikatoren, die o.g. Basisdatensätze und die Ergebnisse der schriftlichen Bewertung sind auf Anfrage im Leitliniensekretariat erhältlich.

Stimmberechtigte Beteiligte der AG Qualitätsindikatoren:

- DGU: PD Dr. med. Christof Börgermann, Prof. Dr. med. Oliver Hakenberg, Prof. Dr. med. h. c. Manfred Wirth,
- DRG: Prof. Dr. med. Ulrich Mueller-Lisse
- DGHO: Prof. Dr. Bernhard Wörmann,
- DEGRO: Prof. Dr. med. Frederik Wenz
- DGP /BDP: Prof. Dr. med. Glen Kristiansen
- BPS (Patientenvertreter): Dipl. Ing. Paul Enders Dipl. Ing. Jens-Peter Zacharias,
- Arbeitsgemeinschaft Deutscher Tumorzentren (ADT): Frau Kindt (Dr. Bernd Hoschke)
- Zertifizierungskommission/DKG: Dr. med. Simone Wesselmann

Moderation:

- DKG/OL-Office: Dr. med. Markus Follmann, MPH, MSc, Dipl. -Soz. Wiss Thomas Langer
- AWMF: Dr. med. Monika Nothacker, MPH

7. Externe Begutachtung und Verabschiedung

7.1. Erstellung der Leitlinie 2006-2009

Die S3-Leitlinie zum Prostatakarzinom konnte vom 7.7.09 bis 2.8.09 öffentlich kommentiert werden. Es gingen in dieser Zeit insgesamt Kommentare von 23 Personen oder Organisationen ein. Von diesen Kommentaren bezogen sich 19 auf Inhalte der Leitlinie und vier auf formale Aspekte. Auf Wunsch können die Kommentare im ÄZQ eingesehen werden.

Redaktionelle Änderungen wurden in Absprache mit den verantwortlichen Kapitelautoren und der Steuergruppe vorgenommen. Für fünf Empfehlungen erfolgte eine schriftliche Neuabstimmung.

Die Kommentare (ggf. mehrere Aspekte pro Kommentator) und die daraus resultierten Änderungen der Leitlinie sind in Kapitel 12.1 aufgeführt.

7.2. 1. Aktualisierung 2011

Die aktualisierte Fassung der Leitlinie konnte vom 12.09. bis 12.10.2011 öffentlich kommentiert werden. Es gingen in dieser Zeit insgesamt Kommentare von 29 Personen oder Organisationen ein. Von diesen Kommentaren bezogen sich 22 auf Inhalte der Leitlinie und 7 auf formale Aspekte. Von den inhaltlichen Kommentaren bezogen sich 9 Kommentare ausschließlich auf Änderungen an Hintergrundtexten. Auf Wunsch können die vollständigen Kommentare im ÄZQ eingesehen werden.

In Absprache mit den verantwortlichen Kapitelautoren und der Steuergruppe wurden redaktionelle Änderungen vorgenommen oder Empfehlungen zur Neuabstimmung vorgeschlagen.

Die Kommentare (ggf. mehrere Aspekte pro Kommentator) und die daraus resultierten Änderungen der Leitlinie sind im Anhang aufgeführt.

7.3. 2. Aktualisierung 2014

Die aktualisierte Fassung der Leitlinie konnte vom 17.04. bis 29.05.2014 öffentlich kommentiert werden. Es gingen in dieser Zeit insgesamt 76 Kommentare von 24 Personen oder Organisationen ein. In Absprache mit den verantwortlichen Kapitelautoren und der Steuergruppe wurden Änderungen vorgenommen. Die Kommentare und die daraus resultierten Änderungen der Leitlinie bzw. Antworten sind im Anhang 12.8 aufgeführt.

8. Redaktionelle Unabhängigkeit

Die Leitlinienerstellung erfolgte in redaktioneller Unabhängigkeit von den finanzierenden Trägern.

An alle Teilnehmer an der Leitlinienerstellung 2009 wurden Formulare zur Erklärung von Interessenkonflikten verschickt. Die Bewertung inwiefern durch die jeweiligen Interessenkonflikte die erforderliche Neutralität für die Tätigkeit als Experte in Frage gestellt ist, sollte im Rahmen einer Selbsterklärung der Experten erfolgen. Ein Ausschluss von Experten wurde bei Erstellung der 1. Auflage der Leitlinie nicht vorgenommen.

Für die Aktualisierung der Leitlinie 2011 haben ebenfalls alle Beteiligten das aktuelle Formblatt der AWMF zur Erklärung von Interessenkonflikte ausgefüllt. Die darin offengelegten Beziehungen und Sachverhalte sind in Kapitel 12.10.1 dargestellt. Das Thema Interessenkonflikte wurde während des Aktualisierungsprozesses mehrfach in der Leitliniengruppe besprochen. Ein Ausschluss von Experten wurde nicht vorgenommen. Die Gefahr von unangemessener Beeinflussung durch Interessenkonflikte wurde dadurch reduziert, dass die Recherche, Auswahl und Bewertung der Literatur durch Methodikerinnen und Methodiker (des ÄZQ) ohne bedeutende Beziehungen zur Industrie oder Interessengruppen erfolgte. Die formale Konsensbildung und die interdisziplinäre Erstellung, sowie die Möglichkeit der öffentlichen Begutachtung bildeten weitere Elemente, die das Risiko von Verzerrungen (auch aufgrund von Interessenkonflikten einzelner Personen) reduzieren können.

Für die Aktualisierung der Leitlinie 2014 haben erneut alle Beteiligten das aktuelle Formblatt der AWMF zur Erklärung von Interessenkonflikte ausgefüllt. Die darin offengelegten Beziehungen und Sachverhalte sind in Kapitel 12.10.2 dargestellt. Das Thema Interessenkonflikte wurde während des Aktualisierungsprozesses mehrfach in der Leitliniengruppe besprochen. Experten wurde angehalten, sich bei den Abstimmungen zu enthalten, bei denen sie einen Interessenkonflikt haben. Enthaltungen wurden im Protokoll der Konsensuskonferenz dokumentiert. Die Gefahr von unangemessener Beeinflussung durch Interessenkonflikte wurde dadurch reduziert, dass die Recherche, Auswahl und Bewertung der Literatur durch Methodikerinnen und Methodiker (des ÄZQ) ohne bedeutende Beziehungen zur Industrie oder Interessengruppen erfolgte. Die formale Konsensbildung und die interdisziplinäre Erstellung, sowie die Möglichkeit der öffentlichen Begutachtung bildeten weitere Elemente, die das Risiko von Verzerrungen (auch aufgrund von Interessenkonflikten einzelner Personen) reduzieren können.

9. Verbreitung und Implementierung

Die abgestimmten Empfehlungen der aktualisierten Leitlinie wurde auf dem Jahreskongress der Deutschen Gesellschaft für Urologie im September 2013 vorgestellt. Weiterhin sind folgende Aktivitäten zur Verbreitung und Implementierung geplant:

1. Erstellung einer Kurzfassung
2. Aktualisierung der Patientenleitlinien
3. Publikation der Leitliniendokumente auf den Internetseiten der DGU sowie der weiteren beteiligten Fachgesellschaften und Organisationen
4. Publikation der aktualisierten Leitlinieninhalte in Fachzeitschriften
5. Bundesweite Fortbildungsveranstaltungen
6. Im Rahmen der 2. Aktualisierung sind Vorschläge für Qualitätsindikatoren aus den Empfehlungen erstellt worden. Verantwortliche in der Qualitätssicherung (z.B. Träger der sektorübergreifenden Qualitätssicherung) sind dazu aufgerufen, diese Vorschläge zu anwendbaren Qualitätsindikatoren weiter zu entwickeln. Hierdurch kann die Implementierung der in dieser Leitlinie empfohlenen Maßnahmen unterstützt werden.

10. Gültigkeitsdauer der Leitlinie

Die Leitlinie ist bis zur nächsten Aktualisierung gültig, höchstens jedoch bis September 2016. Vorgesehen sind weitere regelmäßige modulare Aktualisierungen in einem etwa 2-3 jährlichen Abstand.

Kommentare und Änderungsvorschläge zur Leitlinie bitte an folgende Adresse:

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12. Anhänge

12.1. Schlüsselfragen und Autoren 2009/2011/2014

Schlüsselfragen	Autoren	Jahr / Aktualisierung
Lokal begrenztes Prostatakarzinom		
Behandlung des Low-Risk-Karzinom	Fröhner, Börgermann	2. Aktualisierung 2014
Stellenwert von Komorbiditätsklassifikationen als Unterstützung bei der Therapieentscheidung beim frühen Prostatakarzinom	Fröhner, Wirth, Wedding	2. Aktualisierung 2014
Stellenwert des Watchful Waiting und der Active Surveillance.	Weißbach, Graefen, Burchardt, Grimm, Fiebrandt, Fornara, Heidenreich, Rübben, Wagner, Wernert, Wiegel	Ersterstellung 2009 und/oder 1. Aktualisierung 2011
Stellenwert der radikalen Prostatektomie: Für welche Patienten ist die radikale Prostatektomie am geeigneten?	Wirth, Grimm, Enders, Fröhner, Thomas, Thüroff, Steuber, Heidenreich, Vögeli	Ersterstellung 2009 und/oder 1. Aktualisierung 2011
Stellenwert der perkutanen Strahlentherapie: Für welche Patienten die Radiotherapie?	Böhmer, Hölscher, Machtens, Wenz, Wiegel, Höcht, Sedlmayer, Martin, Moser, Hinkelbein, Zacharias.	Ersterstellung 2009 und/oder 1. Aktualisierung 2011
Stellenwert der Brachytherapie/Seedbehandlung: Für welche Patienten die LDR-Brachytherapie?	Borchers, Machtens, Jakse, Alberti, Henkel, Schmitz-Dräger, Zacharias	Ersterstellung 2009 und/oder 1. Aktualisierung 2011
Stellenwert der Brachytherapie/Seedbehandlung: Für welche Patienten die HDR-Brachytherapie?	Böhmer, Alberti, Deger, Galalae, Goldner, Martin, Wiegel	Ersterstellung 2009 und/oder 1. Aktualisierung 2011
Stellenwert der hormonablativen Therapie: Für welche Patienten die primäre hormonablativen Therapie?	Ebert, Lümnen	Ersterstellung 2009 und/oder 1. Aktualisierung 2011

Schlüsselfragen	Autoren	Jahr / Aktualisierung
Stellenwert der Lymphadenektomie: Wann ist die Lymphadenektomie sinnvoll?	Thüroff, Thomas, Burchard, Heidenreich, Küfer, Wiegel	Ersterstellung 2009 und/oder 1. Aktualisierung 2011
Stellenwert der adjuvanten und neoadjuvanten Therapie.	Miller, Borchers, Fichtner, Rübben, Schostak, Wiegel	Ersterstellung 2009 und/oder 1. Aktualisierung 2011
Stellenwert anderer interventioneller Verfahren.	Jocham, Jakse, Tedsen, Doehn, Schmitz-Dräger, Blana, Schostak, Enders	Ersterstellung 2009 und/oder 1. Aktualisierung 2011
Lokal fortgeschrittenes Prostatakarzinom		
Ist Watchful Waiting in Kategorie T3 oder T4 vertretbar?	Weißbach, Heidenreich	Ersterstellung 2009 und/oder 1. Aktualisierung 2011
Welchen Patienten in der klinischen Kategorie T3 soll eine operative Therapie angeboten werden? Gibt es Indikationen, bei denen die T4-Kategorie operiert werden kann?	Wirth, Grimm, Fröhner, Thomas, Thüroff, Steuber, Heidenreich, Vögeli, Enders	Ersterstellung 2009 und/oder 1. Aktualisierung 2011
Sollen Patienten in der Kategorie cT3 eine andere RT erhalten als Patienten in der Kategorie cT1/2? Kann die RT oder BT in der Kategorie cT4 kurativ sein? Soll der klinisch-präoperativ definierte cN-Status die Therapie-Entscheidung beeinflussen?	Böhmer, Hölscher, Machtens, Wenz, Wiegel, Höcht, Sedlmayer, Martin, Moser, Hinkelbein, Zacharias.	Ersterstellung 2009 und/oder 1. Aktualisierung 2011
Kann die HDR in der Kategorie cT4 kurativ sein?	Böhmer, Alberti, Deger, Galalae, Goldner, Martin, Wiegel	Ersterstellung 2009 und/oder 1. Aktualisierung 2011
Gibt es eine Indikationsstellung für die primäre hormonablativ Therapie beim nicht-metastasierten PCa?	Ebert, Lümnen	Ersterstellung 2009 und/oder 1. Aktualisierung 2011

Schlüsselfragen	Autoren	Jahr / Aktualisierung
Sollen Patienten in der klinischen Kategorie T3 und T4, die eine lokale kurativ intendierte Therapie (RPE, RT, BT) erhalten, lymphadenektomiert werden?	Thüroff, Thomas, Burchard, Heidenreich, Küfer, Wiegel	Erstellung 2009 und/oder 1. Aktualisierung 2011
Sollen alle Patienten in der klinischen Kategorie T3 und T4, die eine lokale kurativ intendierte Therapie (RPE, RT, BT) erhalten, adjuvant oder/und neoadjuvant therapiert werden?	Miller, Borchers, Fichtner, Rübber, Schostak, Wiegel	Erstellung 2009 und/oder 1. Aktualisierung 2011
Mit welcher Zielsetzung können HIFU, Kryo- bzw. Hyperthermie für die Kategorie T3/4 eingesetzt werden?	Jakse, Jocham, Doehn, Tedsen, Schmitz-Dräger, Blana, Schostak, Fiebrandt	Erstellung 2009 und/oder 1. Aktualisierung 2011
Lymphknotenpositives PCa: Welche Therapie?	Wolff, Hinkelbein, Höcht, Thomas, Thüroff,	Erstellung 2009 und/oder 1. Aktualisierung 2011
Rezidiertes oder metastasiertes Prostatakarzinom		
Geriatrisches Assessment bei Patienten vor Chemotherapie	Wedding, Weißbach	2. Aktualisierung 2014
Systemtherapie (inkl. Kombinationstherapie) des kastrationsresistenten Prostatakarzinom	Wörmann, Zastrow, Palmedo, Miller, Wirth	2. Aktualisierung 2014
Behandlung ossärer Metastasen	Wörmann, Zastrow, Palmedo, Miller, Heidenreich, Wirth	2. Aktualisierung 2014
Behandlung des metastasierten PCa: Therapie der symptomatischen/asymptomatischen Knochenmetastasen.	Rohde, Albrecht, Palmedo, Wörmann, Lümmen, Luboldt, Lein, Wolff	Erstellung 2009 und/oder 1. Aktualisierung 2011
Behandlung des metastasierten PCa: Supportivtherapie: Maßnahmen bei belastenden Symptomen (Tumor-/Therapiebedingt).	Wörmann, Albrecht, Enders, Schmitz-Dräger	Erstellung 2009 und/oder 1. Aktualisierung 2011

Schlüsselfragen	Autoren	Jahr / Aktualisierung
Behandlung des metastasierten PCa: Therapie der Harnstauung bei kastrationsresistentem PCa.	Weißbach, Heidenreich	Ersterstellung 2009 und/oder 1. Aktualisierung 2011
Behandlung des metastasierten PCa: Bildgebung im Verlauf des metastasierten PCa (ging ein in Diagnostik des Rezidivs/Staging).	Luboldt, Beyersdorff, Palmedo	Ersterstellung 2009 und/oder 1. Aktualisierung 2011
Besonderheiten von Rezidivtumoren: Therapie des PSA-Rezidivs nach RPE (lokal/systemisch).	Wiegel, Alberti, Börgermann, Hakenberg, Heidenreich, Sedlmayer	Ersterstellung 2009 und/oder 1. Aktualisierung 2011
Besonderheiten von Rezidivtumoren: Therapie des PSA-Rezidivs nach Bestrahlung.	Hakenberg, Heidenreich, Alberti, Börgermann, Sedlmayer	Ersterstellung 2009 und/oder 1. Aktualisierung 2011
Therapie des kastrationsresistenten PCa: Welche Medikamente bei kastrationsresistentem PCa?	Wirth, Fröhner, Grimm, Miller, Pummer, Schulz, Wörmann, Wolff, Hakenberg, Heidenreich, Rohde	Ersterstellung 2009 und/oder 1. Aktualisierung 2011
Wann ist die maximale Androgendeprivation der einfachen Androgendeprivation (Orchiektomie, LHRH-Analoga) überlegen?	Rhode, Grimm, Lümmen, Wolff	Ersterstellung 2009 und/oder 1. Aktualisierung 2011
Stellenwert der intermittierenden Androgenblockade: Intermittierende Androgenblockade: Standardbehandlung?	Grimm, Wolff, Hammerer, Lümmen, Rohde	Ersterstellung 2009 und/oder 1. Aktualisierung 2011
Diagnostik/ Stadieneinteilung		
Stellenwert des PET/CT bzw. PET/MRT beim PSA-Rezidiv nach radikaler Prostatektomie bzw. Strahlentherapie	Kotzerke, Miller, Wiegel	2. Aktualisierung 2014
Stellenwert der DNA-Zytometrie	Kristiansen, Weißbach, Dietz, Böcking, Wernert	2. Aktualisierung 2014
Stellenwert immunhistochemischer Zu-	Kristiansen, Wernert, Weißbach	2. Aktualisierung 2014

Schlüsselfragen	Autoren	Jahr / Aktualisierung
satzuntersuchungen		
Diagnostik, Stadieneinteilung, Befundbewertung: Stadieneinteilung, Ausbreitungsdiagnostik.	Miller, Beyersdorff, Enders, Fornara, Göckel-Beining, Graefen, Krause, Müller-Lisse, Palmedo, Schrader	Ersterstellung 2009 und/oder 1. Aktualisierung 2011
Diagnostik, Stadieneinteilung, Befundbewertung: Pathomorphologische Untersuchungen.	Wernert, Jakse, Kahl, Ludoldt, Wetterauer	Ersterstellung 2009 und/oder 1. Aktualisierung 2011
Risikofaktoren/Prävention/Früherkennung		
Risikoadaptierte Zeitabstände, Altersbeginn der Früherkennung	Rübben, Börgermann, Egidi	2. Aktualisierung 2014
Risikofaktoren/Prävention inklusive Ernährung: Prävention für PCa.	Schmitz-Dräger, Fiebrandt, Lümmen	Ersterstellung 2009 und/oder 1. Aktualisierung 2011
Prävention inklusive Ernährung: Stellenwert der Ernährung bei manifestem PCa.	Schmitz-Dräger, Fiebrandt, Lümmen	Ersterstellung 2009 und/oder 1. Aktualisierung 2011
Stellenwert der Früherkennung/Screening: Ist PCa-Screening sinnvoll?	Rübben, Börgermann, Dubben, Fiebrandt, Fornara, Loertzer, Luboldt, Schulz, Semjonow, Stöckle, Vögeli, Weißbach,	Ersterstellung 2009 und/oder 1. Aktualisierung 2011
Stellenwert der Früherkennung/Screening: Wann ist ein PCa insignifikant?	Fornara, Rübben, Wagner, Wernert, Wiegel	Ersterstellung 2009 und/oder 1. Aktualisierung 2011
Testosteronsubstitution im Zusammenhang mit dem PCa.	Ackermann, Behre, Nieschlag, Volkmer, Wetterauer	Ersterstellung 2009 und/oder 1. Aktualisierung 2011
Stellenwert der Biopsie: Biopsie - wann und wie?	Rübben, Börgermann, Fornara, Hammerer, Loertzer, Luboldt, Schulz, Semjonow	Ersterstellung 2009 und/oder 1. Aktualisierung 2011
Reha/Nachsorge		
Stellenwert der Rehabilitation nach kurativer Therapie.	Jünemann, Ebermayer, Kaufmann, Otto, Weißbach	Ersterstellung 2009 und/oder 1. Aktualisierung 2011

Schlüsselfragen	Autoren	Jahr / Aktualisierung
Stellenwert von Verlaufskontrollen/Nachsorge-Parametern: Verlaufskontrolle: Wann und wie?	Graefen, Alberti	Erstellung 2009 und/oder 1. Aktualisierung 2011
Tumorrezidiv: Definition und Diagnostik.	Sedlmayer, Alberti, Börgermann, Hakenberg, Palmedo	Erstellung 2009 und/oder 1. Aktualisierung 2011
Stellenwert der Lebensqualität: Psychosoziale Aspekte und Lebensqualität beim PCa.	Jocham, Tedsen, Doehn, Koller, Rohde, Vertreter der Selbsthilfegruppen	Erstellung 2009 und/oder 1. Aktualisierung 2011

12.2. Methodik und Ergebnisse der Recherchen zur Erstellung der Leitlinie 2009

12.2.1. Recherche zum Thema Epidemiologie, Risikofaktoren, Prävention und Ernährung

12.2.1.1. Epidemiologie

Zum Thema Epidemiologie wurden keine systematischen Recherchen durchgeführt.

12.2.1.2. Risikofaktoren

Zum Thema Risikofaktoren wurden die folgenden Recherchen durchgeführt:

Recherchezeitraum: ab 1.1.2000

Suchstrategie 1 (Leitlinien und aggregierte Evidenz):

Suchworte „prostate“ und „cancer“; Datenbanken: Cochrane Collaboration, National Guidelines Clearinghouse (NGC, USA), Guidelines International Network (GIN), AWMF; Suchzeitpunkt: 03.11.2007

Suchstrategie 2 (Metaanalysen und Leitlinien in PubMed):

Suchworte “prostate” und “cancer”, Limits: ab 2000, English, German, Meta-Analysis, Practice Guideline, Clinical Conference, Consensus Development Conference, Guideline; Datenbanken: PubMed; Suchzeitpunkt: 03.11.2007

Suchstrategie 3 (systematische Reviews in PubMed):

Suchworte: ((systematic and review) OR metaanalysis OR meta-analysis) AND ((prevention) OR ("prevention and control"[Subheading]) OR ("Primary Prevention"[Mesh]) AND ((prostate and cancer) OR ("Prostatic Neoplasms"[Mesh])); Datenbanken: PubMed; Suchzeitpunkt: 07.11.2007; Trefferzahl: n=2389, davon durchgesehene Review: Treffer: n= 793 +Pubmed-Filter für Metaanalysen angewendet: Treffer: 20; Ausschlusskriterien: Unsystematische Reviews, Experimentelle Publikationen ohne klinischen Bezug, Veröffentlichung vor 2000, Literatur zu Vitamin E oder Selen

Eingeschlossene Volltexte: n=20

Suchstrategie 4 (Alter als Risikofaktor):

Suchworte: ((meta-analysis) OR (systematic and review) AND (prognos* OR survival OR failure OR outcome)) AND ("Prostatic Neoplasms"[Mesh]) AND (("Age Factors"[Mesh]) OR ("Life Expectancy"[Mesh])), Trefferzahl: 8, Eingeschlossene Volltexte: n=0

12.2.1.3. Testosteronsubstitution

Recherchezeitraum: 1.1.1996 - 26.4.2007

Suchstrategie: ("testosterone"[MeSH Terms] OR testosterone [Text Word]) AND (("replantation"[TIAB] NOT Medline[SB]) OR "replantation"[MeSH Terms] OR replacement[Text Word]) AND (("prostatic neoplasms"[TIAB] NOT Medline[SB]) OR "prostatic neoplasms"[MeSH Terms] OR prostate cancer[Text Word])

Trefferzahl: 121

Eingeschlossene Volltexte: 3 aggregierte Evidenzquellen, 12 Primärstudien, 19 Publikationen als Kontextliteratur

12.2.1.4. Prävention

Recherchezeitraum: 1.1.2000 bis 07.11.2007 bzw. für Suchstrategie 6 bis 04.12.2007

Such-Strategien zu Ernährung und Prävention – aggregierte Evidenz:

Suchstrategie 1 (Leitlinien und aggregierte Evidenz): Suchworte „prostate“ und „cancer“; Datenbanken: Cochrane Collaboration, National Guidelines Clearinghouse (NGC, USA), Guidelines International Network (GIN), AWMF

Suchstrategie 2 (Metaanalysen und Leitlinien in PubMed): Suchworte “prostate” und “cancer”, Limits: ab 2000, English, German, Meta-Analysis, Practice Guideline, Clinical Conference, Consensus Development Conference, Guideline

Suchstrategie 3 (systematische Reviews in PubMed): Suchworte: ((systematic and review) OR metaanalysis OR meta-analysis) AND ((prevention) OR ("prevention and control"[Subheading]) OR ("Primary Prevention"[Mesh]) OR (finasteride) OR ("Finasteride"[Mesh])) AND ((prostate and cancer) OR ("Prostatic Neoplasms"[Mesh]))

Trefferzahl: n=66, Recherchezeitraum 1.1.2000 bis 4.12.2007

Suchstrategie 4 (ergänzende Primärpublikationen in PubMed): Suchworte: (prevention and prostate and cancer AND (("2000/01/01"[PDat] : "2007/12/03"[PDat]))) AND (("Finasteride"[Mesh]) OR (finasteride OR dutasteride OR alpha-reductase OR (alpha and reductase)) OR ("Testosterone 5-alpha-Reductase"[Mesh]))

Trefferzahl: 197,

Suchstrategie 5: Suchworte: (("Selenium"[Mesh]) OR (Selenium)) AND (prevention OR chemoprevention) AND (prostate and cancer) AND (("2000/01/01"[PDat] : "2007/12/04"[PDat]) AND (Humans[Mesh]) AND (English[lang] OR German[lang])).

Trefferzahl: 179

Suchstrategie 6: (prostate and cancer) AND ((vitamin and e) OR (vitamin e) OR (tocopherol) OR ("Vitamin E"[Mesh])) AND (prevention OR chemoprevention) Limits: Publication Date from 2000/01/01 to 2007/12/04

Trefferzahl: 173

Ergebnis: 23 aggregierte Evidenzquellen, 24 Primärstudien, 7 Publikationen als Kontextliteratur

Eingeschlossene Volltexte: 3 aggregierte Evidenzquellen, 24 Primärstudien

12.2.2. Recherche zum Thema Früherkennung und Biopsie

Recherchezeitraum: 1.1.2000- 22.10.2007

Suchstrategie aggregierte Evidenz: prostate and cancer and screening and ((systematic and review) or metaanalysis or meta-analysis)

Treffer: 203

Recherchezeitraum: 1.1.2000- 2.5.2008

Suchstrategie Primärpublikationen: ("Mass Screening"[MeSH Major Topic] AND ("2000/01/01"[PDat] : "2008/05/02"[PDat])) AND ("Prostatic Neoplasms"[MeSH Major Topic] AND ("2000/01/01"[PDat] : "2008/05/02"[PDat])) AND (prostate specific antigen AND ("2000/01/01"[PDat] : "2008/05/02"[PDat])) AND ("2002/01/01"[PDat] : "2008/05/02"[PDat]))

Trefferzahl: 398

Eingeschlossene Volltexte: 3 aggregierte Evidenzquellen, 30 Primärstudien

In 2009 ergänzt: Andriole et al, Schröder et al.

12.2.3. Recherche zum Thema Diagnostik und Stadieneinteilung

12.2.3.1. Klinischen und apparativen Diagnostik

(Verfahren alphabetisch geordnet):

Computertomographie

Recherchezeitraum 1.1.2000-22.11.2007

Suchstrategie 3 (systematische Reviews):

Suchworte: (CT OR (compute* AND and tomogra*)) AND ("Prostatic Neoplasms"[Mesh]) AND ((systematic and review) OR meta-analysis OR metaanalysis)

Datenbanken: PubMed

Trefferzahl: 15

Suchstrategie 4 (ergänzende Primärpublikationen in PubMed) ab 2000:

Suchworte: (((diagnosis OR diagnoses OR diagnostic OR diagnostical) OR (accurate OR accuracy OR accurately)) OR ("Sensitivity and Specificity"[Mesh])) AND ("Prostatic Neoplasms"[MeSH Major Topic]) AND ("Tomography, X-Ray Computed"[MeSH Major Topic]) AND (English[lang] OR German[lang])) Limits: Publication Date from 1990/01/01 to

2000/01/01, Humans, English, German
 (((diagnosis OR diagnoses OR diagnostic OR diagnostical) OR (accurate OR accuracy OR accurately)) OR ("Sensitivity and Specificity"[Mesh])) AND ("Prostatic Neoplasms"[MeSH Major Topic]) AND ("Tomography, X-Ray Computed"[MeSH Major Topic]) AND ("2000/01/01"[PDat] : "2007/11/19"[PDat]) AND (English[lang] OR German[lang]))
 Datenbanken: PubMed

Trefferzahl: 138

Recherchezeitraum 1.1.1990-22.11.2007:

Suchstrategie 5 (ergänzende Primärpublikationen in PubMed) von 1990- 2000:
 (((diagnosis OR diagnoses OR diagnostic OR diagnostical) OR (accurate OR accuracy OR accurately)) OR ("Sensitivity and Specificity"[Mesh])) AND ("Prostatic Neoplasms"[MeSH Major Topic]) AND ("Tomography, X-Ray Computed"[MeSH Major Topic]) AND (English[lang] OR German[lang])) Limits: Publication Date from 1990/01/01 to 2000/01/01, Humans, English, German

Trefferzahl: 67

DRU:

Recherchezeitraum 1.1.2000-23.11.2007

Suchstrategie 6 (aggregierte Evidenz): (DRE OR digital rectal examination) AND ("Prostatic Neoplasms"[Mesh]) AND ((systematic and review) OR meta-analysis OR metaanalysis)

Trefferzahl: 27

Suchstrategie 7 (ergänzende Primärpublikationen in PubMed):

Suchworte: (DRE OR clinical examination) AND prostate AND (prostatectomy or RPE) AND (stage or staging)

Datenbanken: PubMed

Trefferzahl: 238

MRT:

Recherchezeitraum: 1.1.2000 – 19.11.2007

Suchstrategie 8 (systematische Reviews in PubMed):

Suchworte: ("Magnetic Resonance Imaging"[Mesh]) AND (("Prostatic Neoplasms"[Mesh] AND (Humans[Mesh])) AND ((systematic and review) OR meta-analysis OR metaanalysis AND (Humans[Mesh])) AND (Humans[Mesh]))

Datenbanken: PubMed

Trefferzahl: 6

Suchstrategie 9 (ergänzende Primärpublikationen):

Suchworte: (((diagnosis OR diagnoses OR diagnostic OR diagnostical) OR (accurate OR accuracy OR accurately)) OR ("Sensitivity and Specificity"[Mesh])) AND ("Prostatic Neoplasms"[MeSH Major Topic]) AND ("Magnetic Resonance Imaging"[MeSH Major Topic]) AND ("2000/01/01"[PDat] : "2007/11/19"[PDat]) AND (Humans[Mesh]) AND (English[lang] OR German[lang]))

Datenbanken: PubMed

Trefferzahl: 317

Szintigraphie:

Recherchezeitraum: 1.1.2000 – 6.11.2007 bzw. 19.11.2007

Suchstrategie 10 (systematische Reviews):

Suchworte: ("Radionuclide Imaging"[Mesh] AND (("2000/01/01"[PDat] : "2007/11/06"[PDat] AND (Humans[Mesh]))) and ("Prostatic Neoplasms"[Mesh] AND (("2000/01/01"[PDat] : "2007/11/06"[PDat] AND (Humans[Mesh]))) AND ((systematic and review) OR meta-analysis OR metaanalysis AND ("2000/01/01"[PDat] : "2007/11/06"[PDat] AND (Humans[Mesh]))) AND ("2000/01/01"[PDat] : "2007/11/06"[PDat] AND (Humans[Mesh]))

Datenbanken: PubMed

Trefferzahl: 2

Suchstrategie 11 (ergänzende Primärpublikationen):

Suchworte: (prostate and cancer) AND (((diagnosis OR diagnoses OR diagnostic OR diagnostical) OR (accurate OR accuracy OR accurately)) OR ("Sensitivity and Specificity"[Mesh]) AND ((bone and scan) OR scintigraphy OR (radionuclide and imaging)) AND (("2002/07/01"[PDat] : "2007/11/19"[PDat] AND (Humans[Mesh]) AND (English[lang] OR German[lang])))

Datenbanken: PubMed

Trefferzahl: 476

TRUS

Recherchezeitraum: 1.1.2000-6.11.2007 bzw. 20.11.2007

Suchstrategie 12 (systematische Reviews):

Suchworte: ("Ultrasonography"[Mesh] AND (("2000/01/01"[PDat] : "2007/11/06"[PDat] AND (Humans[Mesh]))) AND ("Prostatic Neoplasms"[Mesh] AND (("2000/01/01"[PDat] : "2007/11/06"[PDat] AND (Humans[Mesh]))) AND ("2000/01/01"[PDat] : "2007/11/06"[PDat] AND (Humans[Mesh]))) AND ((systematic and review) OR metaanalysis OR meta-analysis AND ("2000/01/01"[PDat] : "2007/11/06"[PDat] AND (Humans[Mesh]))) AND ("2000/01/01"[PDat] : "2007/11/06"[PDat] AND (Humans[Mesh]))

Datenbanken: PubMed

Trefferzahl: 16

Suchstrategie 13 (ergänzende Primärpublikationen):

Suchworte: ("Ultrasonography"[MeSH Major Topic]) AND ("Prostatic Neoplasms"[MeSH Major Topic]) AND (diagnosis OR diagnoses OR diagnostic OR diagnostical OR accurate OR accuracy OR accurately OR sensitivity OR specificity) AND (("2000/01/01"[PDat] : "2007/11/20"[PDat] AND (Humans[Mesh]) AND (English[lang] OR German[lang])))

Trefferzahl: 167

Suchstrategie 14 (ergänzende Primärpublikationen 1990-2000):

Suchworte: ("Ultrasonography"[MeSH Major Topic]) AND ("Prostatic Neoplasms"[MeSH Major Topic]) AND (diagnosis OR diagnoses OR diagnostic OR diagnostical OR accurate OR accuracy OR accurately OR sensitivity OR specificity) AND (("2000/01/01"[PDat] : "2007/11/20"[PDat] AND (Humans[Mesh]) AND (English[lang] OR German[lang])))

("Ultrasonography"[MeSH Major Topic]) AND ("Prostatic Neoplasms"[MeSH Major Topic]) AND (diagnosis OR diagnoses OR diagnostic OR diagnostical OR accurate OR accuracy OR accurately OR sensitivity OR specificity) AND (Humans[Mesh]) AND (English[lang] OR German[lang]) Limits: Publication Date from 1990/01/01 to 1999/12/31
Datenbanken: PubMed

Trefferzahl: 81

Volltexte gesamt: 9 aggregierte Evidenzquellen, 51 Primärstudien

Eingeschlossene Volltextet: 1 aggregierte Evidenzquelle, 7 Primärstudien

12.2.3.2. **Pathomorphologische Diagnostik**

Dieses Kapitel orientiert sich an den Empfehlungen des College of American Pathologists [15], der WHO/UICC [16], des Royal College of Pathologists (RCPATH, UK) [17] sowie des Berufsverbandes Deutscher Pathologen und der Deutschen Gesellschaft für Pathologie [18]. Dabei geht es in den Anforderungen an einigen Stellen über die genannten Konsensuspapiere hinaus. Dem Kapitel liegt weiterhin vom Autor eingebrachte Literatur zugrunde. Da hier keine systematische Recherche von Publikationen erfolgte, wurden keine Evidenztabelle erstellt.

12.2.4. **Recherche zum Thema Therapie des nichtmetastasierten Prostatakarzinoms**

12.2.4.1. **Therapieplanung und Aufklärung**

Das Kapitel beruht auf den Quell-Leitlinien [3; 5; 6] und einer tabellarischen Zusammenstellung der Therapieeffekte aus den zu den Therapieverfahren vorhandenen Studien oder aggregierten Evidenzquellen, die aus den spezifischen Recherchen zu den jeweiligen Therapieverfahren identifiziert wurden.

12.2.4.2. **Active Surveillance**

Recherchezeitraum: 1.1.2000 - 01.08.2006

Aktualisierungsrecherche: 19.03.2009 (Trefferzahlen nicht dargestellt, aus Aktualisierungsrecherche erfolgte kein Einschluss neuer Volltexte)

Such-Strategie zum Stellenwert des Watchful-Waiting beim Prostatakarzinom:

("Modul zur Identifikation von Publikationen zum Thema Prostatakarzinom")

AND

("watchful-waiting"[tiab] OR "wait-and-see"[tiab] OR "expectant management"[tiab] OR "conservative management"[tiab] OR "deferred treatment"[tiab])

Trefferzahl: 162

Such-Strategie zum Stellenwert der active-surveillance-Strategie:

("Modul zur Identifikation von Publikationen zum Thema Prostatakarzinom")

AND

(Nach Ergebnisprüfung entfernt: Filter für Studienqualität)

AND ("active-surveillance"[tiab] OR "expectant management"[tiab])

Trefferzahl: 102

Eingeschlossene Volltexte: 7 aggregierte Evidenzquellen, 14 Primärstudien (im Hintergrundtext: 7 Publikationen als Kontextliteratur, 4 Publikationen zur Lebensqualität)

Such-Strategie zum insignifikanten Prostatakarzinom (ab 1.1.2000- 23.5.2008): ((prostate OR prostatic) AND (*carcinoma OR tumor OR tumour OR cancer OR neoplas* OR malign*)) AND ("indolent" OR "clinically indolent" OR "clinically significant" OR "clinically insignificant")

Trefferzahl: 705

12.2.4.3. **Insignifikantes Prostatakarzinom**

Suchzeitraum: 1.1.1960 – 23.5.2008

Suchworte: ((prostate OR prostatic) AND (*carcinoma OR tumor OR tumour OR cancer OR neoplas* OR malign*)) AND ("indolent" OR "clinically indolent" OR "clinically significant" OR "clinically insignificant")

Trefferzahl: 705

Eingeschlossene Volltexte: 30 Einzelstudien, 1 syst. Review

12.2.5. **Recherche zum Thema Lokale Therapie des lokal begrenzten Prostatakarzinoms**

12.2.5.1. **Recherche Radikale Prostatektomie**

Recherchezeitraum: 1.1.2000 - 15.5.2007

Such-Strategie zum Stellenwert der radikalen Prostatektomie beim lokal betrenzten Prostatakarzinom:

"localized prostate cancer" OR "localised prostate cancer" OR "local prostate cancer" OR "localized prostatic carcinoma" OR "organ confined" OR "locally confined" OR "clinical localized disease" OR "localized tumor" OR "localized tumour" OR "localised tumour" OR "localised cancer*" OR "localized cancer*"

AND

(prostatectomy[ti] OR (postprostatectomy OR post-prostatectomy OR preprostatectomy OR pre-prostatectomy))

Trefferzahl: 714

Eingeschlossene Volltexte: 3 aggregierte Evidenzquellen, 3 Primärstudien

Weitere Primärliteratur zu Volumen vs. Morbidität bzw. Mortalität (Systematische Übersicht bei Nuttall et al., 2004) wurde durch die Autoren ergänzt.

12.2.5.2. **Perkutane Strahlentherapie**

Recherchezeitraum: 1.1.2000 - 23.1.2008

Such-Strategie zum Stellenwert der Strahlentherapie:

("Modul zur Identifikation von Publikationen zum Thema Prostatakarzinom")

AND

(radiotherapy[ti] OR radiotherapeutic[ti] OR radiation[ti] OR "Interstitial Radiation" OR

brachytherapy[ti] OR "Dose Fractionation"[ti] OR fractionation[ti] OR fractionated[ti] OR Irradiation[ti])

Trefferzahl: 656

Eingeschlossene Volltexte: 4 aggregierte Evidenzquellen, 36 Primärstudien

12.2.5.3. LDR-Brachytherapie

Recherchezeitraum : 1.1.2000 - 21.5.2007

Such-Strategie zum Stellenwert der LDR-Brachytherapie/Seedbehandlung:

In Suchstrategie zu Strahlentherapie enthalten

Eingeschlossene Volltexte: 17 Primärstudien, 10 Publikationen zur Lebensqualität, 1 Publikation als Kontextliteratur

12.2.5.4. HDR-Brachytherapie

Recherchezeitraum: 1.1.2000- 21.5.2007

Asugewertet wurde Suchstrategie zur Strahlentherapie und zusätzlich:

Such-Strategie zum Stellenwert der HDR-Brachytherapie:

("high-dose-rate"[All Fields] OR "HDR"[All Fields] OR "hdr"[All Fields]) AND "Brachytherapy"[Mesh] AND "Prostatic Neoplasms"[Mesh] AND ((English[lang] OR German[lang]) AND (Meta-Analysis[ptyp] OR Practice Guideline[ptyp] OR Randomized Controlled Trial[ptyp] OR Review[ptyp]))

Trefferzahl: 22

Eingeschlossene Volltexte: 18 Primärstudien, 21 Publikationen als Kontextliteratur

12.2.5.5. Lymphadenektomie

Recherchezeitraum: 1.1.2000 - 10.09.2007

Such-Strategie zum Stellenwert der Lymphadenektomie:

Suchworte: lymphadenectomy[ti] OR lymphadenectomies[ti] OR "lymph node dissection"[ti] OR "lymph node dissections"[ti] OR "lymph node excision"[ti] OR "lymph node excisions"[ti]) AND prostat*[ti]

Trefferzahl: 83

Eingeschlossene Volltexte: 17 Primärstudien, 3 Publikationen als Kontextliteratur

12.2.5.6. Andere interventionelle Verfahren

1. Cryotherapie:

Suchzeitraum und Suchbegriffe:

(cryotherapy OR cryosurgery OR cryoablat*) AND ((prostate OR prostatic) AND (*carcinoma OR tumor OR tumour OR cancer OR neoplas* OR malign*)) AND ("2006/12/01"[EDat] : "2008/09/11"[EDat]))

Hier wurde aufgrund des erst seit wenigen Jahren eingesetzten Verfahrens ab 2006 gesucht.

Trefferzahl: 102

Eingeschlossene Volltexte: 3 aggregierte Evidenzquellen

2. High-intensity focused ultrasound (HIFU):
Recherchen für 1. Auflage 2009:

((high-intensity[tiab] AND ultrasound[tiab]) OR "focused ultrasound"[tiab])
AND ("Modul zur Identifikation von Publikationen zum Thema Prostatakarzinom")

Eingeschlossene Volltexte: 4 aggregierte Evidenzquellen, 15 Primärstudien

3. Hyperthermia
(hyperthermia[tiab] OR hypertherm*[tiab] OR thermotherap*[tiab] OR thermotherap*[tiab])
AND
("Modul zur Identifikation von Publikationen zum Thema Prostatakarzinom")

+ 4. Magnetfeld-Therapien:
((magnet*[ti] OR magnetic[tiab])
AND
("Modul zur Identifikation von Publikationen zum Thema Prostatakarzinom")

Eingeschlossene Volltexte: 5 Primärstudien

12.2.6. Recherche zum Thema Lokale Therapie des lokal fortgeschrittenen Prostatakarzinoms

12.2.6.1. Radikale Prostatektomie

Recherchedatum: 01.04.2008

Suchstrategie: (prostate OR prostatic) AND (*carcinoma OR tumor OR tumour OR cancer OR neoplas* OR malign*) AND Prostatectomy AND (advanced OR T3 OR T4) AND (survival OR prognosis OR relapse) Limits: **Entrez Date from 2000/01/01 to 2008/05/16, Humans, English, German**

Eingeschlossene Volltexte: 20 Primärstudien

12.2.6.2. Perkutane Strahlentherapie

Recherchedatum: 31.08.2008

Suchstrategie: ((prostate OR prostatic) AND (*carcinoma OR tumor OR tumour OR cancer OR neoplas* OR malign*)) (advanced OR T3 OR T4) AND radiotherapy AND (survival OR prognosis OR relapse) Limits: **Publication Date from 2000/01/01 to 2008/08/31**

Trefferzahl: 578

Eingeschlossene Volltexte: 3 aggregierte Evidenzquellen, 41 Primärstudien

12.2.6.3. HDR-Brachytherapie

Recherchedatum: 23.07.2008

Suchstrategie: ((prostate OR prostatic) AND (*carcinoma OR tumor OR tumour OR cancer OR neoplas* OR malign*)) AND ((("Brachytherapy"[Mesh]) OR (brachytherapy)) AND ("high-dose-rate" OR "high dose rate" OR "HDR" OR "hdr"))

Trefferzahl: 280

Eingeschlossene Volltexte: 9 Primärstudien

12.2.6.4. Lymphadenektomie beim lokal fortgeschrittenen PCa

Recherchedatum: 03.09.2008

Suchstrategie: ("Lymph Node Excision"[Mesh]) AND ((prostate OR prostatic) AND (*carcinoma OR tumor OR tumour OR cancer OR neoplas* OR malign*)) AND (("2000/01/01"[EDat] : "2008/09/03"[EDat]) AND (English[lang] OR German[lang]))

Trefferzahl: 337

Eingeschlossene Volltexte: 18 Primärstudien

12.2.6.5. Andere interventionelle Verfahren

Recherchedatum: 14.10.2008

Suchstrategie: (("Ultrasound, High-Intensity Focused, Transrectal"[Mesh]) OR (HIFU[tiab] OR "high-intensity focused ultrasound" OR "high intensity focused ultrasound")) AND ((prostate OR prostatic) AND (*carcinoma OR tumor OR tumour OR cancer OR neoplas* OR malign*)) Limits: **Publication Date from 2005/03/01 to 2008/10/14**

12.2.6.5.1. Stellenwert der HIFU beim lokal fortgeschrittenen PCa

Siehe Angaben zur Recherche HIFU beim lokal begrenzten PCa

12.2.6.5.2. Stellenwert der Kryotherapie beim lokal fortgeschrittenen PCa

Recherchedatum: 09.09.2008

Suchstrategie: (cryotherapy OR cryosurgery OR cryoablat*) AND ((prostate OR prostatic) AND (*carcinoma OR tumor OR tumour OR cancer OR neoplas* OR malign*)) AND (("2006/12/01"[EDat] : "2008/09/11"[EDat])) AND [Modul Prostata local fortgeschritten]

Eingeschlossene Volltexte: 3 aggregierte Evidenzquellen, 6 Primärstudien

12.2.6.6. Adjuvante perkutane Strahlentherapie

Recherchedatum: 13.01.2009

Suchstrategie: ((prostate[tiab] OR prostatic[tiab]) AND (*carcinoma[tiab] OR tumor[tiab] OR tumour[tiab] OR cancer[tiab] OR neoplas*[tiab] OR malign*[tiab])) AND ((randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR placebo[tiab] OR clinical trials as topic[mesh:noexp] OR randomly[tiab] OR trial[ti]) AND humans[mh]) AND (((("Radiotherapy"[Mesh]) OR (radiation OR radiotherapy)) AND (adjuvant))

Trefferzahl: 203

Eingeschlossene Volltexte: 3 aggregierte Evidenzquellen, 9 Primärstudien

12.2.6.7. Therapie des lymphknotenpositiven Prostatakarzinoms

Recherchedatum: 06.02.2009

Suchstrategie: Search ((prostate[tiab] OR prostatic[tiab]) AND (*carcinoma[tiab] OR tumor[tiab] OR tumour[tiab] OR cancer[tiab] OR neoplas*[tiab] OR malign*[tiab])) AND ((randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR placebo[tiab] OR clinical trials as topic[mesh:noexp] OR randomly[tiab] OR trial[ti]) AND humans[mh]) AND ("nodal disease"[tiab] OR "nodal involvement"[tiab] OR "node positive"[tiab] OR "node-positive"[tiab] OR "N+"[tiab] OR "N1"[tiab] OR "N2"[tiab] OR "N3"[tiab] OR "lymph node spread"[tiab] OR "lymph node metastasis"[tiab] OR "node involvement"[tiab]) AND (treatment[tiab] OR therapy[tiab] OR intervention[tiab] AND (("2000/01/01"[PDat] : "2009/02/06"[PDat])))

Trefferzahl: 259

Eingeschlossene Volltexte: 1 aggregierte Evidenzquelle, 11 Primärstudien

12.2.6.8. Neoadjuvante und adjuvante Hormontherapie des lokal begrenzten und des lokal fortgeschrittenen Prostatakarzinoms

Recherchedatum: 03.09.2008

Such-Strategie zum Stellenwert der adjuvanten Therapie:

adjuvant[ti] OR adjuvant*[ti])
AND ((prostat*[ti] OR
("Modul zur Identifikation von Publikationen zum Thema Prostatakarzinom"))

Such-Strategie zum Stellenwert der neo-adjuvanten Therapie:

neo-adjuvant[ti] OR neoadjuvant*[ti]) AND
((prostat*[ti] OR ("Modul zur Identifikation von Publikationen zum Thema Prostatakarzinom"))

Ergebnis: 1 aggregierte Evidenzquelle, 3 Primärstudien, 19 Publikationen als Kontextliteratur

Such-Strategie zum Stellenwert der Hormontherapie:

("Modul zur Identifikation von Publikationen zum Thema Prostatakarzinom")
AND

((Therapeutics[mh] OR therapy[majr] OR "therapeutic use"[sh])
AND (therap*[tiab] OR treat*[tiab] OR manage*[tiab] OR strategy[tiab] OR procedure[tiab] OR administ*[tiab] OR respon*[tiab] OR medication[tiab] OR care[tiab] OR caring[tiab]))

AND

(Block zur Identifikation von Therapie-Studien guter Qualität) OR (Randomized Controlled Trial[pt] OR Randomized Controlled Trials[mh] OR Controlled Clinical Trial[pt] OR Clinical Trial, Phase I[pt] OR Clinical Trial, Phase II[pt] OR Clinical Trial, Phase III[pt] OR Clinical Trial, Phase IV[pt] OR Multicenter Studies[mh] OR Comparative Study[mh] OR Clinical Trial[pt] OR Clinical Trials[mh] OR Statistics[mh] OR Statistics, Nonparamet-

ric[mh] OR statistics and numerical data[sh] OR Follow-up Studies[mh] OR random allocation[mh]))

AND

((("Androgen Antagonists" OR "Anti Androgen" OR "Antiandrogenic Agent" OR "Antian-drogenic Drug" OR (Bicalutamide OR Cyoctol OR Cyproterone OR "Cyproterone Ace-tate" OR Epi-testosterone OR Flutamide OR Hydroxyflutamide "Inocoterone Acetate" OR "Lavanducyanin" OR Methylestrenolone OR Nilutamide OR "Osaterone Acetate" OR Ox-endolon OR Propylmesterolone OR Spironolactone OR Topterone "Trichloro Alpha Chloromethyl Alpha Hydroxypropionanilide" OR "Alpha,Alpha,Alpha Trifluoro 2 Methyl 4 Nitro Meta Lactotoluidide" OR "WS 9659 B" OR Zano-terone)) OR (Hormon*[ti] AND prostat*[ti]))

Eingeschlossene Volltexte: 4 aggregierte Evidenzquellen, 30 Primärstudien

A) Quellen aggregierter Evidenz und B) Primärliteratur

Siehe zu diesem Kapitel auch die Angaben in den Kapitel zur Strahlentherapie und radikalen Prostatektomie

12.2.6.9. Primäre Hormontherapie und Watchful Waiting

Recherchedatum: 19.7.2007, 23.7.2008

Suchsstrategie: (prostate OR prostatic) AND (*carcinoma OR tumor OR tumour OR cancer OR neoplas* OR malign*) AND advanced AND ((watchful AND waiting) OR (wait AND see) OR (expectant AND management) OR (conservative AND management) OR (deferred AND treatment))

Trefferzahl: 94

Eingeschlossene Volltexte: 6 aggregierte Evidenzquellen, 16 Primärstudien

12.2.7. Recherche zum Thema Diagnostik und Therapie des rezidierten oder metastasierten Prostatakarzinoms

Dieses Kapitel wurde auf der Basis der Quell-Leitlinien [3; 5; 6] sowie aufgrund von Li-teratur erstellt, die durch die Autorengruppe eingebracht wurde.

12.2.7.1. Therapie des PSA-Rezidivs / der PSA-Progression sowie der PSA-Persistenz

Recherchedatum: 07.02.2009

Suchstrategie: (("Salvage Therapy"[Mesh]) OR ("Recurrence"[Mesh]) OR (recurrence OR relapse) OR salvage) AND ((prostate[tiab] OR prostatic[tiab]) AND (*carcinoma[tiab] OR tumor[tiab] OR tumour[tiab] OR cancer[tiab] OR neoplas*[tiab] OR malign*[tiab])) AND ((randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR placebo[tiab] OR clinical trials as topic[mesh:noexp] OR randomly[tiab] OR trial[ti]) AND humans[mh]) Limits: Publication Date from 2000/01/01 to 2009/02/07

Trefferzahl: 360

Eingeschlossene Volltexte: 3 aggregierte Evidenzquellen, 12 Primärstudien

Literatur zur PSA-Persistenz wurde von den Autoren eingebracht

12.2.7.2. Hormontherapie des metastasierten Prostatakarzinoms

Recherchedatum: 21.10.2008

Suchstrategie: ((prostate[tiab] OR prostatic[tiab]) AND (*carcinoma[tiab] OR tumor[tiab] OR tumour[tiab] OR cancer[tiab] OR neoplas*[tiab] OR malign*[tiab])) AND ("Androgen Antagonists"[tiab] OR "Anti Androgen"[tiab] OR "Antiandrogenic Agent"[tiab] OR "Antiandrogenic Drug"[tiab] OR hormone[tiab] OR hormonal[tiab] OR endocrin*[tiab]) AND ((randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR placebo[tiab] OR clinical trials as topic[mesh:noexp] OR randomly[tiab] OR trial[ti]) AND humans[mh]) Limits: **Publication Date from 2000/01/01 to 2008/10/21, English, German**

Trefferzahl: 769

Eingeschlossene Volltexte: 4 aggregierte Evidenzquellen, 6 Primärstudien

12.2.7.3. Therapie des androgenunabhängigen oder kastrationsresistenten PCa

Recherchedatum: 22.10.2008

Suchstrategie: ((prostate[tiab] OR prostatic[tiab]) AND (*carcinoma[tiab] OR tumor[tiab] OR tumour[tiab] OR cancer[tiab] OR neoplas*[tiab] OR malign*[tiab])) AND ("hormone-refractory" OR "hormone refractory" OR chemotherapy[tiab] OR docetaxel[tiab] OR prednisolone[tiab] OR mitoxanthrone[tiab] OR dexamethasone OR ketoconazole OR hydrocortisone OR thalidomide OR doxorubicin OR paclitaxel OR carboplatin OR estramustine OR vinblastine) AND ((randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR placebo[tiab] OR clinical trials as topic[mesh:noexp] OR randomly[tiab] OR trial[ti]) AND humans[mh]) Limits: **Entrez Date from 2000/01/01 to 2008/10/22, English, German**

Trefferzahl:

Eingeschlossene Volltexte: 1 aggregierte Evidenzquelle, 7 Primärstudien

12.2.7.4. Therapie von Knochenmetastasen

Recherchedatum: 14.2.2009

Suchstrategie: ((prostate[tiab] OR prostatic[tiab]) AND (*carcinoma[tiab] OR tumor[tiab] OR tumour[tiab] OR cancer[tiab] OR neoplas*[tiab] OR malign*[tiab])) AND (bone AND (metastasis OR metastases)) AND ("Radioisotopes"[Mesh] OR radionuclide*[tiab] OR "Radiotherapy"[Mesh] OR radiation OR radiotherapy OR ("Diphosphonates"[Mesh])) AND ((randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR placebo[tiab] OR drug therapy[sh] OR randomly[tiab] OR trial[tiab] OR groups[tiab]) AND humans[mh]) Limits: **Publication Date from 2000/01/01 to 2009/02/14**

Trefferzahl: 385

Eingeschlossene Volltexte Strahlentherapie: 1 aggregierte Evidenzquelle, 5 Primärstudien

Eingeschlossene Volltexte Radionuklide: 2 aggregierte Evidenzquellen, 2 Primärstudien

Eingeschlossene Volltexte Bisphosphonate: 1 aggregierte Evidenzquelle, 5 Primärstudien

(2 Primärstudien, Saad 2002 und Saad 2004, nach Konsultation ergänzt)

12.2.7.5. Therapie der tumorbedingten Harnstauung

Recherchedatum: 22.7.2007

Such-Strategie zur Therapie der Harnstauungsnieren bei kastrationsresistentem Prostatakarzinom:

((("hydronephrosis"[MeSH Terms] OR Hydronephrosis[Text Word]) OR "Ureteral obstruction"[All Fields]) AND ("Pelvic Neoplasms"[Mesh] OR "Prostatic Neoplasms"[Mesh]) AND (("2002/07/02"[PDAT] : "2007/07/02"[PDAT]) AND "humans"[MeSH Terms] AND (English[lang] OR German[lang])))

((("pelvic neoplasms"[TIAB] NOT Medline[SB]) OR "pelvic neoplasms"[MeSH Terms] OR pelvic cancer[Text Word]) OR (((("prostatic neoplasms"[TIAB] NOT Medline[SB]) OR "prostatic neoplasms"[MeSH Terms] OR prostate cancer[Text Word]) AND ("locally advanced"[All Fields] OR "Metastatic"[All Fields]))) AND (("stents"[TIAB] NOT Medline[SB]) OR "stents"[MeSH Terms] OR Stent[Text Word]))

Eingeschlossene Volltexte: 14 Primärstudien

12.2.7.6. Supportiv- und Palliativtherapie

Für den Abschnitt Supportivtherapie wurden zusätzlich zu den Quell-Leitlinien weitere Leitlinien und Primärliteratur von den Autoren eingebracht.

Für den Abschnitt Palliativtherapie erfolgte im Februar 2009 eine systematische Suche nach themenbezogenen Leitlinien. Nach Sichtung und Bewertung der Ergebnisse wurden neben den Quell-Leitlinien [3; 5; 6] die evidenzbasierten Leitlinien ‚Hausärztliche Leitlinie Palliativversorgung‘ der Leitliniengruppe Hessen 2009 [19], die Therapieempfehlungen der deutschen Arzneimittelkommission zu Tumorschmerz [20], die ‚Clinical practice guideline‘ des ‚American College of Physicians‘ 2008 zu Palliativversorgung [21], die NCCN-Leitlinie 2008 zu Palliativmedizin [22] und die S3-Leitlinie zur Diagnostik, Therapie und Nachsorge des Mammakarzinoms 2008 [23] herangezogen.

12.2.8. Recherche zum Thema Rehabilitation und Nachsorge

12.2.8.1. Rehabilitation nach kurativer Therapie

Recherchedatum: 08.10.2008

Suchstrategie: (((prostate OR prostatic) AND (*carcinoma OR tumor OR tumour OR cancer OR neoplas* OR malign*)) AND (rehabilitation OR "recovery of function"[mh] OR "exercise"[mh] OR "education"[mh] OR "counseling"[mh])) OR (((prostate OR prostatic) AND (*carcinoma OR tumor OR tumour OR cancer OR neoplas* OR malign*)) AND (rehabilitation OR "recovery of function"[tiab] OR "exercise"[tiab] OR "education"[tiab] OR "counseling"[tiab])) AND ((randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR placebo[tiab] OR drug therapy[sh] OR randomly[tiab] OR trial[tiab] OR groups[tiab]) AND humans[mh])

Trefferzahl: 565

Eingeschlossene Volltexte: 1 aggregierte Evidenzquelle, 7 Primärstudien

12.2.8.2. Nachsorge und Verlaufskontrollen

Diese beiden Abschnitte wurden unter Bezugnahme der Quell-Leitlinien [3; 5; 6] und aufgrund von Literatur, die durch die Autoren beigetragen wurde, erstellt.

12.2.8.3. Testosteronsubstitution

Siehe Recherche zur Testosteronsubstitution in Abschnitt 12.2.1.3.

12.2.9. Recherche zum Thema Psychosoziale Aspekte und Lebensqualität

Recherchedatum: 15.11.2007

Die Studien zu psychosozialen Aspekten und Lebensqualität sind in ihrem Design nicht in das verwendete SIGN-Schema einzuordnen, deshalb wurden sie nicht in Evidenztabelle extrahiert.

12.3. Methodik und Ergebnisse der Recherchen zur 1. Aktualisierung 2011**12.3.1. Recherche zum Thema Stellenwert der Früherkennung / Screening****12.3.1.1. Fragestellung**

Population	Intervention	Kontrolle	Outcomes	Time aspects
Menschen ohne bekanntes Prostatakarzinom	Screeningprogramm zur Früherkennung eines Prostatakarzinoms	Normalversorgung	Gesamt mortalität Prostatakrebspezifische Mortalität Morbidität (PSA-Kinetik, Histologie) Lebensqualität Nebenwirkungen/ Schäden	Keine Einschränkungen

12.3.1.2. Recherchestrategien

Ausschlusskriterien für erste Relevanzsichtung:

A1: andere Erkrankung

A2: anderes Thema (z. B. Therapie, animal testing, in vitro)

A3: anderer Publikationstyp (nicht RCT oder SR oder Metaanalyse oder HTA aus Europa)

PubMed (10. Februar 2011)

Nr.	Suchfrage	Anzahl
#8	#3 AND #6 Limits: English, German, Publication date from 2007/08	571
#7	#3 AND #6	1763
#6	#4 OR #5	2166383
#5	(randomized controlled trial [pt] OR controlled clinical trial [pt] randomized [tiab] OR placebo [tiab] OR drug therapy [sh] OR randomly [tiab] OR trial [tiab] OR groups [tiab]) AND humans [mh]	2062287
#4	systematic[sb]	149480
#3	#1 AND #2	6774
#2	"screening"[All Fields] OR "mass screening"[MeSH Terms] OR "early detection of cancer"[MeSH Terms] OR "early detection of cancer"[All Fields]	303453
#1	Prostate cancer (Details: "prostatic neoplasms"[MeSH Terms] OR ("prostatic"[All Fields] AND "neoplasms"[All Fields]) OR "prostatic neoplasms"[All Fields] OR ("prostate"[All Fields] AND "cancer"[All Fields]) OR "prostate cancer"[All Fields])	91664

Anzahl der Treffer: 571

Davon relevant: 298

Cochrane (03. Januar 2011)

Nr.	Suchfrage	Anzahl
#1	"prostate cancer in Title, Abstract or Keywords and screening in Title, Abstract or Keywords, from 2007 to 2011	139

- Cochrane Database of Systematic Reviews (4)
- Database of Abstracts of Reviews of Effects (2)
- Cochrane Central Register of Controlled Trials (122)
- Cochrane Methodology Register (3)
- Health Technology Assessment Database (1)
- NHS Economic Evaluation Database (7)

Anzahl der Treffer: 139

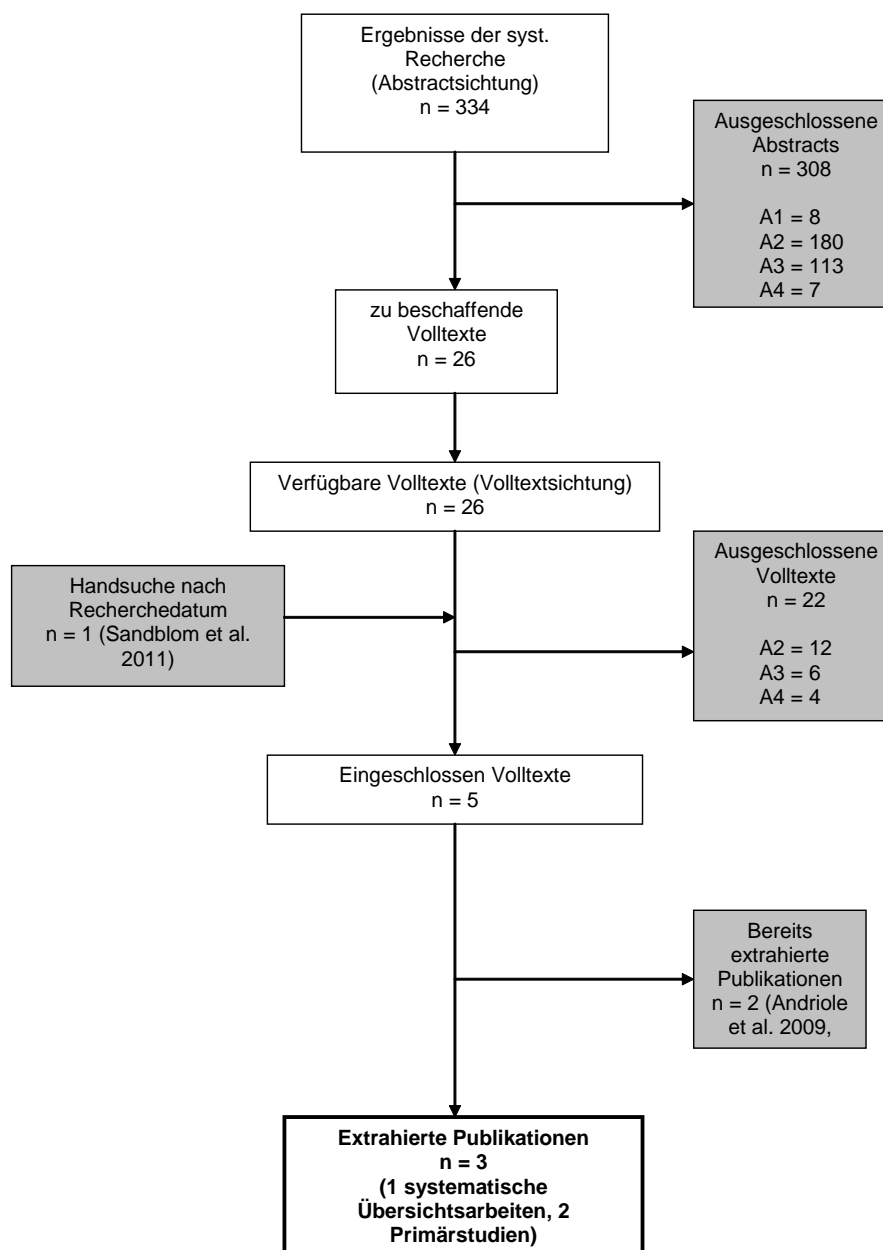
Davon neu: 45

Davon relevant: 36

12.3.1.3. Ein- und Ausschlusskriterien

Einschlussgründe	
E1 Zielgruppe	Patienten ohne bekanntes Prostatakarzinom
E2 Publikationstyp	Randomisierte kontrollierte Studien (RCTs) oder systematische Übersicht mit/ohne Metaanalyse oder HTA aus RCTs
E3: Suchzeitraum	Publikationen seit August 2008 (letzte Recherche S3 Leitlinien-Gruppe)
E4: Sprachen	deutsch, englisch
E5 Intervention	Screening (Untersuchung einer gesunden Population) auf Prostatakarzinom
Ausschlussgründe	
A1	andere Erkrankung
A2	Nicht Fragestellung (siehe oben)
A3	Anderer Publikationstyp (Editorial, Fallbericht, Brief etc.)
A4	Doppelpublikation oder aktuellere Publikation vorhanden

12.3.1.4. Ergebnisse der Recherche



12.3.1.4.1. Eingeschlossene Publikationen

1. Djulbegovic M, Beyth RJ, Neuberger MM, Stoffs TL, Vieweg J, Djulbegovic B, Dahm P. Screening for prostate cancer: systematic review and meta-analysis of randomised controlled trials. *BMJ* 2010;341:c4543.
2. Hugosson J, Carlsson S, Aus G, Bergdahl S, Khatami A, Lodding P, Pihl CG, Stranne J, Holmberg E, Lilja H. Mortality results from the Goteborg randomised population-based prostate-cancer screening trial. *Lancet Oncol* 2010;11(8):725-32.
3. Andriole GL, Crawford ED, Grubb RL, III, Buys SS, Chia D, Church TR, Fouad MN, Gelmann EP, Kvale PA, Reding DJ, Weissfeld JL, Yokochi LA, O'Brien B, Clapp JD, Rathmell JM, Riley TL, Hayes RB, Kramer BS, Izmirlian G, Miller AB, Pinsky PF, Prorok PC, Gohagan JK, Berg CD. Mortality results from a randomized prostate-cancer screening trial. *N Engl J Med* 2009;360(13):1310-9.
4. Schroder FH, Hugosson J, Roobol MJ, Tammela TL, Ciatto S, Nelen V, Kwiatkowski M, Lujan M, Lilja H, Zappa M, Denis LJ, Recker F, Berenguer A, Maattanen L,

Bangma CH, Aus G, Villers A, Rebillard X, van der KT, Blijenberg BG, Moss SM, de Koning HJ, Auvinen A. Screening and prostate-cancer mortality in a randomized European study. *N Engl J Med* 2009;360(13):1320-8.

12.3.1.4.2. Ausgeschlossene Publikationen (Volltextscreening)

Ausschlussgrund A2: Anderes Thema (nicht Fragestellung)

1. Kilpelainen TP, Tammela TL, Maattanen L, Kujala P, Stenman UH, Ia-Opas M, Murtola TJ, Auvinen A. False-positive screening results in the Finnish prostate cancer screening trial. *Br J Cancer* 2010;102(3):469-74.
2. Kilpelainen TP, Auvinen A, Maattanen L, Kujala P, Ruutu M, Stenman UH, Tammela TL. Results of the three rounds of the Finnish Prostate Cancer Screening Trial--the incidence of advanced cancer is decreased by screening. *Int J Cancer* 2010;127(7):1699-705.
3. van Leeuwen PJ, Connolly D, Gavin A, Roobol MJ, Black A, Bangma CH, Schroder FH. Prostate cancer mortality in screen and clinically detected prostate cancer: estimating the screening benefit. *Eur J Cancer* 2010;46(2):377-83.
4. Wolters T, Roobol MJ, Steyerberg EW, van den Bergh RC, Bangma CH, Hugosson J, Ciatto S, Kwiatkowski M, Villers A, Lujan M, Nelen V, Tammela TL, Schroder FH. The effect of study arm on prostate cancer treatment in the large screening trial ERSPC. *Int J Cancer* 2010;126(10):2387-93.
5. Bergdahl AG, Aus G, Lilja H, Hugosson J. Risk of dying from prostate cancer in men randomized to screening: differences between attendees and nonattendees. *Cancer* 2009;115(24):5672-9.
6. Croswell JM, Kramer BS, Kreimer AR, Prorok PC, Xu JL, Baker SG, Fagerstrom R, Riley TL, Clapp JD, Berg CD, Gohagan JK, Andriole GL, Chia D, Church TR, Crawford ED, Fouad MN, Gelmann EP, Lamerato L, Reding DJ, Schoen RE. Cumulative incidence of false-positive results in repeated, multimodal cancer screening. *Ann Fam Med* 2009;7(3):212-22.
7. Roobol MJ, Kerkhof M, Schroder FH, Cuzick J, Sasieni P, Hakama M, Stenman UH, Ciatto S, Nelen V, Kwiatkowski M, Lujan M, Lilja H, Zappa M, Denis L, Recker F, Berenguer A, Ruutu M, Kujala P, Bangma CH, Aus G, Tammela TL, Villers A, Rebillard X, Moss SM, de Koning HJ, Hugosson J, Auvinen A. Prostate cancer mortality reduction by prostate-specific antigen-based screening adjusted for nonattendance and contamination in the European Randomised Study of Screening for Prostate Cancer (ERSPC). *Eur Urol* 2009;56(4):584-91.
8. Grubb RL, Pinsky PF, Greenlee RT, Izmirlian G, Miller AB, Hickey TP, Riley TL, Mabie JE, Levin DL, Chia D, Kramer BS, Reding DJ, Church TR, Yokochi LA, Kvale PA, Weissfeld JL, Urban DA, Buys SS, Gelmann EP, Ragard LR, Crawford ED, Prorok PC, Gohagan JK, Berg CD, Andriole GL. Prostate cancer screening in the Prostate, Lung, Colorectal and Ovarian cancer screening trial: update on findings from the initial four rounds of screening in a randomized trial. *BJU international* 2008;102:1524-30.
9. Stephens RL, Xu Y, Volk RJ, Scholl LE, Kamin SL, Holden EW, Stroud LA. Influence of a patient decision aid on decisional conflict related to PSA testing: a structural equation model. *Health Psychol* 2008;27(6):711-21.
10. Carlsson S, Aus G, Wessman C, Hugosson J. Anxiety associated with prostate cancer screening with special reference to men with a positive screening test (elevated PSA) - Results from a prospective, population-based, randomised study. *European journal of cancer* 2007;43:2109-16.
11. Postma R, Schröder FH, van-Leenders GJ, Hoedemaeker RF, Vis AN, Roobol MJ, van-der-Kwast TH. Cancer detection and cancer characteristics in the European Randomized Study of Screening for Prostate Cancer (ERSPC)--Section Rotterdam. A comparison of two rounds of screening. *European urology* 2007;52:89-97.
12. Volk RJ, Hawley ST, Kneuper S, Holden EW, Stroud LA, Cooper CP, Berkowitz JM, Scholl LE, Saraykar SS, Pavlik VN. Trials of decision aids for prostate cancer screening: a systematic review. *Am J Prev Med* 2007;33(5):428-34.#

Ausschlussgrund A3: Anderer Publikationstyp (Editorial, Fallbericht, Brief etc.)

1. Brooks DD, Wolf A, Smith RA, Dash C, Guessous I. Prostate cancer screening 2010: updated recommendations from the American Cancer Society. *J Natl Med Assoc* 2010;102(5):423-9.
2. Wolf AM, Wender RC, Etzioni RB, Thompson IM, D'Amico AV, Volk RJ, Brooks DD, Dash C, Guessous I, Andrews K, DeSantis C, Smith RA. American Cancer Society guideline for the early detection of prostate cancer: update 2010. *CA Cancer J Clin* 2010;60(2):70-98.
3. Boyle P, Brawley OW. Prostate cancer: current evidence weighs against population screening. *CA Cancer J Clin* 2009;59(4):220-4.
4. Greene KL, Albertsen PC, Babaian RJ, Carter HB, Gann PH, Han M, Kuban DA, Sartor AO, Stanford JL, Zietman A, Carroll P. Prostate specific antigen best practice statement: 2009 update. *J Urol* 2009;182(5):2232-41.
5. Kjellman A, Akre O, Norming U, Tornblom M, Gustafsson O. 15-year followup of a population based prostate cancer screening study. *J Urol* 2009;181(4):1615-21.
6. Schroder FH. Screening for prostate cancer (PC)--an update on recent findings of the European Randomized Study of Screening for Prostate Cancer (ERSPC). *Urol Oncol* 2008;26(5):533-41.

Ausschlussgrund A4: Doppelpublikation, veraltete Publikation

1. Bryant RJ, Hamdy FC. Screening for prostate cancer: an update. *Eur Urol* 2008;53(1):37-44.
2. Aus G, Bergdahl S, Lodding P, Lilja H, Hugosson J. Prostate cancer screening decreases the absolute risk of being diagnosed with advanced prostate cancer--results from a prospective, population-based randomized controlled trial. *European urology* 2007;51:659-64.
3. Ilic D, O'Connor D, Green S, Wilt T. Screening for prostate cancer: a Cochrane systematic review (Brief record). *Cancer Causes and Control* 2007;18:279-85.
4. Lin K, Lipsitz R, Miller T, Janakiraman S. Benefits and Harms of Prostate-Specific Cancer Screening: An Evidence Update for the U.S. Preventive Services Task Force. Evidence Synthesis No. 63. AHRQ Publication No. 08-05121-EF-1. Rockville, Maryland: Agency for Healthcare Research and Quality. August 2008.

12.3.2. Recherche zu den Fragestellungen im Kapitel Diagnostik und Stadieneinteilung

12.3.2.1. Fragestellungen

Population	Inter-vention	Control	Referenz-standard	Outcomes	Time aspects
Patienten mit V.a. Prostatakarzinom	TRUS – (Graustufen-sonographie)	Systematische Biopsie	Histologie vorzugsweise aus OP-Präparat	Testgüteparameter	Ab 10/2007 bis 1/2011
Patienten mit V.a. Prostatakarzinom	Sono-graphie kontrastverstärkte	TRUS - gesteuerte Biopsie	Histologie vorzugsweise aus OP-Präparat	Testgüteparameter Klinische Konsequenzen	Ab 10/2007 bis 1/2011
Patienten mit V.a. Prostatakarzinom	Elasto-graphie	TRUS	Histologie vorzugsweise aus OP-Präparat	Testgüteparameter klinische Konsequenzen	Ab 01/2000, da neues Thema

Population	Inter-vention	Control	Referenz-standart	Outcomes	Time aspects
Patienten mit V.a. Prostatakarzinom	Histoscanning	gesteuerte Biopsie			
Patienten mit V.a. Prostatakarzinom	MRT – einschließlich MRS, DCE-MRT und diff. gew. MRT	TRUS gesteuerte systematische Biopsie	Histologie vorzugsweise aus OP-Präparat	Testgüteparameter für Diagnose und lokales Staging Klinische Konsequenzen	Ab 10/2007 bis 12/2010
Patienten mit persistierend erhöhtem PSA-Wert nach mind. 1 negativer Biopsie	MRT einschließlich MRS, DCE MRT und diff. gew. MRT + MRT gesteuerte oder TRUS gesteuerte systematische Biopsie	TRUS gesteuerte systematische Biopsie	Histologie vorzugsweise aus OP-Präparat	Testgüteparameter für Diagnose Klinische Konsequenzen	Ab 10/2007 bis 12/2010
Patienten mit durch Biopsie nachgewiesenem Prostatakarzinom	Cholin PET/CT zum Staging	MRT, Knochenszintigraphie, ggf. Keine Kontrollgruppe	Histologie vorzugsweise aus OP-Präparat	Testgüteparameter für Staging Klinische Konsequenzen	Ab 2000 bis 12/2010

12.3.2.2. Recherchen

12.3.2.2.1. Histoscanning

Prostate AND Cancer AND (Histoscanning OR "computer-aided ultrasonography" OR computer aided ultrasonography) AND diagnosis

12.3.2.2.2. Elastographie

PubMed (19. Dezember 2010)

Nr.	Suchfrage	Anzahl
#4	#1 AND #2 Limits: English, German	66
#3	#1 AND #2	67
#2	Elastography (Details: "elasticity imaging techniques"[MeSH Terms] OR ("elasticity"[All Fields] AND "imaging"[All Fields] AND "techniques"[All Fields]) OR "elasticity imaging techniques"[All Fields] OR "elastography"[All Fields])	2065

#1	Prostate cancer (Details: "prostatic neoplasms"[MeSH Terms] OR ("prostatic"[All Fields] AND "neoplasms"[All Fields]) OR "prostatic neoplasms"[All Fields] OR ("prostate"[All Fields] AND "cancer"[All Fields]) OR "prostate cancer"[All Fields])	90615
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Anzahl der Treffer: 66

Cochrane (19. Dezember 2010)

Nr.	Suchfrage	Anzahl
#1	"prostate cancer in Title, Abstract or Keywords and elastography OR elasticity imaging in Title, Abstract or Keywords	1

- Cochrane Database of Systematic Reviews (0)
- Database of Abstracts of Reviews of Effects (0)
- Cochrane Central Register of Controlled Trials (1)
- Cochrane Methodology Register (0)
- Health Technology Assessment Database (0)
- NHS Economic Evaluation Database (0)

Anzahl der Treffer: 1

Davon neu: 0

12.3.2.2.3. Sonographie

Ausschlusskriterien für erste Relevanzsichtung:

A1: andere Erkrankung

A2: anderes Thema (nicht Diagnose)

A3: Methodik (Letter, Editorial u.ä.)

PubMed (19. Dezember 2010)

Nr.	Suchfrage	Anzahl
#4	Search #1 AND #2 Limits: English, German, Publication date from 2007/10	479
#3	#1 AND #2	3483
#2	Ultrasonography (Details: "ultrasonography"[Subheading] OR "ultrasonography"[All Fields] OR "ultrasonography"[MeSH Terms])	294615
#1	Prostate cancer (Details: "prostatic neoplasms"[MeSH Terms] OR ("prostatic"[All Fields] AND "neoplasms"[All Fields]) OR "prostatic neoplasms"[All Fields] OR ("prostate"[All Fields] AND "cancer"[All Fields]) OR "prostate cancer"[All Fields])	90615

Anzahl der Treffer: 479

Davon relevant: 212

Cochrane (19. Dezember 2010)

Nr.	Suchfrage	Anzahl
#1	"prostate cancer in Title, Abstract or Keywords and ultrasonography in Title, Abstract or Keywords, from 2007 to 2010	24

- Cochrane Database of Systematic Reviews (1)
- Database of Abstracts of Reviews of Effects (0)
- Cochrane Central Register of Controlled Trials (21)
- Cochrane Methodology Register (0)
- Health Technology Assessment Database (2)
- NHS Economic Evaluation Database (0)

Anzahl der Treffer: 24

Davon neu: 8

Davon relevant: 5

12.3.2.2.4. MRT

Ausschlusskriterien für erste Relevanzsichtung

A1: andere Erkrankung

A2: anderes Thema (nicht Primärdiagnostik)

A3: Methodik (Letter, Editorial u.ä., Fallberichte, Feasibility Studie)

A4: nicht systematischer Review

A5: retrospektiv

A6 >20

PubMed (10. Dezember 2010)

Nr.	Suchfrage	Anzahl
#4	Search #1 AND #2 Limits: English, German, Publication date from 2007/10	668
#3	#1 AND #2	2342
#2	Magnetic Resonance Imaging (Details: "magnetic resonance imaging"[MeSH Terms] OR ("magnetic"[All Fields] AND "resonance"[All Fields] AND "imaging"[All Fields]) OR "magnetic resonance imaging"[All Fields])	267768
#1	Prostate cancer (Details: "prostatic neoplasms"[MeSH Terms] OR ("prostatic"[All Fields] AND "neoplasms"[All Fields]) OR "prostatic neoplasms"[All Fields] OR ("prostate"[All Fields] AND "cancer"[All Fields]) OR "prostate cancer"[All Fields])	90394

Anzahl der Treffer: 668

Davon relevant: 298

Cochrane (10. Dezember 2010)

Nr.	Suchfrage	Anzahl
#1	"prostate cancer in Title, Abstract or Keywords and magnetic resonance imaging in Title, Abstract or Keywords, from 2007 to 2010	19

- Cochrane Database of Systematic Reviews (0)
- Database of Abstracts of Reviews of Effects (3)
- Cochrane Central Register of Controlled Trials (13)
- Cochrane Methodology Register (0)
- Health Technology Assessment Database (1)
- NHS Economic Evaluation Database (2)

Anzahl der Treffer: 19

Davon neu: 7

Davon relevant: 2

12.3.2.2.5. PET/CT

Ausschlusskriterien für erste Relevanzsichtung

A1: andere Erkrankung

A2: anderes Thema (nicht Staging)

A3: Methodik (Letter, Editorial u.ä.)

A4: retrospektiv

A5 < 25

A6 kein PET/CT

PubMed (19. Dezember 2010)

Nr.	Suchfrage	Anzahl
#4	#1 AND #4 Limits: English, German	322
#5	#1 AND #4	345
#4	#2 AND #3	21237
#3	Positron emission tomography (Details: "positron-emission tomography"[MeSH Terms] OR ("positron-emission"[All Fields] AND "tomography"[All Fields]) OR "positron-emission tomography"[All Fields] OR ("positron"[All Fields] AND "emission"[All Fields] AND "tomography"[All Fields]) OR "positron emission tomography"[All Fields])	35755
#2	Computed tomography (Details: "tomography, x-ray computed"[MeSH Terms] OR ("tomography"[All Fields] AND "x-ray"[All Fields] AND "computed"[All	313143

Nr.	Suchfrage	Anzahl
	Fields]) OR "x-ray computed tomography"[All Fields] OR ("computed"[All Fields] AND "tomography"[All Fields]) OR "computed tomography"[All Fields])	
#1	Prostate cancer (Details: "prostatic neoplasms"[MeSH Terms] OR ("prostatic"[All Fields] AND "neoplasms"[All Fields]) OR "prostatic neoplasms"[All Fields] OR ("prostate"[All Fields] AND "cancer"[All Fields]) OR "prostate cancer"[All Fields])	90615

Anzahl der Treffer: 322

Davon relevant: 212

Cochrane (19. Dezember 2010)

Nr.	Suchfrage	Anzahl
#1	"prostate cancer in Title, Abstract or Keywords and computed tomography in Title, Abstract or Keywords and positron emission tomography in Title, Abstract or Keywords	5

- Cochrane Database of Systematic Reviews (0)
- Database of Abstracts of Reviews of Effects (0)
- Cochrane Central Register of Controlled Trials (5)
- Cochrane Methodology Register (0)
- Health Technology Assessment Database (0)
- NHS Economic Evaluation Database (0)

Anzahl der Treffer: 5

Davon neu: 1

Davon relevant: 0

12.3.2.3. Ausschlusskriterien

12.3.2.3.1. Histoscanning

A1: andere Erkrankung

A2: andere Fragestellung

A3: anderer Publikationstyp (keine Studie/Review, Fallberichte)/inadäquate Methodik

A4: unsystematischer Review

12.3.2.3.2. Elastographie

A1: andere Erkrankung

A2: anderer Publikationstyp (keine Studie/Review, Fallberichte (bis n=9))

A3: erkennbar unsystematischer Review

A4: anderes Thema/hauptsächlich Biopsietechniken

A5: Doppelpublikation oder nicht erhältlich

12.3.2.3.3. Sonographie

A1: andere Erkrankung

A2: anderes Thema (nicht Diagnose)

A3: Methodik (Letter, Editorial u.ä.)

A4: retrospektive Studien

A5: unsystematischer Review

A6: bereits in extrahiertem Review enthalten

A7: Doppelpublikation oder nicht erhältlich

12.3.2.3.4. MRT

A1: andere Erkrankung

A2: anderes Thema (nicht Primärdiagnostik)

A3: Methodik (Letter, Editorial u.ä., Fallberichte, Feasibility Studie)

A4: nicht systematischer Review

A5: $n \leq 50$

A6: bereits in extrahiertem Review enthalten

A7: Doppelpublikation oder nicht erhältlich

12.3.2.3.5. PET/CT

A1: andere Erkrankung

A2: anderes Thema (nicht Staging)

A3: Methodik (Letter, Editorial u.ä.)

A4: retrospektiv

A5: nicht systematischer Review

A6: < 25

A7: kein PET/CT

A8: Doppelpublikation oder nicht erhältlich

12.3.2.4. Rechercheergebnisse

12.3.2.4.1. Histoscanning

Insgesamt 15 Treffer, davon 6 Volltexte bestellt und 2 Publikationen eingeschlossen

Eingeschlossene Volltexte:

5. Braeckman J, Autier P, Garbar C, Marichal MP, Soviany C, Nir R, Nir D, Michielsen D, Bleiberg H, Egevad L, Emberton M. Computer-aided ultrasonography (HistoScanning): a novel technology for locating and characterizing prostate cancer. *BJU Int* 2008;101(3):293-8.
6. Braeckman J, Autier P, Soviany C, Nir R, Nir D, Michielsen D, Treurnicht K, Jarmulowicz M, Bleiberg H, Govindaraju S, Emberton M. The accuracy of transrectal ultrasonography supplemented with computer-aided ultrasonography for detecting small prostate cancers. *BJU Int* 2008;102(11):1560-5.

Ausgeschlossene Volltexte**A2 (andere Fragestellung)**

1. Aigner F, Frauscher F. RE: Computer-aided ultrasonography (HistoScanning): a novel technology for locating and characterizing prostate cancer. *BJU Int* 2009;103(1):115-6.

A3 (anderer Publikationstyp (keine Studie/Review, Fallberichte)/inadäquate Methodik)

1. Dinter DJ, Weidner AM, Wenz F, Pelzer AE, Michel MS, Schoenberg SO. Bildgebung der Prostata. *Der Urologe Ausg A* 2010;49(8):963-75.

A4 (unsystematischer Review)

1. Moradi M, Mousavi P, Abolmaesumi P. Computer-aided diagnosis of prostate cancer with emphasis on ultrasound-based approaches: a review. *Ultrasound Med Biol* 2007;33(7):1010-28.
2. Ukimura O. Evolution of precise and multimodal MRI and TRUS in detection and management of early prostate cancer. *Expert Rev Med Devices* 2010;7(4):541-54.

12.3.2.4.2. Elastographie

Insgesamt 66 Treffer, davon 35 Volltexte bestellt und 14 Publikationen eingeschlossen

Eingeschlossene Volltexte:

1. Tsutsumi M, Miyagawa T, Matsumura T, Kawazoe N, Ishikawa S, Shimokama T, Shiina T, Miyanaga N, Akaza H. The impact of real-time tissue elasticity imaging (elastography) on the detection of prostate cancer: clinicopathological analysis. *Int J Clin Oncol* 2007;12(4):250-5.
2. Sumura M, Shigeno K, Hyuga T, Yoneda T, Shiina H, Igawa M. Initial evaluation of prostate cancer with real-time elastography based on step-section pathologic analysis after radical prostatectomy: a preliminary study. *Int J Urol* 2007;14(9):811-6.
3. Sommerfeld HJ, Garcia-Schurmann JM, Schewe J, Kuhne K, Cubick F, Berges RR, Lorenz A, Pesavento A, Scheipers U, Ermert H, Pannek J, Philippou S, Senge T. [Prostate cancer diagnosis using ultrasound elastography. Introduction of a novel technique and first clinical results]. *Urologe A* 2003;42(7):941-5.
4. Scattoni V, Zlotta A, Montironi R, Schulman C, Rigatti P, Montorsi F. Extended and saturation prostatic biopsy in the diagnosis and characterisation of prostate cancer: a critical analysis of the literature. *Eur Urol* 2007;52(5):1309-22.
5. Salomon G, Kollerman J, Thederan I, Chun FK, Budaus L, Schlomm T, Isbarn H, Heinzer H, Huland H, Graefen M. Evaluation of prostate cancer detection with ultrasound real-time elastography: a comparison with step section pathological analysis after radical prostatectomy. *Eur Urol* 2008;54(6):1354-62.
6. Nelson ED, Slotoroff CB, Gomella LG, Halpern EJ. Targeted biopsy of the prostate: the impact of color Doppler imaging and elastography on prostate cancer detection and Gleason score. *Urology* 2007;70(6):1136-40.
7. Miyanaga N, Akaza H, Yamakawa M, Oikawa T, Sekido N, Hinotsu S, Kawai K, Shimazui T, Shiina T. Tissue elasticity imaging for diagnosis of prostate cancer: a preliminary report. *Int J Urol* 2006;13(12):1514-8.

8. Miyagawa T, Tsutsumi M, Matsumura T, Kawazoe N, Ishikawa S, Shimokama T, Miyayana N, Akaza H. Real-time elastography for the diagnosis of prostate cancer: evaluation of elastographic moving images. *Jpn J Clin Oncol* 2009;39(6):394-8.
9. König K, Scheipers U, Pesavento A, Lorenz A, Ermert H, Senge T. Initial experiences with real-time elastography guided biopsies of the prostate. *J Urol* 2005;174(1):115-7.
10. Kamoi K, Okihara K, Ochiai A, Ukimura O, Mizutani Y, Kawauchi A, Miki T. The utility of transrectal real-time elastography in the diagnosis of prostate cancer. *Ultrasound Med Biol* 2008;34(7):1025-32.
11. Gravas S, Mamoulakis C, Rioja J, Tzortzis V, de RT, Wijkstra H, de la RJ. Advances in ultrasound technology in oncologic urology. *Urol Clin North Am* 2009;36(2):133-45, vii.
12. Eggert T, Khaled W, Wenske S, Ermert H, Noldus J. [Impact of elastography in clinical diagnosis of prostate cancer. A comparison of cancer detection between B-mode sonography and elastography-guided 10-core biopsies]. *Urologe A* 2008;47(9):1212-7.
13. Cochlin DL, Ganatra RH, Griffiths DF. Elastography in the detection of prostatic cancer. *Clin Radiol* 2002;57(11):1014-20.

Ausgeschlossene Volltexte

A3 (erkennbar unsystematischer Review)

1. Ukimura O. Evolution of precise and multimodal MRI and TRUS in detection and management of early prostate cancer. *Expert Rev Med Devices* 2010;7(4):541-54.
2. Trabulsi EJ, Sackett D, Gomella LG, Halpern EJ. Enhanced transrectal ultrasound modalities in the diagnosis of prostate cancer. *Urology* 2010;76(5):1025-33.
3. Seitz M, Strittmatter F, Roosen A, Tilki D, Gratzke C. Current status of ultrasound imaging in prostate cancer. *Panminerva Med* 2010;52(3):189-94.
4. Purohit RS, Shinohara K, Meng MV, Carroll PR. Imaging clinically localized prostate cancer. *Urol Clin North Am* 2003;30(2):279-93.
5. Pallwein L, Mitterberger M, Pelzer A, Bartsch G, Strasser H, Pinggera GM, Aigner F, Gradl J, Zur ND, Frauscher F. Ultrasound of prostate cancer: recent advances. *Eur Radiol* 2008;18(4):707-15.
6. Pallwein L, Mitterberger M, Gradl J, Aigner F, Horninger W, Strasser H, Bartsch G, Zur ND, Frauscher F. Value of contrast-enhanced ultrasound and elastography in imaging of prostate cancer. *Curr Opin Urol* 2007;17(1):39-47.
7. Oehr P, Bouchelouche K. Imaging of prostate cancer. *Curr Opin Oncol* 2007;19(3):259-64.
8. Moradi M, Mousavi P, Abolmaesumi P. Computer-aided diagnosis of prostate cancer with emphasis on ultrasound-based approaches: a review. *Ultrasound Med Biol* 2007;33(7):1010-28.
9. Lorenzen J, Sinkus R, Adam G. [Elastography: Quantitative imaging modality of the elastic tissue properties]. *Rofo* 2003;175(5):623-30.
10. Loch T. Urologic imaging for localized prostate cancer in 2007. *World J Urol* 2007;25(2):121-9.
11. Linden RA, Halpern EJ. Advances in transrectal ultrasound imaging of the prostate. *Semin Ultrasound CT MR* 2007;28(4):249-57.
12. Janssen J. [(E)US elastography: current status and perspectives]. *Z Gastroenterol* 2008;46(6):572-9.
13. Ginat DT, Destounis SV, Barr RG, Castaneda B, Strang JG, Rubens DJ. US elastography of breast and prostate lesions. *Radiographics* 2009;29(7):2007-16.
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12.3.2.4.3. Sonographie

Insgesamt 217 Treffer, davon 32 Volltexte bestellt und 15 Publikationen eingeschlossen

Eingeschlossene Volltexte

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A5 (unsystematischer Review)

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12.3.2.4.4. A7 (Doppelpublikation oder nicht erhältlich)

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12.3.2.4.5. MRT

Insgesamt 300 Treffer, davon 62 Volltexte bestellt und 31 Publikationen eingeschlossen

Eingeschlossene Volltexte

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A2 (anderes Thema (nicht Primärdiagnostik))

1. Katahira K, Takahara T, Kwee TC, Oda S, Suzuki Y, Morishita S, Kitani K, Hamada Y, Kitaoka M, Yamashita Y. Ultra-high-b-value diffusion-weighted MR imaging for the detection of prostate cancer: evaluation in 201 cases with histopathological correlation. *Eur Radiol* 2011;21(1):188-96.
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A3 (Methodik (Letter, Editorial u.ä., Fallberichte, Feasibility Studie))

1. Sciarra A, Panebianco V, Ciccariello M, Salciccia S, Lisi D, Osimani M, Alfarone A, Gentilucci A, Parente U, Passariello R, Gentile V. Magnetic resonance spectroscopic imaging (1H-MRSI) and dynamic contrast-enhanced magnetic resonance (DCE-MRI): pattern changes from inflammation to prostate cancer. *Cancer Invest* 2010;28(4):424-32.
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4. 239. Masterson TA, Touijer K. The role of endorectal coil MRI in preoperative staging and decision-making for the treatment of clinically localized prostate cancer. *MAGMA* 2008;21(6):371-7.

A4 (nicht systematischer Review)

1. Puech P, Huglo D, Petyt G, Lemaitre L, Villers A. Imaging of organ-confined prostate cancer: functional ultrasound, MRI and PET/computed tomography. *Curr Opin Urol* 2009;19(2):168-76.
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A5 (n ≤ 50)

1. Akin O, Riedl CC, Ishill NM, Moskowitz CS, Zhang J, Hricak H. Interactive dedicated training curriculum improves accuracy in the interpretation of MR imaging of prostate cancer. *Eur Radiol* 2010;20(4):995-1002.
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5. Yagci AB, Ozari N, Aybek Z, Duzcan E. The value of diffusion-weighted MRI for prostate cancer detection and localization. *Diagn Interv Radiol* 2010.
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12. Chandra RV, Heinze S, Dowling R, Shadbolt C, Costello A, Pedersen J. Endorectal magnetic resonance imaging staging of prostate cancer. *ANZ J Surg* 2007;77(10):860-5.
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A6 (bereits in extrahiertem Review enthalten)

1. Chen M, Dang HD, Wang JY, Zhou C, Li SY, Wang WC, Zhao WF, Yang ZH, Zhong CY, Li GZ. Prostate cancer detection: comparison of T2-weighted imaging, diffusion-weighted imaging, proton magnetic resonance spectroscopic imaging, and the three techniques combined. *Acta Radiol* 2008;49(5):602-10.
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A7 (Doppelpublikation oder nicht erhältlich)

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2. Delongchamps NB, Rouanne M, Flam T, Beuvon F, Liberatore M, Zerbib M, Cornud F. Multiparametric magnetic resonance imaging for the detection and localization of prostate cancer: combination of T2-weighted, dynamic contrast-enhanced and diffusion-weighted imaging. *BJU Int* 2010.
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12.3.2.4.6. PET/CT

Insgesamt 212 Treffer, davon 57 Volltexte bestellt und 21 Publikationen eingeschlossen

Eingeschlossene Volltexte

1. Picchio M, Briganti A, Fanti S, Heidenreich A, Krause BJ, Messa C, Montorsi F, Reske SN, Thalmann GN. The Role of Choline Positron Emission Tomography/Computed Tomography in the Management of Patients with Prostate-Specific Antigen Progression After Radical Treatment of Prostate Cancer. *Eur Urol* 2010.
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Ausgeschlossene Volltexte

A2 (anderes Thema: nicht Staging)

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A3 (Methodik (Letter, Editorial u.ä.))

1. Heidenreich A, Albers P, Classen J, Graefen M, Gschwend J, Kotzerke J, Krege S, Lehmann J, Rohde D, Schmidberger H, Uder M, Zeeb H. Imaging studies in metastatic urogenital cancer patients undergoing systemic therapy: recommendations of a multidisciplinary consensus meeting of the Association of Urological Oncology of the German Cancer Society. *Urol Int* 2010;85(1):1-10.
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A4 (retrospektiv)

1. Fuccio C, Castellucci P, Schiavina R, Santi I, Allegri V, Pettinato V, Boschi S, Martorana G, Al-Nahhas A, Rubello D, Fanti S. Role of 11C-choline PET/CT in the restag-

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A5 (nicht systematischer Review)

1. Mease RC. Radionuclide based imaging of prostate cancer. *Curr Top Med Chem* 2010;10(16):1600-16.
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mography-computerized tomography and laparoscopic radioisotope guided sentinel lymph node dissection. *J Urol* 2006;176(5):2014-8.

6. Salminen E, Hogg A, Binns D, Frydenberg M, Hicks R. Investigations with FDG-PET scanning in prostate cancer show limited value for clinical practice. *Acta Oncol* 2002;41(5):425-9.

A7 (kein PET/CT)

1. Han EJ, H O J, Choi WH, Yoo IR, Chung SK. Significance of incidental focal uptake in prostate on 18-fluoro-2-deoxyglucose positron emission tomography CT images. *Br J Radiol* 2010;83(995):915-20.
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12. Kotzerke J, Prang J, Neumaier B, Volkmer B, Guhlmann A, Kleinschmidt K, Hautmann R, Reske SN. Experience with carbon-11 choline positron emission tomography in prostate carcinoma. *Eur J Nucl Med* 2000;27(9):1415-9.

A8 (Doppelpublikation oder nicht erhältlich)

1. Beer AJ, Eiber M, Souvatzoglou M, Holzapfel K, Ganter C, Weirich G, Maurer T, Kubler H, Wester HJ, Gaa J, Krause BJ. Restricted Water Diffusibility as Measured by Diffusion-weighted MR Imaging and Choline Uptake in (11)C-Choline PET/CT are Correlated in Pelvic Lymph Nodes in Patients with Prostate Cancer. *Mol Imaging Biol* 2010.
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12.3.3. Recherche zu Active Surveillance bei lokal begrenztem Prostatakarzinom

12.3.3.1. Fragestellungen

Population	Intervention	Control	Outcomes	Time aspects
Pat mit PCa	Active Surveillance (Deskription der Einschlusskriterien)	RPE, EBRT (es wurden keine kontrollierten Studien erwartet)	Zeit bis zur Metastasierung, Überleben Ggf. stratifiziert nach low risk und intermediate risk	Nachbeobachtung mind. 2J
Pat. mit PCa und AS	a)Monitoring-kriterien b)Trigger für definitive Therapie unter besonderer Berücksichtigung von PSA-DT und PSA-V	-	Anteil Pat. mit definitiver Therapie Anteil Progression nach Therapie PCa-spezifische Mortalität	-

12.3.3.2. Recherchen

PubMed (17. Januar 2011)

Nr.	Suchfrage	Anzahl
#4	#1 AND #2 Limits: English, German, Publication date from 2006/06	813
#3	#1 AND #2	2010
#2	active surveillance OR "expectant management" OR "deferred treatment" OR "delayed intervention" OR "defensive strategies" OR "PSA kinetics" OR "PSA velocity" OR "PSA doubling time" OR "PSA density" (Details: ("watchful waiting"[MeSH Terms] OR ("watchful"[All Fields] AND "waiting"[All Fields]) OR "watchful waiting"[All Fields] OR ("active"[All Fields] AND "surveillance"[All Fields]) OR "active surveillance"[All Fields]) OR "expectant management"[All Fields] OR "deferred treatment"[All Fields] OR "delayed intervention"[All Fields] OR "defensive strategies"[All Fields] OR "PSA kinetics"[All Fields] OR "PSA velocity"[All Fields] OR "PSA doubling time"[All Fields] OR "PSA density"[All Fields])	10134

Nr.	Suchfrage	Anzahl
#1	Prostate cancer (Details: "prostatic neoplasms"[MeSH Terms] OR ("prostatic"[All Fields] AND "neoplasms"[All Fields]) OR "prostatic neoplasms"[All Fields] OR ("prostate"[All Fields] AND "cancer"[All Fields]) OR "prostate cancer"[All Fields])	91220

Anzahl der Treffer: 813

Davon relevant: 751

Cochrane (17. Januar 2011)

Nr.	Suchfrage	Anzahl
#1	(active surveillance OR watchful waiting OR expectant management OR deferred treatment OR delayed intervention OR defensive strategies OR PSA kinetics OR PSA velocity OR PSA doubling time OR PSA density):ti,ab,kw and (prostate cancer):ti,ab,kw, from 2006 to 2011	69

- Cochrane Database of Systematic Reviews (4)
- Database of Abstracts of Reviews of Effects (1)
- Cochrane Central Register of Controlled Trials (62)
- Cochrane Methodology Register (1)
- Health Technology Assessment Database (1)
- NHS Economic Evaluation Database (0)

Anzahl der Treffer: 69

Davon neu: 32

Davon relevant: 31

Ausschlusskriterien für erste Relevanzsichtung:

- andere Erkrankung
- Methodik (Letter, Editorial u.ä.)

12.3.3.3. Ein- und Ausschlusskriterien

Einschlussgründe	
E1 Zielgruppe	Patienten mit Low Risk oder ggf. Intermediate Risk
E2 Publikationstyp	Systematische Übersichtsarbeit, RCT, prospektive kontrollierte Studie, prospektive Fallserie, retrospektive Auswertung von Registern alle n>100
E3: Suchzeitraum	Juni 2006 bis 17.1.2011

E4: Sprachen	Englisch, Deutsch,
E5 Intervention	Active Surveillance
Ausschlussgründe	
A1	Methodik (Brief, experimentelle Studie, Editorial, unsystematischer Review, retrospektive Studie außer Registerstudie)
A2	Nicht das Thema (Publikation behandelt nicht Patienten mit AS)
A3	Nicht die Patientengruppe mit lokal begrenztem PCa
A4	Nachbeobachtungszeit unter 2J
A5	Doppelpublikation (Dublette) oder gleicher Inhalt, bereits für Erstauflage extrahiert
A6	Veraltete, d.h. aktuellere Studiendaten sind bereits publiziert
A7	Setting nicht übertragbar (z.B. ökonomische Analyse nicht aus der BRD)
A8	N<100
A9	AS aber nicht vereinbarte Aspekte
A10	Nicht bestellbar

12.3.3.4. Ergebnisse der Recherche

12.3.3.4.1. Eingeschlossene systematische Reviews

1. Bastian PJ, Carter BH, Bjartell A, Seitz M, Stanislaus P, Montorsi F, Stief CG, Schroder F. Insignificant prostate cancer and active surveillance: from definition to clinical implications. *Eur Urol* 2009;55(6):1321-30.
2. van den Bergh RC, Roemeling S, Roobol MJ, Wolters T, Schroder FH, Bangma CH. Prostate-specific antigen kinetics in clinical decision-making during active surveillance for early prostate cancer—a review. *Eur Urol* 2008;54(3):505-16. C.N. et al, 2009
3. Harnden P, Naylor B, Shelley MD, Clements H, Coles B, Mason MD. The clinical management of patients with a small volume of prostatic cancer on biopsy: what are the risks of progression? A systematic review and meta-analysis. *Cancer* 2008;112(5):971-81.
4. Pickles T, Ruether JD, Weir L, Carlson L, Jakulj F. Psychosocial barriers to active surveillance for the management of early prostate cancer and a strategy for increased acceptance. *BJU Int* 2007;100(3):544-51.
5. Ramirez ML, Nelson EC, Vere White RW, Lara PN, Jr., Evans CP. Current applications for prostate-specific antigen doubling time. *Eur Urol* 2008;54(2):291-300.

12.3.3.4.2. Eingeschlossene Einzelstudien

Fallserien/Kohorten unter Active Surveillance

1. Finelli A, Trottier G, Lawrentschuk N, Sowerby R, Zlotta AR, Radomski L, Timilshina N, Evans A, van der Kwast TH, Toi A, Jewett MA, Trachtenberg J, Fleshner NE. Im-

- pect of 5alpha-Reductase Inhibitors on Men Followed by Active Surveillance for Prostate Cancer. *Eur Urol* 2010.
2. Al Otaibi M., Ross P, Fahmy N, Jeyaganth S, Trottier H, Sircar K, Begin LR, Souhami L, Kassouf W, Aprikian A, Tanguay S. Role of repeated biopsy of the prostate in predicting disease progression in patients with prostate cancer on active surveillance. *Cancer* 2008;113(2):286-92.
 3. Bailey DE, Jr., Wallace M, Latini DM, Hegarty J, Carroll PR, Klein EA, Albertsen PC. Measuring illness uncertainty in men undergoing active surveillance for prostate cancer. *Appl Nurs Res* 2009.
 4. van den Bergh RC, Roemeling S, Roobol MJ, Aus G, Hugosson J, Rannikko AS, Tammela TL, Bangma CH, Schroder FH. Outcomes of men with screen-detected prostate cancer eligible for active surveillance who were managed expectantly. *Eur Urol* 2009;55(1):1-8.
 5. van den Bergh RC, Essink-Bot ML, Roobol MJ, Wolters T, Schroder FH, Bangma CH, Steyerberg EW. Anxiety and distress during active surveillance for early prostate cancer. *Cancer* 2009;115(17):3868-78.
 6. van den Bergh RC, Steyerberg EW, Khatami A, Aus G, Pihl CG, Wolters T, van Leeuwen PJ, Roobol MJ, Schroder FH, Hugosson J. Is delayed radical prostatectomy in men with low-risk screen-detected prostate cancer associated with a higher risk of unfavorable outcomes? *Cancer* 2010;116(5):1281-90.
 7. van den Bergh RC, Essink-Bot ML, Roobol MJ, Schroder FH, Bangma CH, Steyerberg EW. Do anxiety and distress increase during active surveillance for low risk prostate cancer? *Journal of Urology* 2010;183(5):1786-91.
 8. van den Bergh RC, van Vugt HA, Korfage IJ, Steyerberg EW, Roobol MJ, Schroder FH, Essink-Bot ML. Disease insight and treatment perception of men on active surveillance for early prostate cancer. *BJU Int* 2010;105(3):322-8.
 9. Burnet KL, Parker C, Dearnaley D, Brewin CR, Watson M. Does active surveillance for men with localized prostate cancer carry psychological morbidity? *BJU Int* 2007;100(3):540-3.
 10. Carter HB, Kettermann A, Warlick C, Metter EJ, Landis P, Walsh PC, Epstein JI. Expectant management of prostate cancer with curative intent: an update of the Johns Hopkins experience. *Journal of Urology* 2007;178(6):2359-64.
 11. Cooperberg MR, Cowan JE, Hilton JF, Reese AC, Zaid HB, Porten SP, Shinohara K, Meng MV, Greene KL, Carroll PR. Outcomes of active surveillance for men with intermediate-risk prostate cancer. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology* 2011;29(2):228-34.
 12. Dall'Era MA, Konety BR, Cowan JE, Shinohara K, Stauf F, Cooperberg MR, Meng MV, Kane CJ, Perez N, Master VA, Carroll PR. Active surveillance for the management of prostate cancer in a contemporary cohort. *Cancer* 2008;112(12):2664-70.
 13. Daubenmier JJ, Weidner G, Marlin R, Crutchfield L, Dunn-Emke S, Chi C, Gao B, Carroll P, Ornish D. Lifestyle and health-related quality of life of men with prostate cancer managed with active surveillance. *Urology* 2006;67(1):125-30.
 14. Eggener SE, Mueller A, Berglund RK, Ayyathurai R, Soloway C, Soloway MS, Abouassaly R, Klein EA, Jones SJ, Zappavigna C, Goldenberg L, Scardino PT, Eastham JA, Guillonneau B. A multi-institutional evaluation of active surveillance for low risk prostate cancer. *Journal of Urology* 2009;181(4):1635-41.
 15. Frattaroli J, Weidner G, Dnistrian AM, Kemp C, Daubenmier JJ, Marlin RO, Crutchfield L, Yglecias L, Carroll PR, Ornish D. Clinical events in prostate cancer lifestyle trial: results from two years of follow-up. *Urology* 2008;72(6):1319-23.
 16. Gorin MA, Soloway CT, Eldefrawy A, Soloway MS. Factors That Influence Patient Enrollment in Active Surveillance for Low-risk Prostate Cancer. *Urology* 2011.
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 18. Krakowsky Y, Loblaw A, Klotz L. Prostate cancer death of men treated with initial active surveillance: clinical and biochemical characteristics. *Journal of Urology* 2010;184(1):131-5.
 19. Latini DM, Hart SL, Knight SJ, Cowan JE, Ross PL, DuChane J, Carroll PR. The relationship between anxiety and time to treatment for patients with prostate cancer on surveillance. *Journal of Urology* 2007;178(3 Pt 1):826-31.

20. Loeb S, Roehl KA, Helfand BT, Kan D, Catalona WJ. Can prostate specific antigen velocity thresholds decrease insignificant prostate cancer detection? *Journal of Urology* 2010;183(1):112-6. (E)
21. Oliffe JL, Davison BJ, Pickles T, Mroz L. The self-management of uncertainty among men undertaking active surveillance for low-risk prostate cancer. *Qual Health Res* 2009;19(4):432-43
22. Roemeling S, Roobol MJ, de Vries SH, Wolters T, Gosselaar C, van Leenders GJ, Schroder FH. Active surveillance for prostate cancers detected in three subsequent rounds of a screening trial: characteristics, PSA doubling times, and outcome. *Eur Urol* 2007;51(5):1244-50.
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24. Shappley WV, III, Kenfield SA, Kasperzyk JL, Qiu W, Stampfer MJ, Sanda MG, Chan JM. Prospective study of determinants and outcomes of deferred treatment or watchful waiting among men with prostate cancer in a nationwide cohort. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology* 2009;27(30):4980-5.
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12.3.3.4.3. Ausgeschlossene Publikationen (Volltextscreening)

A1: Methodik (Brief, experimentelle Studie, Editorial, unsystematischer Review, retrospektive Studie außer Registerstudie)

1. Bangma CH, Roobol MJ, Steyerberg EW. Predictive models in diagnosing indolent cancer. *Cancer* 2009;115(13 Suppl):3100-6.
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5. Dall'Era MA, Carroll PR. Outcomes and follow-up strategies for patients on active surveillance. *Curr Opin Urol* 2009;19(3):258-62.
6. Kirby RS, Fitzpatrick JM. Are the National Institute for Health and Clinical Excellence guidelines that promulgate active surveillance for low-risk prostate cancer justified by the available evidence? *BJU Int* 2008;102(11):1492-3.
7. Zietman A. Active surveillance: a safe, low-cost prognostic test for prostate cancer. *BJU Int* 2008;101(9):1059-60.
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A4: Nachbeobachtungszeit < 2 Jahre

1. van den Bergh RC, Vasarainen H, van der Poel HG, Vis-Maters JJ, Rietbergen JB, Pickles T, Cornel EB, Valdagni R, Jaspars JJ, van der HJ, Staerman F, Oomens EH, Rannikko A, Roemeling S, Steyerberg EW, Roobol MJ, Schroder FH, Bangma CH. Short-term outcomes of the prospective multicentre 'Prostate Cancer Research International: Active Surveillance' study. *BJU Int* 2010;105(7):956-62.

A5: Doppelpublikation (Dublette) oder gleicher Inhalt/bereits extrahiert

1. Khatami A, Aus G, Damber JE, Lilja H, Lodding P, Hugosson J. PSA doubling time predicts the outcome after active surveillance in screening-detected prostate cancer: results from the European randomized study of screening for prostate cancer, Sweden section. *Int J Cancer* 2007;120(1):170-4.
2. Klotz L. Active surveillance versus radical treatment for favorable-risk localized prostate cancer. *Curr Treat Options Oncol* 2006;7(5):355-62.
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4. Harnden P, Shelley MD, Naylor B, Coles B, Mason MD. Does the extent of carcinoma in prostatic biopsies predict prostate-specific antigen recurrence? A systematic review. *Eur Urol* 2008;54(4):728-39.

A7: Setting nicht übertragbar (z.B. ökonomische Analyse nicht aus der BRD)

1. Manoharan M, Eldefrawy A, Katkooori D, Antebi E, Soloway MS. Comparison of urologist reimbursement for managing patients with low-risk prostate cancer by active surveillance versus total prostatectomy. *Prostate Cancer Prostatic Dis* 2010;13(4):307-10.
2. Hayes JH, Ollendorf DA, Pearson SD, Barry MJ, Kantoff PW, Stewart ST, Bhatnagar V, Sweeney CJ, Stahl JE, McMahon PM. Active surveillance compared with initial treatment for men with low-risk prostate cancer: a decision analysis. *JAMA* 2010;304(21):2373-80.

A8: Fallzahl <100

1. Cooperberg MR, Konety BR. Management of localized prostate cancer in men over 65 years. *Curr Opin Urol* 2009;19(3):309-14.
2. van den Bergh RC, Roemeling S, Roobol MJ, Aus G, Hugosson J, Rannikko AS, Tammela TL, Bangma CH, Schroder FH. Gleason score 7 screen-detected prostate cancers initially managed expectantly: outcomes in 50 men. *BJU Int* 2009;103(11):1472-7.
3. Isharwal S, Makarov DV, Sokoll LJ, Landis P, Marlow C, Epstein JI, Partin AW, Carter HB, Veltri RW. ProPSA and Diagnostic Biopsy Tissue DNA Content Combination Improves Accuracy to Predict Need for Prostate Cancer Treatment Among Men Enrolled in an Active Surveillance Program. *Urology* 2011.

A9: AS aber nicht vereinbarte Aspekte (siehe Fragestellungen)

Die folgenden Arbeiten wurden zunächst als potentiell relevant für das Thema Active Surveillance gewertet, wurden aber für die Überarbeitung im Weiteren aus Kapazitätsgründen nach Abwägen des Erkenntnisgewinns v.a. in Bezug auf die zu erwartende Sicherheit der Ergebnisse nicht berücksichtigt, da sie in den vereinbarten Fragestellungen nicht enthalten waren. Dies betrifft zum Einen Arbeiten, die sich mit der Definition/Erkennung des sogenannten insignifikanten Prostatakarzinoms beschäftigen, einschließlich retrospektiv erhobener histopathologischer Analysen und Zum Anderen Arbeiten zu Prognosefaktoren bei AS einschließlich neuer molekularer Marker.

1. Raventos CX, Orsola A, de T, I, Cecchini L, Trilla E, Planas J, Morote J. Preoperative prediction of pathologically insignificant prostate cancer in radical prostatectomy specimens: the role of prostate volume and the number of positive cores. *Urol Int* 2010;84(2):153-8.
2. Jang TL, Bekelman JE, Liu Y, Bach PB, Basch EM, Elkin EB, Zelefsky MJ, Scardino PT, Begg CB, Schrag D. Physician visits prior to treatment for clinically localized prostate cancer. *Arch Intern Med* 2010;170(5):440-50.
3. Duffield AS, Lee TK, Miyamoto H, Carter HB, Epstein JI. Radical prostatectomy findings in patients in whom active surveillance of prostate cancer fails. *Journal of Urology* 2009;182(5):2274-8.
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- selection of candidates for active surveillance in patients with low-risk prostate cancer. *BJU Int* 2010;105(11):1548-52.
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 33. Vieth R, Choo R, Deboer L, Danjoux C, Morton GC, Klotz L. Rise in prostate-specific antigen in men with untreated low-grade prostate cancer is slower during spring-summer. *Am J Ther* 2006;13(5):394-9.

A10: Nicht bestellbar/ePub

1. Hegarty JM, Wallace M, Comber H. Uncertainty and quality of life among men undergoing active surveillance for prostate cancer in the United States and Ireland. *Am J Mens Health* 2008;2(2):133-42.
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3. Dall'Era MA, Cowan JE, Simko J, Shinohara K, Davies B, Konety BR, Meng MV, Perez N, Greene K, Carroll PR. Surgical management after active surveillance for low-risk prostate cancer: pathological outcomes compared with men undergoing immediate treatment. *BJU Int* 2010.
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12.3.4. Recherche zum Thema Radikale Prostatektomie bei Patienten mit hohem Risikoprofil

12.3.4.1. Fragestellung – Lokal begrenztes PCa (high risk)

Population	Intervention	Kontrolle	Outcomes	Time aspects
Patienten mit lokal begrenztem Prostatakarzinom des hohen Risikos	Radikale Prostatektomie (offen, laparoskopisch, roboter-assitiert.)	Perkutane Strahlentherapie, interstitielle Brachytherapie, Watchful Waiting	Mortalität (inkl. 5-Jahres Überleben, krankheitsfreies Überleben, PCa spezifisches Überleben) Morbidity Lebensqualität Nebenwirkungen /Schäden	-

12.3.4.2. Fragestellung – Lokal fortgeschrittenes PCa

Population	Intervention	Kontrolle	Outcomes	Time aspects
Patienten mit lokal fortgeschrittenem Prostatakarzinom (>T3)	Radikale Prostatektomie (offen, laparoskopisch, roboter-assitiert.)	externe Strahlentherapie, interstitielle Brachytherapie, Watchful Waiting	Mortalität (inkl. 5-Jahres Überleben, krankheitsfreies Überleben) Morbidity (PSA-Kinetik, Histologie) Lebensqualität Nebenwirkungen/Schäden	Keine Einschränkungen

12.3.4.3. Recherchen

Anmerkung: die eingeschlossenen Studien zum lokal begrenzten Prostatakarzinoms des hohen Risikos wurden im Rahmen der Aktualisierungsrecherche zur perkutanen Strahlentherapie beim lokal begrenzten Prostatakarzinom des hohen Risikos identifiziert (siehe Recherchestrategie dort).

Ausschlusskriterien für erste Relevanzsichtung:

andere Erkrankung

Methodik (Letter, Editorial u.ä.)

PubMed (10. Februar 2011)

Nr.	Suchfrage	Anzahl
#5	#1 AND #2 AND #3 Limits: English, German, Publication date from 2008/03	153
#4	#1 AND #2 AND #3	879
#3	"locally advanced" OR T3 OR T4 (Details: "locally advanced"[All Fields] OR T3[All Fields] OR T4[All Fields])	58373
#2	prostatectomy (Details: "prostatectomy"[MeSH Terms] OR "prostatectomy"[All Fields])	24635
#1	Prostate cancer (Details: "prostatic neoplasms"[MeSH Terms] OR ("prostatic"[All Fields] AND "neoplasms"[All Fields]) OR "prostatic neoplasms"[All Fields] OR ("prostate"[All Fields] AND "cancer"[All Fields]) OR "prostate cancer"[All Fields])	91664

Anzahl der Treffer: 153

Cochrane (10. Februar 2011)

Nr.	Suchfrage	Anzahl
#1	"prostate cancer in Title, Abstract or Keywords and prostatectomy in Title, Abstract or Keywords and locally advanced OR T3 OR T4 in Title, Abstract or Keywords, from 2008 to 2011	8

- Cochrane Database of Systematic Reviews (4)
- Database of Abstracts of Reviews of Effects (1)
- Cochrane Central Register of Controlled Trials (3)
- Cochrane Methodology Register (0)
- Health Technology Assessment Database (0)
- NHS Economic Evaluation Database (0)

Anzahl der Treffer: 8

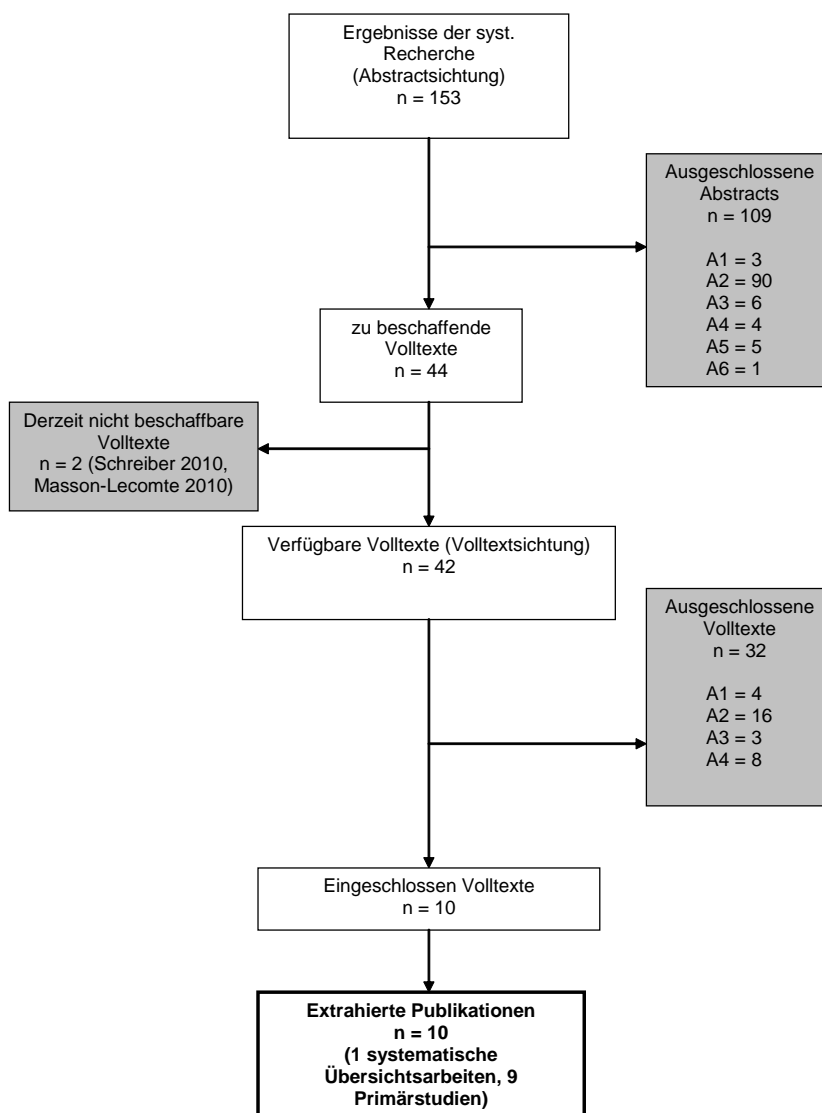
Davon neu: 4

Davon relevant: 0

12.3.4.4. Ein- und Ausschlusskriterien

Einschlussgründe	
E1 Zielgruppe	Patienten mit lokal fortgeschrittenem primärem Prostatakarzinom (cT3-cT4)
E2 Publikationstyp	Klinische Studien inklusive Fallserien oder systematischer Review/HTA-Bericht (mit oder ohne Metaanalyse)
E3: Suchzeitraum	Publikationen seit August 2008 (letzte Recherche S3 Leitlinien-Gruppe)
E4: Sprachen	deutsch, englisch
E5 Intervention	Radikale Prostatektomie
Ausschlussgründe	
A1	andere Population
A2	Nicht Fragestellung (siehe oben)
A3	Anderer Publikationstyp (Editorial, Fallserie n<50, Fallbericht, Brief etc.)
A4	Unsystematischer Review
A5	Doppelpublikation oder aktuellere Publikation vorhanden

12.3.4.5. Ergebnisse der Recherche



12.3.4.5.1. Eingeschlossene Publikationen

Zur RPE beim lokal begrenzten Prostatakarzinom mit hohem Risiko im Vergleich zu anderen Therapieoptionen

1. Bill-Axelsson A, Holmberg L, Ruutu M, Garmo H, Stark JR, Busch C, Nordling S, Haggman M, Andersson SO, Bratell S, Spangberg A, Palmgren J, Steineck G, Adami HO, Johansson JE. Radical prostatectomy versus watchful waiting in early prostate cancer. *The New England journal of medicine* 2011;364(18):1708-17.
2. Cooperberg MR, Vickers AJ, Broering JM, Carroll PR. Comparative risk-adjusted mortality outcomes after primary surgery, radiotherapy, or androgen-deprivation therapy for localized prostate cancer. *Cancer* 2010;116(22):5226-34.
3. Abdollah F, Sun M, Thuret R, Jeldres C, Tian Z, Briganti A, Shariat SF, Perrotte P, Rigatti P, Montorsi F, Karakiewicz PI. A competing-risks analysis of survival after alternative treatment modalities for prostate cancer patients: 1988-2006. *Eur Urol* 2011;59(1):88-95.
4. Arcangeli G, Strigari L, Arcangeli S, Petrongari MG, Saracino B, Gomellini S, Papalia R, Simone G, De CP, Gallucci M. Retrospective comparison of external beam radio-

therapy and radical prostatectomy in high-risk, clinically localized prostate cancer. *Int J Radiat Oncol Biol Phys* 2009;75(4):975-82.

5. Takizawa I, Hara N, Nishiyama T, Kaneko M, Hoshii T, Tsuchida E, Takahashi K. Oncological results, functional outcomes and health-related quality-of-life in men who received a radical prostatectomy or external beam radiation therapy for localized prostate cancer: a study on long-term patient outcome with risk stratification. *Asian J Androl* 2009;11(3):283-90.
6. Zhou EH, Ellis RJ, Cherullo E, Colussi V, Xu F, Chen WD, Gupta S, Whalen CC, Bodner D, Resnick MI, Rimm AA, Koroukian SM. Radiation therapy and survival in prostate cancer patients: a population-based study. *Int J Radiat Oncol Biol Phys* 2009;73(1):15-23.
7. Zelefsky MJ, Eastham JA, Cronin AM, Fuks Z, Zhang Z, Yamada Y, Vickers A, Scardino PT. Metastasis after radical prostatectomy or external beam radiotherapy for patients with clinically localized prostate cancer: a comparison of clinical cohorts adjusted for case mix. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology* 2010;28(9):1508-13.

Zur RPE beim lokal fortgeschrittenen Prostatakarzinom

1. Namiki S, Tochigi T, Ishidoya S, Ito A, Numata I, Arai Y. Long-term quality of life following primary treatment in men with clinical stage T3 prostate cancer. *Qual Life Res* 2011;20(1):111-8.
2. Hsu CY, Wildhagen MF, Van PH, Bangma CH. Prognostic factors for and outcome of locally advanced prostate cancer after radical prostatectomy. *BJU Int* 2010;105(11):1536-40.
3. Mearini L, Zucchi A, Costantini E, Bini V, Nunzi E, Porena M. Outcomes of radical prostatectomy in clinically locally advanced NOM0 prostate cancer. *Urol Int* 2010;85(2):166-72.
4. Ham WS, Park SY, Rha KH, Kim WT, Choi YD. Robotic radical prostatectomy for patients with locally advanced prostate cancer is feasible: results of a single-institution study. *J Laparoendosc Adv Surg Tech A* 2009;19(3):329-32.
5. Xylinas E, Drouin SJ, Comperat E, Vaessen C, Renard-Penna R, Misrai V, Bitker MO, Chartier-Kastler E, Richard F, Cussenot O, Roupret M. Oncological control after radical prostatectomy in men with clinical T3 prostate cancer: a single-centre experience. *BJU Int* 2009;103(9):1173-8.
6. Patel VR, Palmer KJ, Coughlin G, Samavedi S. Robot-assisted laparoscopic radical prostatectomy: perioperative outcomes of 1500 cases. *J Endourol* 2008;22(10):2299-305.
7. White WM, Sadetsky N, Waters WB, Carroll PR, Litwin MS. Quality of life in men with locally advanced adenocarcinoma of the prostate: an exploratory analysis using data from the CaPSURE database. *J Urol* 2008;180(6):2409-13.
8. Yossepowitch O, Eggener SE, Serio AM, Carver BS, Bianco FJ, Jr., Scardino PT, Eastham JA. Secondary therapy, metastatic progression, and cancer-specific mortality in men with clinically high-risk prostate cancer treated with radical prostatectomy. *Eur Urol* 2008;53(5):950-9.
9. Verhagen PC, Schroder FH, Collette L, Bangma CH. Does local treatment of the prostate in advanced and/or lymph node metastatic disease improve efficacy of androgen-deprivation therapy? A systematic review. *Eur Urol* 2010;58(2):261-9.
10. Walz J, Joniau S, Chun FK, Isbarn H, Jeldres C, Yossepowitch O, Chao-Yu H, Klein EA, Scardino PT, Reuther A, Poppel HV, Graefen M, Huland H, Karakiewicz PI. Pathological results and rates of treatment failure in high-risk prostate cancer patients after radical prostatectomy. *BJU Int* 2010.

12.3.4.5.2. Ausgeschlossene Publikationen (Volltextscreening)

Ausschlussgrund A1: Andere Population

1. Murphy DG, Kerger M, Crowe H, Peters JS, Costello AJ. Operative details and oncological and functional outcome of robotic-assisted laparoscopic radical prostatectomy: 400 cases with a minimum of 12 months follow-up. *Eur Urol* 2009;55(6):1358-66.

2. Shikanov S, Song J, Royce C, Al-Ahmadie H, Zorn K, Steinberg G, Zagaja G, Shalhav A, Eggener S. Length of positive surgical margin after radical prostatectomy as a predictor of biochemical recurrence. *J Urol* 2009;182(1):139-44.
3. Ploussard G, Salomon L, Allory Y, Terry S, Vordos D, Hoznek A, Abbou CC, Vacherot F, de la TA. Pathological findings and prostate-specific antigen outcomes after laparoscopic radical prostatectomy for high-risk prostate cancer. *BJU Int* 2010;106(1):86-90.
4. Rodriguez-Covarrubias F, Castillejos-Molina RA, Sotomayor M, Gabilondo F, Feria-Bernal G. The role of radical prostatectomy in the management of patients with high-grade prostate cancer and/or locally advanced disease. *Rev Invest Clin* 2009;61(6):456-60.

Ausschlussgrund A2: Anderes Thema (nicht Fragestellung)

1. Budaus L, Spethmann J, Isbarn H, Schmitges J, Beesch L, Haese A, Salomon G, Schlomm T, Fisch M, Heinzer H, Huland H, Graefen M, Steuber T. Inverse stage migration in patients undergoing radical prostatectomy: results of 8916 European patients treated within the last decade. *BJU Int* 2011.
2. Lee HW, Seo SI, Jeon SS, Lee HM, Choi HY. Can we predict real T3 stage prostate cancer in patients with clinical T3 (cT3) disease before radical prostatectomy? *Yonsei Med J* 2010;51(5):700-7.
3. Pierorazio PM, Epstein JI, Humphreys E, Han M, Walsh PC, Partin AW. The significance of a positive bladder neck margin after radical prostatectomy: the American Joint Committee on Cancer Pathological Stage T4 designation is not warranted. *J Urol* 2010;183(1):151-7.
4. Ploussard G, Rotondo S, Salomon L. The prognostic significance of bladder neck invasion in prostate cancer: is microscopic involvement truly a T4 disease? *BJU Int* 2010;105(6):776-81.
5. Villari D, Nesi G, Della MA, Palli D, Ceroti M, Castigli M, Filocamo MT, Li M, V, Nicita G. Radical retropubic prostatectomy for prostate cancer with microscopic bladder neck involvement: survival and prognostic implications. *BJU Int* 2010;105(7):946-50.
6. Yamamoto S, Kawakami S, Yonese J, Fujii Y, Tsukamoto T, Okubo Y, Kijima T, Ishikawa Y, Fukui I. Feasibility of antegrade radical prostatectomy for clinically locally advanced prostate cancer: a comparative study with clinically localized disease. *Int J Urol* 2010;17(8):720-5.
7. Inagaki T, Kohjimoto Y, Nishizawa S, Kuramoto T, Nanpo Y, Fujii R, Matsumura N, Shintani Y, Uekado Y, Hara I. PSA at postoperative three months can predict biochemical recurrence in patients with pathological T3 prostate cancer following radical prostatectomy. *Int J Urol* 2009;16(12):941-6.
8. Ploussard G, Rotondo S, Salomon L. Bladder neck involvement as pT4 disease in prostate cancer: implications for prognosis and patient surveillance. *Future Oncol* 2009;5(6):803-10.
9. Schelin S, Madsen M, Palmqvist E, Makela E, Klintonberg C, Aus G. Long-term follow-up after triple treatment of prostate cancer stage pT3. *Scand J Urol Nephrol* 2009;43(3):186-91.
10. Shelley MD, Kumar S, Coles B, Wilt T, Staffurth J, Mason MD. Adjuvant hormone therapy for localised and locally advanced prostate carcinoma: a systematic review and meta-analysis of randomised trials. *Cancer Treat Rev* 2009;35(7):540-6.
11. Walz J, Chun FK, Klein EA, Reuther A, Graefen M, Huland H, Karakiewicz PI. Risk-adjusted hazard rates of biochemical recurrence for prostate cancer patients after radical prostatectomy. *Eur Urol* 2009;55(2):412-9.
12. Richstone L, Bianco FJ, Shah HH, Kattan MW, Eastham JA, Scardino PT, Scherr DS. Radical prostatectomy in men aged ≥ 70 years: effect of age on upgrading, upstaging, and the accuracy of a preoperative nomogram. *BJU Int* 2008;101(5):541-6.
13. Trabulsi EJ, Linden RA, Gomella LG, McGinnis DE, Strup SE, Lallas CD. The addition of robotic surgery to an established laparoscopic radical prostatectomy program: effect on positive surgical margins. *Can J Urol* 2008;15(2):3994-9.
14. Vickers AJ, Bianco FJ, Gonen M, Cronin AM, Eastham JA, Schrag D, Klein EA, Reuther AM, Kattan MW, Pontes JE, Scardino PT. Effects of pathologic stage on the learning curve for radical prostatectomy: evidence that recurrence in organ-confined cancer is largely related to inadequate surgical technique. *Eur Urol* 2008;53(5):960-6.

15. Yee DS, Narula N, Amin MB, Skarecky DW, Ahlering TE. Robot-assisted radical prostatectomy: current evaluation of surgical margins in clinically low-, intermediate-, and high-risk prostate cancer. *J Endourol* 2009;23(9):1461-5.
16. Vickers AJ, Savage CJ, Bianco FJ, Klein EA, Kattan MW, Secin FP, Guilloneau BD, Scardino PT. Surgery confounds biology: The predictive value of stage-, grade- and prostate-specific antigen for recurrence after radical prostatectomy as a function of surgeon experience. *Int J Cancer* 2011;128(7):1697-702.

Ausschlussgrund A3: Anderer Publikationstyp (Editorial, Fallserie n<50, Fallbericht, Brief etc.)

1. Egevad L, Srigley JR, Delahunt B. International Society of Urological Pathology (ISUP) consensus conference on handling and staging of radical prostatectomy specimens: rationale and organization. *Mod Pathol* 2011;24(1):1-5.
2. Magi-Galluzzi C, Evans AJ, Delahunt B, Epstein JI, Griffiths DF, van der Kwast TH, Montironi R, Wheeler TM, Srigley JR, Egevad LL, Humphrey PA. International Society of Urological Pathology (ISUP) Consensus Conference on Handling and Staging of Radical Prostatectomy Specimens. Working group 3: extraprostatic extension, lymphovascular invasion and locally advanced disease. *Mod Pathol* 2011;24(1):26-38.
3. Boorjian SA, Blute ML. Surgical management of high risk prostate cancer: the Mayo Clinic experience. *Urol Oncol* 2008;26(5):530-2.92.
4. Casey JT, Meeks JJ, Greco KA, Wu SD, Nadler RB. Outcomes of locally advanced (T3 or greater) prostate cancer in men undergoing robot-assisted laparoscopic prostatectomy. *J Endourol* 2009;23(9):1519-22.

Ausschlussgrund A4: Unsystematischer Review

1. Boorjian SA, Karnes RJ, Viterbo R, Rangel LJ, Bergstralh EJ, Horwitz EM, Blute ML, Buyyounouski MK. Long-term survival after radical prostatectomy versus external-beam radiotherapy for patients with high-risk prostate cancer. *Cancer* 2011.
2. Heidenreich A, Schrader AJ. [Node-positive prostate cancer. Value of radical prostatectomy]. *Urologe A* 2010;49(10):1266-73.
3. Rosenthal SA, Sandler HM. Treatment strategies for high-risk locally advanced prostate cancer. *Nat Rev Urol* 2010;7(1):31-8.
4. Xylinas E, Dache A, Roupret M. Is radical prostatectomy a viable therapeutic option in clinically locally advanced (cT3) prostate cancer? *BJU Int* 2010;106(11):1596-600.
5. You D, Jeong IG, Kim CS. Role of radical prostatectomy for high-risk prostate cancer. *Korean J Urol* 2010;51(9):589-95.
6. Payne H. Management of locally advanced prostate cancer. *Asian J Androl* 2009;11(1):81-7.
7. Stratton KL, Chang SS. Locally advanced prostate cancer: the role of surgical management. *BJU Int* 2009;104(4):449-54.
8. Zantl N, Gschwend JE. [Value of cystoprostatectomy in locally advanced prostate carcinoma]. *Urologe A* 2008;47(11):1447-52.

12.3.5. Recherche zum Thema LDR-Brachytherapie

12.3.5.1. Fragestellungen

Population	Intervention	Kontrolle	Outcomes	Time aspects
Patienten mit mittlerem und hohem Risiko (PSA-Wert > 10 und/oder Gleason-Score > 7 und/oder cT-Kategorie > T2b)	LDR-Brachytherapie	Radikale Prostatektomie, perkutane Strahlentherapie Watchful Waiting, Hormontherapie	Mortalität (inkl. 5-Jahres Überleben, krankheitsfreies Überleben) Morbidity (PSA-Kinetik, Histologie) Lebensqualität Nebenwirkungen/Schäden	Keine Einschränkungen
Patienten mit lokal begrenztem Prostatakarzinom (<T3).	LDR-Brachytherapie + perkutane Strahlentherapie	Radikale Prostatektomie, perkutane Strahlentherapie Watchful Waiting/Active Surveillance, LDR-Brachytherapie allein	Mortalität (inkl. 5-Jahres Überleben, krankheitsfreies Überleben) Morbidity (PSA-Kinetik, Histologie) Lebensqualität Nebenwirkungen/Schäden	Keine Einschränkungen
Patienten mit lokal begrenztem Prostatakarzinom (<T3).	LDR-Brachytherapie + adjuvante Hormontherapie	LDR-Brachytherapie allein	Mortalität (inkl. 5-Jahres Überleben, krankheitsfreies Überleben) Morbidity (PSA-Kinetik, Histologie) Lebensqualität Nebenwirkungen/Schäden	Keine Einschränkungen

12.3.5.2. Recherchen

Ausschlusskriterien für erste Relevanzsichtung:

A1: andere Erkrankung

A2: Methodik (Letter, Editorial u.ä.)

PubMed (10. März 2011)

Nr.	Suchfrage	Anzahl
#5	#1 AND #2 AND #3 Limits: English, German, Publication date from 2000	255
#4	#1 AND #2 AND #3	293
#3	low dose rate OR LDR (Details: (low[All Fields] AND dose[All Fields] AND rate[All Fields]) OR LDR[All Fields])	29964
#2	brachytherapy (Details: "brachytherapy"[MeSH Terms] OR "brachytherapy"[All Fields])	15455
#1	Prostate cancer (Details: "prostatic neoplasms"[MeSH Terms] OR ("prostatic"[All Fields] AND "neoplasms"[All Fields]) OR "prostatic neoplasms"[All Fields] OR ("prostate"[All Fields] AND "cancer"[All Fields]) OR "prostate cancer"[All Fields])	92213

Anzahl der Treffer: 255

Davon relevant: 231

Cochrane (10. März 2011)

Nr.	Suchfrage	Anzahl
#1	"prostate cancer in Title, Abstract or Keywords and brachytherapy in Title, Abstract or Keywords and low dose rate OR LDR Title, Abstract or Keywords, from 2008 to 2011	13

- Cochrane Database of Systematic Reviews (1)
- Database of Abstracts of Reviews of Effects (0)
- Cochrane Central Register of Controlled Trials (10)
- Cochrane Methodology Register (0)
- Health Technology Assessment Database (1)
- NHS Economic Evaluation Database (1)

Anzahl der Treffer: 13

Davon neu: 7

Davon relevant: 6

12.3.5.3. Ein- und Ausschlusskriterien

Für Frage 1

Einschlussgründe	
E1 Zielgruppe	Patienten mit mittlerem und hohem Risiko (PSA-Wert > 10 und/oder Gleason-Score > 7 und/oder cT-Kategorie > T2b)
E2 Publikationstyp	RCT oder systematischer Review, ggf. mit Metaanalyse aus RCTs und Kohortenstudien, Fallserien mit Fallzahl > 50

Einschlussgründe

E3: Suchzeitraum	Publikationen seit August 2008 (letzte Recherche S3 Leitlinien-Gruppe)
E4: Sprachen	deutsch, englisch
E5 Intervention	LDR-Brachytherapie

Für Frage 2**Einschlussgründe**

E1 Zielgruppe	Patienten mit lokal begrenztem Prostatakarzinom (<T3).
E2 Publikationstyp	RCT oder systematischer Review, ggf. mit Metaanalyse aus RCTs und Kohortenstudien, Fallserien mit Fallzahl > 50
E3: Suchzeitraum	Publikationen seit 2000 (Primärforschung, da neues Thema)
E4: Sprachen	deutsch, englisch
E5 Intervention	LDR-Brachytherapie + perkutane Strahlentherapie

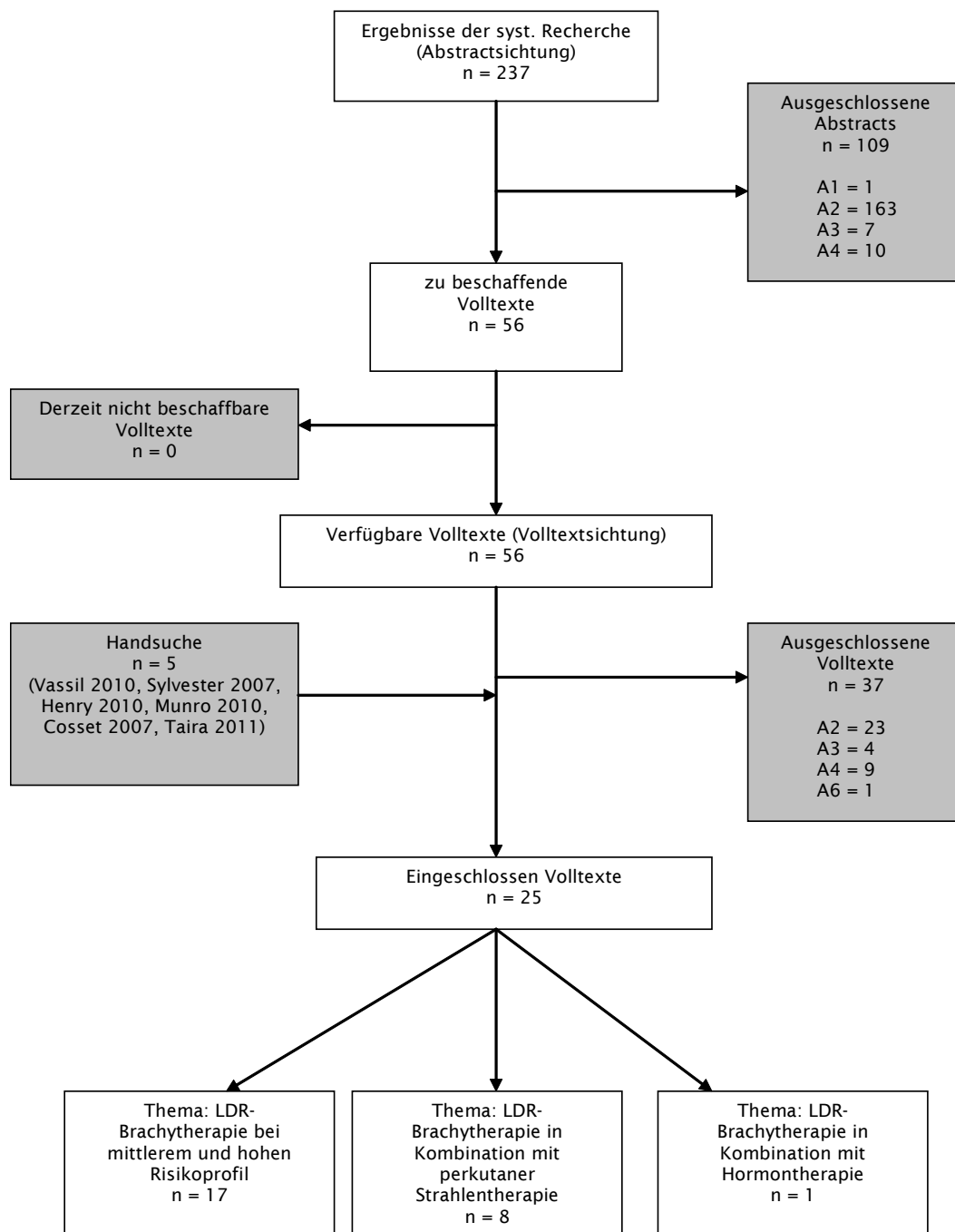
Für Frage 3**Einschlussgründe**

E1 Zielgruppe	Patienten mit lokal begrenztem Prostatakarzinom (<T3).
E2 Publikationstyp	RCT oder systematischer Review, ggf. mit Metaanalyse aus RCTs und Kohortenstudien, Fallserien mit Fallzahl > 50
E3: Suchzeitraum	Publikationen seit August 2008 (letzte Recherche S3 Leitlinien-Gruppe)
E4: Sprachen	deutsch, englisch
E5 Intervention	LDR-Brachytherapie + adjuvante Hormontherapie

Ausschlussgründe für Fragen 1-3

A1	andere Population
A2	Nicht Fragestellung (siehe oben)
A3	Anderer Publikationstyp (Kohortenstudie, Fallserie, Editorial, Fallbericht, Brief etc.)
A4	Unsystematischer Review
A5	Doppelpublikation oder aktuellere Publikation vorhanden
A6	Außerhalb des Suchzeitraums

Ergebnisse der Recherche



12.3.5.3.1. Eingeschlossene Publikationen

Thema LDR-Brachytherapie bei mittlerem und hohem Risiko

17. Stone NN, Stone MM, Rosenstein BS, Unger P, Stock RG. Influence of pretreatment and treatment factors on intermediate to long-term outcome after prostate brachytherapy. *J Urol* 2011;185(2):495-500.
18. Hinnen KA, Battermann JJ, van Roermund JG, Moerland MA, Jurgenliemk-Schulz IM, Frank SJ, van VM. Long-term biochemical and survival outcome of 921 patients treated with J-125 permanent prostate brachytherapy. *Int J Radiat Oncol Biol Phys* 2010;76(5):1433-8.

19. Pickles T, Keyes M, Morris WJ. Brachytherapy or conformal external radiotherapy for prostate cancer: a single-institution matched-pair analysis. *Int J Radiat Oncol Biol Phys* 2010;76(1):43-9.
20. Prada PJ, Juan G, Gonzalez-Suarez H, Fernandez J, Jimenez I, Amon J, Cepeda M. Prostate-specific antigen relapse-free survival and side-effects in 734 patients with up to 10 years of follow-up with localized prostate cancer treated by permanent iodine implants. *BJU Int* 2010;106(1):32-6.
21. Stone NN, Stock RG, Cesaretti JA, Unger P. Local control following permanent prostate brachytherapy: effect of high biologically effective dose on biopsy results and oncologic outcomes. *Int J Radiat Oncol Biol Phys* 2010;76(2):355-60.
22. Taira AV, Merrick GS, Galbreath RW, Wallner KE, Butler WM. Natural history of clinically staged low- and intermediate-risk prostate cancer treated with monotherapeutic permanent interstitial brachytherapy. *Int J Radiat Oncol Biol Phys* 2010;76(2):349-54.
23. Ho AY, Burri RJ, Cesaretti JA, Stone NN, Stock RG. Radiation dose predicts for biochemical control in intermediate-risk prostate cancer patients treated with low-dose-rate brachytherapy. *Int J Radiat Oncol Biol Phys* 2009;75(1):16-22.
24. Koukourakis G, Kelekis N, Armonis V, Kouloulis V. Brachytherapy for prostate cancer: a systematic review. *Adv Urol* 2009;327945.
25. Wong WW, Vora SA, Schild SE, Ezzell GA, Andrews PE, Ferrigni RG, Swanson SK. Radiation dose escalation for localized prostate cancer: intensity-modulated radiotherapy versus permanent transperineal brachytherapy. *Cancer* 2009;115(23):5596-606.
26. Kao J, Stone NN, Lavaf A, Dumane V, Cesaretti JA, Stock RG. (125)I monotherapy using D90 implant doses of 180 Gy or greater. *Int J Radiat Oncol Biol Phys* 2008;70(1):96-101.
27. Pinkawa M, Piroth MD, Holy R, Fishedick K, Schaar S, Borchers H, Heidenreich A, Eble MJ. Prostate-specific antigen kinetics following external-beam radiotherapy and temporary (Ir-192) or permanent (I-125) brachytherapy for prostate cancer. *Radiother Oncol* 2010;96(1):25-9.
28. Cosset JM, Flam T, Thiounn N, Gomme S, Rosenwald JC, Asselain B, Pontvert D, Henni M, Debre B, Chauveinc L. Selecting patients for exclusive permanent implant prostate brachytherapy: the experience of the Paris Institut Curie/Cochin Hospital/Necker Hospital group on 809 patients. *Int J Radiat Oncol Biol Phys* 2008;71(4):1042-8.
29. Henry AM, Al-Qaisieh B, Gould K, Bownes P, Smith J, Carey B, Bottomley D, Ash D. Outcomes following iodine-125 monotherapy for localized prostate cancer: the results of leeds 10-year single-center brachytherapy experience. *Int J Radiat Oncol Biol Phys* 2010;76(1):50-6.
30. Munro NP, Al-Qaisieh B, Bownes P, Smith J, Carey B, Bottomley D, Ash D, Henry AM. Outcomes from Gleason 7, intermediate risk, localized prostate cancer treated with iodine-125 monotherapy over 10 years. *Radiother Oncol* 2010;96(1):34-7.
31. Sylvester JE, Grimm PD, Blasko JC, Millar J, Origo PF, III, Skoglund S, Galbreath RW, Merrick G. 15-Year biochemical relapse free survival in clinical Stage T1-T3 prostate cancer following combined external beam radiotherapy and brachytherapy; Seattle experience. *Int J Radiat Oncol Biol Phys* 2007;67(1):57-64.
32. Vassil AD, Murphy ES, Reddy CA, Angermeier KW, Altman A, Chehade N, Ulchaker J, Klein EA, Ciezki JP. Five year biochemical recurrence free survival for intermediate risk prostate cancer after radical prostatectomy, external beam radiation therapy or permanent seed implantation. *Urology* 2010;76(5):1251-7.

Thema LDR-Brachytherapie in Kombination mit perkutaner Strahlentherapie

1. Valakh V, Kirichenko A, Miller R, Sunder T, Miller L, Fuhrer R. Combination of IG-IMRT and permanent source prostate brachytherapy in patients with organ-confined prostate cancer: GU and GI toxicity and effect on erectile function. *Brachytherapy* 2010.
2. Koontz BF, Chino J, Lee WR, Hahn CA, Buckley N, Huang S, Kim J, Reagan R, Joyner R, Anscher MS. Morbidity and prostate-specific antigen control of external beam radiation therapy plus low-dose-rate brachytherapy boost for low, intermediate, and high-risk prostate cancer. *Brachytherapy* 2009;8(2):191-6.

3. Jani AB, Feinstein JM, Pasciak R, Kregel S, Weichselbaum RR. Role of external beam radiotherapy with low-dose-rate brachytherapy in treatment of prostate cancer. *Urology* 2006;67(5):1007-11.
4. Singh AM, Gagnon G, Collins B, Niroomand-Rad A, McRae D, Zhang Y, Regan J, Lynch J, Dritschilo A. Combined external beam radiotherapy and Pd-103 brachytherapy boost improves biochemical failure free survival in patients with clinically localized prostate cancer: results of a matched pair analysis. *Prostate* 2005;62(1):54-60.
5. Kupelian PA, Potters L, Khuntia D, Ciezki JP, Reddy CA, Reuther AM, Carlson TP, Klein EA. Radical prostatectomy, external beam radiotherapy <72 Gy, external beam radiotherapy > or =72 Gy, permanent seed implantation, or combined seeds/external beam radiotherapy for stage T1-T2 prostate cancer. *Int J Radiat Oncol Biol Phys* 2004;58(1):25-33.
6. Nilsson S, Norlen BJ, Widmark A. A systematic overview of radiation therapy effects in prostate cancer. *Acta Oncol* 2004;43(4):316-81.
7. Merrick GS, Butler WM, Galbreath RW, Lief JH. Five-year biochemical outcome following permanent interstitial brachytherapy for clinical T1-T3 prostate cancer. *Int J Radiat Oncol Biol Phys* 2001;51(1):41-8. (in Nilsson 2004 eingeschlossen)
8. Wong WW, Vora SA, Schild SE, Ezzell GA, Andrews PE, Ferrigni RG, Swanson SK. Radiation dose escalation for localized prostate cancer: intensity-modulated radiotherapy versus permanent transperineal brachytherapy. *Cancer* 2009;115(23):5596-606.

Thema: LDR-Brachytherapie in Kombination mit Hormontherapie

1. Stock RG, Yalamanchi S, Hall SJ, Stone NN. Impact of hormonal therapy on intermediate risk prostate cancer treated with combination brachytherapy and external beam irradiation. *J Urol* 2010;183(2):546-50.

12.3.5.3.2. Ausgeschlossene Publikationen (Volltextscreening)

Ausschlussgrund A2: Anderes Thema (nicht Fragestellung)

1. Puthawala AA, Syed AM, Austin PA, Cherlow JM, Perley JM, Shanberg AM, Sawyer DE, Ingram JE, Baghdassarian R, Wachs BH, Perley JE, Londrc A, Espinoza-Ferrel T. Long-term results of treatment for prostate carcinoma by staging pelvic lymph node dissection and definitive irradiation using low-dose rate temporary iridium-192 interstitial implant and external beam radiotherapy. *Cancer* 2001;92(8):2084-94.
2. Pieters BR, Geijsen ED, Koedooder K, Blank LE, Rezaie E, van der Grient JN, de Reijke TM, Koning CC. Treatment Results of PDR Brachytherapy Combined With External Beam Radiotherapy in 106 Patients With Intermediate- to High-Risk Prostate Cancer. *Int J Radiat Oncol Biol Phys* 2011;79(4):1037-42.
3. Burri RJ, Ho AY, Forsythe K, Cesaretti JA, Stone NN, Stock RG. Young men have equivalent biochemical outcomes compared with older men after treatment with brachytherapy for prostate cancer. *Int J Radiat Oncol Biol Phys* 2010;77(5):1315-21.
4. Gomez-Iturriaga PA, Crook J, Borg J, Lockwood G, Fleshner N. Median 5 year follow-up of 125iodine brachytherapy as monotherapy in men aged <or=55 years with favorable prostate cancer. *Urology* 2010;75(6):1412-6.
5. Jabbari S, Weinberg VK, Shinohara K, Speight JL, Gottschalk AR, Hsu IC, Pickett B, McLaughlin PW, Sandler HM, Roach M, III. Equivalent biochemical control and improved prostate-specific antigen nadir after permanent prostate seed implant brachytherapy versus high-dose three-dimensional conformal radiotherapy and high-dose conformal proton beam radiotherapy boost. *Int J Radiat Oncol Biol Phys* 2010;76(1):36-42.
6. Kalakota K, Rakhno E, Pelizzari CA, Jani AB, Liauw SL. Late rectal toxicity after prostate brachytherapy: influence of supplemental external beam radiation on dose-volume histogram analysis. *Brachytherapy* 2010;9:131-6.
7. Krauss D, Kestin L, Ye H, Brabbins D, Ghilezan M, Gustafson G, Vicini F, Martinez A. Lack of Benefit for the Addition of Androgen Deprivation Therapy to Dose-Escalated Radiotherapy in the Treatment of Intermediate- and High-Risk Prostate Cancer. *Int J Radiat Oncol Biol Phys* 2010.

8. McGrath SD, Antonucci JV, Fitch DL, Ghilezan M, Gustafson GS, Vicini FA, Martinez AA, Kestin LL. PSA bounce after prostate brachytherapy with or without neoadjuvant androgen deprivation. *Brachytherapy* 2010;9(2):137-44.
9. Tanaka N, Fujimoto K, Asakawa I, Hirayama A, Yoneda T, Yoshida K, Hirao Y, Hasegawa M, Konishi N. Variations in health-related quality of life in Japanese men who underwent iodine-125 permanent brachytherapy for localized prostate cancer. *Brachytherapy* 2010;9(4):300-6.
10. Zelefsky MJ, Yamada Y, Pei X, Hunt M, Cohen G, Zhang Z, Zaider M. Comparison of Tumor Control and Toxicity Outcomes of High-dose Intensity-modulated Radiotherapy and Brachytherapy for Patients With Favorable Risk Prostate Cancer. *Urology* 2010.
11. Keyes M, Miller S, Moravan V, Pickles T, McKenzie M, Pai H, Liu M, Kwan W, Agranovich A, Spadinger I, Lapointe V, Halperin R, Morris WJ. Predictive factors for acute and late urinary toxicity after permanent prostate brachytherapy: long-term outcome in 712 consecutive patients. *Int J Radiat Oncol Biol Phys* 2009;73(4):1023-32.
12. Morris WJ, Keyes M, Palma D, Spadinger I, McKenzie MR, Agranovich A, Pickles T, Liu M, Kwan W, Wu J, Berthelet E, Pai H. Population-based study of biochemical and survival outcomes after permanent 125I brachytherapy for low- and intermediate-risk prostate cancer. *Urology* 2009;73(4):860-5.
13. Morris WJ, Keyes M, Palma D, McKenzie M, Spadinger I, Agranovich A, Pickles T, Liu M, Kwan W, Wu J, Lapointe V, Berthelet E, Pai H, Harrison R, Kwa W, Bucci J, Racz V, Woods R. Evaluation of dosimetric parameters and disease response after 125 iodine transperineal brachytherapy for low- and intermediate-risk prostate cancer. *Int J Radiat Oncol Biol Phys* 2009;73(5):1432-8.
14. Pe ML, Trabulsi EJ, Kedika R, Pequignot E, Dicker AP, Gomella LG, Valicenti RK. Effect of percentage of positive prostate biopsy cores on biochemical outcome in low-risk PCa treated with brachytherapy or 3D-CRT. *Urology* 2009;73(6):1328-34.
15. Peters CA, Stock RG, Blacksburg SR, Stone NN. Effect of family history on outcomes in patients treated with definitive brachytherapy for clinically localized prostate cancer. *Int J Radiat Oncol Biol Phys* 2009;73(1):24-9.
16. Tanaka N, Fujimoto K, Hirao Y, Asakawa I, Hasegawa M, Konishi N. Variations in international prostate symptom scores, uroflowmetric parameters, and prostate volume after (125I) permanent brachytherapy for localized prostate cancer. *Urology* 2009;74(2):407-11.
17. Morillo V, Guinot JL, Tortajada I, Ricos JV, Arribas L, Maronas M, Estornell M, Casanova J. Secondary effects and biochemical control in patients with early prostate cancer treated with (125)-I seeds. *Clin Transl Oncol* 2008;10(6):359-66.
18. Soumarova R, Homola L, Perkova H, Stursa M. Three-dimensional conformal external beam radiotherapy versus the combination of external radiotherapy with high-dose rate brachytherapy in localized carcinoma of the prostate: comparison of acute toxicity. *Tumori* 2007;93(1):37-44.
19. Merrick GS, Butler WM, Wallner KE, Galbreath RW, Allen Z, Lief JH, Adamovich E. Influence of body mass index on biochemical outcome after permanent prostate brachytherapy. *Urology* 2005;65(1):95-100.
20. Morton GC. The emerging role of high-dose-rate brachytherapy for prostate cancer. *Clin Oncol (R Coll Radiol)* 2005;17(4):219-27.
21. Potters L, Morgenstern C, Calugaru E, Fearn P, Jassal A, Presser J, Mullen E. 12-year outcomes following permanent prostate brachytherapy in patients with clinically localized prostate cancer. *J Urol* 2005;173(5):1562-6.
22. Theodorescu D, Gillenwater JY, Koutrouvelis PG. Prostatourethral-rectal fistula after prostate brachytherapy. *Cancer* 2000;89(10):2085-91.
23. Kubicek GJ, Naguib M, Redfield S, Grayback N, Olszanski A, Dawson G, Brown SI. PSA decrease during combined-modality radiotherapy predicts for treatment outcome. *Int J Radiat Oncol Biol Phys* 2010;78(3):759-62.

Ausschlussgrund A3: Anderer Publikationstyp (Editorial, Fallbericht, Brief etc.)

1. Law AB, McLaren DB. Non-surgical treatment for early prostate cancer. *J R Coll Physicians Edinb* 2010;40(4):340-2.
2. Peinemann F, Grouven U, Bartel C, Borchers H, Pinkawa M, Heidenreich A, Hemkens LG, Schnell IP, Jahn R, Sauerland S. Low-dose rate brachytherapy for men with localized prostate cancer. Peinemann Frank , Grouven Ulrich , Bartel Carmen , Borchers

Holger , Pinkawa Michael , Heidenreich Axel , Hemkens Lars G , Schnell Inderst Petra , Jahn Rebecca , Sauerland Stefan Low dose rate brachytherapy for men with localized prostate cancer Cochran 2010.

3. Borchers H, Pinkawa M, Donner A, Wolter TP, Pallua N, Eble MJ, Jakse G. Rectourethral fistula following LDR brachytherapy. *Urol Int* 2009;82(3):365-6.
4. Wyler SF, Engeler DS, Seelentag W, Ries G, Schmid HP. Health-related quality of life after radical prostatectomy and low-dose-rate brachytherapy for localized prostate cancer. *Urol Int* 2009;82(1):17-23.

Ausschlussgrund A4: Unsystematischer Review

1. Mabweesh NJ, Matzkin H. The role of brachytherapy in the 21st century for prostate cancer. *Minerva Urol Nefrol* 2010;62(2):203-11.
2. Soto DE, McLaughlin PW. Combined permanent implant and external-beam radiation therapy for prostate cancer. *Semin Radiat Oncol* 2008;18(1):23-34.
3. Stubinger SH, Wilhelm R, Kaufmann S, Doring M, Hautmann S, Junemann KP, Galalae R. [Brachytherapy of the prostate cancer]. *Urologe A* 2008;47(3):284-90.
4. Voulgaris S, Nobes JP, Laing RW, Langley SE. State-of-the-art: prostate LDR brachytherapy. *Prostate Cancer Prostatic Dis* 2008;11(3):237-40.
5. Bratt O. The urologist's guide to low dose-rate interstitial brachytherapy with permanent seed implants for localized prostate cancer. *BJU Int* 2007;99(3):497-501.
6. Horwitz EM, Uzzo RG, Miller N, Theodorescu D. Brachytherapy for prostate cancer: follow-up and management of treatment failures. *Urol Clin North Am* 2003;30(4):737-ix.
7. Blasko JC, Mate T, Sylvester JE, Grimm PD, Cavanagh W. Brachytherapy for carcinoma of the prostate: techniques, patient selection, and clinical outcomes. *Semin Radiat Oncol* 2002;12(1):81-94.
8. Siegmund M, Musial A, Weiss J, Alken P. [Ldr brachytherapy, a minimally invasive alternative in the treatment of organ-confined prostate cancer]. *Onkologie* 2001;24 Suppl 5:46-50.
9. Boehmer D, Buchali A, Deger S, Loening SA, Budach V. [Value of radiotherapy in urology]. *Urologe A* 2000;39(2):120-5.

Ausschlussgrund A6:Außerhalb des Suchzeitraums

1. Merrick GS, Butler WM, Wallner KE, Galbreath RW, Lief JH, Allen Z, Adamovich E. Impact of supplemental external beam radiotherapy and/or androgen deprivation therapy on biochemical outcome after permanent prostate brachytherapy. *Int J Radiat Oncol Biol Phys* 2005;61(1):32-43.

12.3.6. Recherchen zum Thema perkutane Strahlentherapie

12.3.6.1. Fragestellungen zum lokal begrenzten Prostatakarzinom

Population	Intervention	Kontrolle	Outcomes	Time aspects
Patienten mit lokal begrenztem Prostatakarzinom (<T3) und hohem Risikoprofil (PSA > 20 ng/ml, Gleason Score \geq 8,	Externe Strahlentherapie +/- Hormontherapie	Radikale Prostatektomie, interstitielle Brachytherapie, Watchful Waiting, Hormontherapie	Mortalität (inkl. 5-Jahres Überleben, krankheitsfreies Überleben) Morbidity (PSA-Kinetik, Histologie) Lebensqualität Nebenwirkungen/Schäden	Keine Einschränkungen

Population	Intervention	Kontrolle	Outcomes	Time aspects
Patienten mit lokal begrenztem Prostatakarzinom (<T3).	Externe Strahlentherapie mit Dosisescalation	Externe Strahlentherapie ohne Dosisescalation	Mortalität (inkl. 5-Jahres Überleben, krankheitsfreies Überleben) Morbidity (PSA-Kinetik, Histologie) Lebensqualität Nebenwirkungen/Schäden	Keine Einschränkungen

12.3.6.1.1. Recherchen

Ausschlusskriterien für Relevanzsichtung festlegen:

A1: andere Erkrankung

A2: Methodik (Letter, Editorial u.ä.)

PubMed (12. April 2011)

Nr.	Suchfrage	Anzahl
#5	#1 AND #2 AND #3 Limits: English, German, Publication date from 2008/06	326
#4	#1 AND #2 AND #3	1040
#3	"high risk" (Details: " high risk "[All Fields])	130956
#2	radiotherapy OR radiation OR radiotherapeutic OR EBRT (Details: ("radiotherapy"[Subheading] OR "radiotherapy"[All Fields] OR "radiotherapy"[MeSH Terms]) OR ("radiation"[MeSH Terms] OR "radiation"[All Fields]) OR ("radiotherapy"[MeSH Terms] OR "radiotherapy"[All Fields] OR "radiotherapeutic"[All Fields]) OR EBRT[All Fields])	681657
#1	Prostate cancer (Details: "prostatic neoplasms"[MeSH Terms] OR ("prostatic"[All Fields] AND "neoplasms"[All Fields]) OR "prostatic neoplasms"[All Fields] OR ("prostate"[All Fields] AND "cancer"[All Fields]) OR "prostate cancer"[All Fields])	92895

Anzahl der Treffer: 326

Davon relevant: 320

Davon noch nicht in 1. Recherche: 263

Cochrane (12. April 2011)

Nr.	Suchfrage	Anzahl
#1	"prostate cancer in Title, Abstract or Keywords and radiotherapy or radiation or radiotherapeutic or EBRT in Title, Abstract or Keywords and high risk in Title, Abstract or Keywords, from 2008 to 2011	31

- Cochrane Database of Systematic Reviews (1)
- Database of Abstracts of Reviews of Effects (0)
- Cochrane Central Register of Controlled Trials (30)
- Cochrane Methodology Register (0)
- Health Technology Assessment Database (0)
- NHS Economic Evaluation Database (0)

12.3.6.1.2. Ein- und Ausschlusskriterien

Für Frage 1

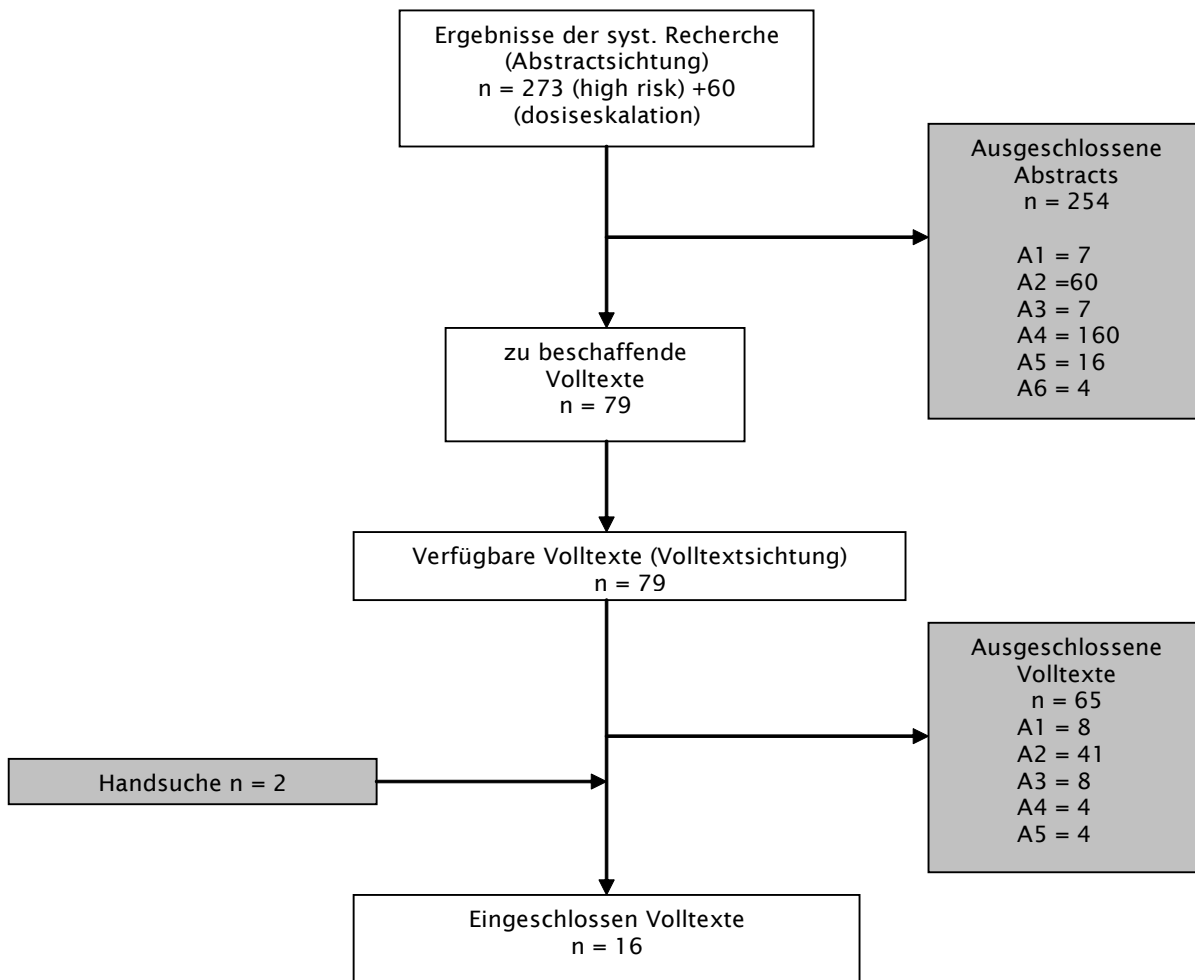
Einschlussgründe	
E1 Zielgruppe	Patienten mit lokal begrenztem Prostatakarzinom (<T3) und hohem Risikoprofil (PSA > 20 ng/ml, Gleason Score > 8,
E2 Publikationstyp	RCT oder systematischer Review, ggf. mit Metaanalyse aus RCTs und Kohortenstudien
E3: Suchzeitraum	Publikationen seit August 2008 (letzte Recherche S3 Leitlinien-Gruppe)
E4: Sprachen	deutsch, englisch
E5 Intervention	Externe Strahlentherapie
Ausschlussgründe	
A1	andere Population
A2	Nicht Fragestellung (siehe oben)
A3	Anderer Publikationstyp (Editorial, Fallbericht, Brief etc.)
A4	Unsystematischer Review
A5	Doppelpublikation oder aktuellere Publikation vorhanden

Für Frage 2

Einschlussgründe	
E1 Zielgruppe	Patienten mit lokal begrenztem und lokal fortgeschrittenem primären Prostatakarzinom (cT1-cT4)
E2 Publikationstyp	RCT oder systematischer Review, ggf. mit Metaanalyse aus RCTs
E3: Suchzeitraum	Publikationen seit August 2008 (letzte Recherche S3 Leitlinien-Gruppe)

Einschlussgründe	
E4: Sprachen	deutsch, englisch
E5 Intervention	Externe Strahlentherapie + Dosisescalation
Ausschlussgründe	
A1	andere Population
A2	Nicht Fragestellung (siehe oben)
A3	Anderer Publikationstyp (Kohortenstudie, Fallserie, Editorial, Fallbericht, Brief etc.)
A4	Unsystematischer Review
A5	Doppelpublikation oder aktuellere Publikation vorhanden

12.3.6.1.3. Ergebnisse der Recherche



12.3.6.1.4. Eingeschlossene Publikationen

1. Abdollah F, Sun M, Thuret R, Jeldres C, Tian Z, Briganti A, Shariat SF, Perrotte P, Rigatti P, Montorsi F, Karakiewicz PI. A competing-risks analysis of survival after al-

- ternative treatment modalities for prostate cancer patients: 1988-2006. *Eur Urol* 2011;59(1):88-95.
2. Arcangeli G, Fowler J, Gomellini S, Arcangeli S, Saracino B, Petrongari MG, Benassi M, Strigari L. Acute and late toxicity in a randomized trial of conventional versus hypofractionated three-dimensional conformal radiotherapy for prostate cancer. *Int J Radiat Oncol Biol Phys* 2011;79(4):1013-21.
 3. Kuban DA, Levy LB, Cheung MR, Lee AK, Choi S, Frank S, Pollack A. Long-term failure patterns and survival in a randomized dose-escalation trial for prostate cancer. Who dies of disease? *Int J Radiat Oncol Biol Phys* 2011;79(5):1310-7.
 4. Al-Mamgani A, Heemsbergen WD, Levendag PC, Lebesque JV. Subgroup analysis of patients with localized prostate cancer treated within the Dutch-randomized dose escalation trial. *Radiother Oncol* 2010;96(1):13-8.
 5. Arcangeli G, Saracino B, Gomellini S, Petrongari MG, Arcangeli S, Sentinelli S, Marzi S, Landoni V, Fowler J, Strigari L. A prospective phase III randomized trial of hypofractionation versus conventional fractionation in patients with high-risk prostate cancer. *Int J Radiat Oncol Biol Phys* 2010;78(1):11-8.
 6. Cooperberg MR, Vickers AJ, Broering JM, Carroll PR. Comparative risk-adjusted mortality outcomes after primary surgery, radiotherapy, or androgen-deprivation therapy for localized prostate cancer. *Cancer* 2010;116(22):5226-34.
 7. Arcangeli G, Strigari L, Arcangeli S, Petrongari MG, Saracino B, Gomellini S, Papalia R, Simone G, De CP, Gallucci M. Retrospective comparison of external beam radiotherapy and radical prostatectomy in high-risk, clinically localized prostate cancer. *Int J Radiat Oncol Biol Phys* 2009;75(4):975-82.
 8. Takizawa I, Hara N, Nishiyama T, Kaneko M, Hoshii T, Tsuchida E, Takahashi K. Oncological results, functional outcomes and health-related quality-of-life in men who received a radical prostatectomy or external beam radiation therapy for localized prostate cancer: a study on long-term patient outcome with risk stratification. *Asian J Androl* 2009;11(3):283-90.
 9. Viani GA, Stefano EJ, Afonso SL. Higher-than-conventional radiation doses in localized prostate cancer treatment: a meta-analysis of randomized, controlled trials. *Int J Radiat Oncol Biol Phys* 2009;74(5):1405-18.
 10. Zietman AL, Bae K, Slater JD, Shipley WU, Efsthathiou JA, Coen JJ, Bush DA, Lunt M, Spiegel DY, Skowronski R, Jabola BR, Rossi CJ. Randomized trial comparing conventional-dose with high-dose conformal radiation therapy in early-stage adenocarcinoma of the prostate: long-term results from proton radiation oncology group/american college of radiology 95-09. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology* 2010;28:1106-11.
 11. Al-Mamgani A, van Putten WL, van der Wielen GJ, Levendag PC, Incrocci L. Dose Escalation and Quality of Life in Patients With Localized Prostate Cancer Treated With Radiotherapy: Long-Term Results of the Dutch Randomized Dose-Escalation Trial (CKTO 96-10 Trial). *Int J Radiat Oncol Biol Phys* 2011;79(4):1004-12.
 12. Al-Mamgani A, van Putten WL, Heemsbergen WD, van Leenders GJ, Slot A, Dielwart MF, Incrocci L, Lebesque JV. Update of Dutch multicenter dose-escalation trial of radiotherapy for localized prostate cancer. *Int J Radiat Oncol Biol Phys* 2008;72(4):980-8.
 13. Al-Mamgani A, Heemsbergen WD, Peeters ST, Lebesque JV. Role of intensity-modulated radiotherapy in reducing toxicity in dose escalation for localized prostate cancer. *Int J Radiat Oncol Biol Phys* 2009;73(3):685-91.
 14. Goldner G, Dimopoulos J, Kirisits C, Potter R. Moderate dose escalation in three-dimensional conformal localized prostate cancer radiotherapy: single-institutional experience in 398 patients comparing 66 Gy versus 70 Gy versus 74 Gy. *Strahlenther Onkol* 2009;185(7):438-45.
 15. Goldner G, Bombosch V, Geinitz H, Becker G, Wachter S, Glocker S, Zimmermann F, Wachter-Gerstner N, Schrott A, Bamberg M, Molls M, Feldmann H, Potter R. Moderate risk-adapted dose escalation with three-dimensional conformal radiotherapy of localized prostate cancer from 70 to 74 Gy. First report on 5-year morbidity and biochemical control from a prospective Austrian-German multicenter phase II trial. *Strahlenther Onkol* 2009;185(2):94-100.
 16. Zhou EH, Ellis RJ, Cherullo E, Colussi V, Xu F, Chen WD, Gupta S, Whalen CC, Bodner D, Resnick MI, Rimm AA, Koroukian SM. Radiation therapy and survival in prostate cancer patients: a population-based study. *Int J Radiat Oncol Biol Phys* 2009;73:15-23

12.3.6.1.5. Ausgeschlossene Publikationen (Volltextscreening)

Ausschlussgrund A1: Andere Population

1. Grubb RL, Kibel AS. High-risk localized prostate cancer: role of radical prostatectomy. *Curr Opin Urol* 2010;20(3):204-10.
2. Engels B, Soete G, Tournel K, Bral S, De CP, Verellen D, Storme G. Helical tomotherapy with simultaneous integrated boost for high-risk and lymph node-positive prostate cancer: early report on acute and late toxicity. *Technol Cancer Res Treat* 2009;8(5):353-9.
3. Milecki P, Baczyk M, Skowronek J, Antczak A, Kwias Z, Martenka P. Benefit of whole pelvic radiotherapy combined with neoadjuvant androgen deprivation for the high-risk prostate cancer. *J Biomed Biotechnol* 2009;2009:625394.
4. Wong WW, Vora SA, Schild SE, Ezzell GA, Andrews PE, Ferrigni RG, Swanson SK. Radiation dose escalation for localized prostate cancer: intensity-modulated radiotherapy versus permanent transperineal brachytherapy. *Cancer* 2009;115(23):5596-606.
5. Payne H. Radiation in high-risk prostate cancer: how much is enough? *BJU Int* 2008;102(6):663-5.
6. Zelefsky MJ, Yamada Y, Fuks Z, Zhang Z, Hunt M, Cahlon O, Park J, Shippy A. Long-term results of conformal radiotherapy for prostate cancer: impact of dose escalation on biochemical tumor control and distant metastases-free survival outcomes. *Int J Radiat Oncol Biol Phys* 2008;71(4):1028-33.
7. Coen JJ, Bae K, Zietman AL, Patel B, Shipley WU, Slater JD, Rossi CJ. Acute and Late Toxicity After Dose Escalation to 82 GyE Using Conformal Proton Radiation for Localized Prostate Cancer: Initial Report of American College of Radiology Phase II Study 03-12. *Int J Radiat Oncol Biol Phys* 2010.
8. Bolla M. What is the role of radiation dose escalation in the treatment of localized prostate cancer? *Nat Clin Pract Urol* 2008;5(8):418-9.

Ausschlussgrund A2: Anderes Thema (nicht Fragestellung)

1. Agoston P, Major T, Frohlich G, Szabo Z, Lovey J, Fodor J, Kasler M, Polgar C. Moderate dose escalation with single-fraction high-dose rate brachytherapy boost for clinically localized intermediate- and high-risk prostate cancer: 5-year outcome of the first 100 consecutively treated patients. *Brachytherapy* 2011.
2. Nguyen PL, Chen RC, Hoffman KE, Trofimov A, Efstathiou JA, Coen JJ, Shipley WU, Zietman AL, Talcott JA. Rectal dose-volume histogram parameters are associated with long-term patient-reported gastrointestinal quality of life after conventional and high-dose radiation for prostate cancer: a subgroup analysis of a randomized trial. *Int J Radiat Oncol Biol Phys* 2010;78(4):1081-5.
3. Pickles T, Keyes M, Morris WJ. Brachytherapy or conformal external radiotherapy for prostate cancer: a single-institution matched-pair analysis. *Int J Radiat Oncol Biol Phys* 2010;76(1):43-9.
4. Ballare A, Di SM, Loi G, Ferrari G, Beldi D, Krengli M. Conformal radiotherapy of clinically localized prostate cancer: analysis of rectal and urinary toxicity and correlation with dose-volume parameters. *Tumori* 2009;95(2):160-8.
5. Brada M, Pijls-Johannesma M, De RD. Current clinical evidence for proton therapy. *Cancer J* 2009;15(4):319-24.
6. Efstathiou JA, Trofimov AV, Zietman AL. Life, liberty, and the pursuit of protons: an evidence-based review of the role of particle therapy in the treatment of prostate cancer. *Cancer J* 2009;15(4):312-8.
7. Wong WW, Vora SA, Schild SE, Ezzell GA, Andrews PE, Ferrigni RG, Swanson SK. Radiation dose escalation for localized prostate cancer: intensity-modulated radiotherapy versus permanent transperineal brachytherapy. *Cancer* 2009;115(23):5596-606.
8. Prada PJ, Gonzalez H, Fernandez J, Bilbao P. High-dose-rate intensity modulated brachytherapy with external-beam radiotherapy improves local and biochemical control in patients with high-risk prostate cancer. *Clin Transl Oncol* 2008;10(7):415-21.
9. Hamstra DA, Bae K, Pilepich MV, Hanks GE, Grignon DJ, McGowan DG, Roach M, Lawton C, Lee RJ, Sandler H. Older Age Predicts Decreased Metastasis and Prostate

- Cancer-Specific Death for Men Treated with Radiation Therapy: Meta-Analysis of Radiation Therapy Oncology Group Trials. *Int J Radiat Oncol Biol Phys* 2011.
10. Alicikus ZA, Yamada Y, Zhang Z, Pei X, Hunt M, Kollmeier M, Cox B, Zelefsky MJ. Ten-year outcomes of high-dose, intensity-modulated radiotherapy for localized prostate cancer. *Cancer* 2010.
 11. Guckenberger M, Ok S, Polat B, Sweeney RA, Flentje M. Toxicity after intensity-modulated, image-guided radiotherapy for prostate cancer. *Strahlenther Onkol* 2010;186(10):535-43.
 12. Gutt R, Tonlaar N, Kunnavakkam R, Karrison T, Weichselbaum RR, Liauw SL. Statin use and risk of prostate cancer recurrence in men treated with radiation therapy. *J Clin Oncol* 2010;28(16):2653-9.
 13. Hirano D, Nagane Y, Satoh K, Mochida J, Sugimoto S, Ichinose T, Takahashi S, Maebayashi T, Saitoh T. Neoadjuvant LHRH analog plus estramustine phosphate combined with three-dimensional conformal radiotherapy for intermediate- to high-risk prostate cancer: a randomized study. *Int Urol Nephrol* 2010;42(1):81-8.
 14. Nguyen PL, Chen MH, Renshaw AA, Loffredo M, Kantoff PW, D'Amico AV. Survival following radiation and androgen suppression therapy for prostate cancer in healthy older men: implications for screening recommendations. *Int J Radiat Oncol Biol Phys* 2010;76(2):337-41.
 15. Pervez N, Small C, MacKenzie M, Yee D, Parliament M, Ghosh S, Mihai A, Amanie J, Murtha A, Field C, Murray D, Fallone G, Pearcey R. Acute toxicity in high-risk prostate cancer patients treated with androgen suppression and hypofractionated intensity-modulated radiotherapy. *Int J Radiat Oncol Biol Phys* 2010;76(1):57-64.
 16. Rodrigues G, Bae K, Roach M, Lawton C, Donnelly B, Grignon D, Hanks G, Porter A, Lepor H, Sandler H. Impact of Ultrahigh Baseline PSA Levels on Biochemical and Clinical Outcomes in Two Radiation Therapy Oncology Group Prostate Clinical Trials. *Int J Radiat Oncol Biol Phys* 2010.
 17. Shimazaki J, Tsuji H, Ishikawa H, Okada T, Akakura K, Suzuki H, Harada M, Tsujii H. Carbon ion radiotherapy for treatment of prostate cancer and subsequent outcomes after biochemical failure. *Anticancer Res* 2010;30(12):5105-11.
 18. Tareen B, Kimmel J, Huang WC. Contemporary treatment of high-risk localized prostate cancer. *Expert Rev Anticancer Ther* 2010;10(7):1069-76.
 19. Valero J, Cambeiro M, Galan C, Teijeira M, Romero P, Zudaire J, Moreno M, Ciervide R, Aristu JJ, Martinez-Monge R. Phase II trial of radiation dose escalation with conformal external beam radiotherapy and high-dose-rate brachytherapy combined with long-term androgen suppression in unfavorable prostate cancer: feasibility report. *Int J Radiat Oncol Biol Phys* 2010;76(2):386-92.
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41. Prada PJ, Gonzalez H, Fernandez J, Bilbao P. High-dose-rate intensity modulated brachytherapy with external-beam radiotherapy improves local and biochemical control in patients with high-risk prostate cancer. *Clin Transl Oncol* 2008;10(7):415-21.

Ausschlussgrund A3: Anderer Publikationstyp (Editorial, Fallbericht, Brief etc.)

1. Engineer R, Bhutani R, Mahantshetty U, Murthy V, Shrivastava SK. From two-dimensional to three-dimensional conformal radiotherapy in prostate cancer: an Indian experience. *Indian J Cancer* 2010;47(3):332-8.
2. Guerrero UT, Khoo V, Staffurth J, Norman A, Buffa F, Jackson A, Adams E, Hansen V, Clark C, Miles E, McNair H, Nutting C, Parker C, Eeles R, Huddart R, Horwich A, Dearnaley DP. Intensity-modulated radiotherapy allows escalation of the radiation dose to the pelvic lymph nodes in patients with locally advanced prostate cancer: preliminary results of a phase I dose escalation study. *Clin Oncol (R Coll Radiol)* 2010;22(3):236-44.
3. Zilli T, Jorcano S, Rouzaud M, Dipasquale G, Nouet P, Toscas JI, Casanova N, Wang H, Escude L, Molla M, Linero D, Weber DC, Miralbell R. Twice-Weekly Hypofractionated Intensity-Modulated Radiotherapy for Localized Prostate Cancer with Low-Risk Nodal Involvement: Toxicity and Outcome from a Dose Escalation Pilot Study. *Int J Radiat Oncol Biol Phys* 2010.
4. Zilli T, Rouzaud M, Jorcano S, Dipasquale G, Nouet P, Toscas JI, Casanova N, Wang H, Escude L, Molla M, Linero D, Weber DC, Miralbell R. Dose escalation study with two different hypofractionated intensity modulated radiotherapy techniques for localized prostate cancer: acute toxicity. *Technol Cancer Res Treat* 2010;9(3):263-70.
5. Coote JH, Wylie JP, Cowan RA, Logue JP, Swindell R, Livsey JE. Hypofractionated intensity-modulated radiotherapy for carcinoma of the prostate: analysis of toxicity. *Int J Radiat Oncol Biol Phys* 2009;74(4):1121-7.
6. Shridhar R, Bolton S, Joiner MC, Forman JD. Dose escalation using a hypofractionated, intensity-modulated radiation therapy boost for localized prostate cancer: preliminary results addressing concerns of high or low alpha/beta ratio. *Clin Genitourin Cancer* 2009;7(3):E52-E57.
7. Jereczek-Fossa BA, Vavassori A, Fodor C, Santoro L, Zerini D, Cattani F, Garibaldi C, Cambria R, Fodor A, Boboc GI, Vitolo V, Ivaldi GB, Musi G, de CO, Orecchia R. Dose escalation for prostate cancer using the three-dimensional conformal dynamic arc technique: analysis of 542 consecutive patients. *Int J Radiat Oncol Biol Phys* 2008;71(3):784-94.
8. Zelefsky MJ, Yamada Y, Fuks Z, Zhang Z, Hunt M, Cahlon O, Park J, Shippey A. Long-term results of conformal radiotherapy for prostate cancer: impact of dose escalation on biochemical tumor control and distant metastases-free survival outcomes. *Int J Radiat Oncol Biol Phys* 2008;71(4):1028-33.

Ausschlussgrund A4: Unsystematischer Review

1. Al-Mamgani A, Lebesque JV, Heemsbergen WD, Tans L, Kirkels WJ, Levendag PC, Incrocci L. Controversies in the treatment of high-risk prostate cancer--what is the optimal combination of hormonal therapy and radiotherapy: a review of literature. *Prostate* 2010;70(7):701-9.
2. Picard JC, Golshayan AR, Marshall DT, Opfermann KJ, Keane TE. The multidisciplinary management of high-risk prostate cancer. *Urol Oncol* 2009.
3. Staffurth J. A review of the clinical evidence for intensity-modulated radiotherapy. *Clin Oncol (R Coll Radiol)* 2010;22(8):643-57.
4. Herfarth K, Sterzing F. [Radiotherapy for locally advanced prostate cancer]. *Urologe A* 2008;47(11):1424-30.

12.3.7. Recherchen zum Thema perkutane Strahlentherapie

12.3.7.1. Fragestellungen zum lokal fortgeschrittenen Prostatakarzinom

Population	Intervention	Kontrolle	Outcomes	Time aspects
Patienten mit lokal fortgeschrittenem Prostatakarzinom ($\geq T3$)	Externe Strahlentherapie	Radikale Prostatektomie, interstitielle Brachytherapie, Watchful Waiting, Hormontherapie	Mortalität (inkl. 5-Jahres Überleben, krankheitsfreies Überleben) Morbidity (PSA-Kinetik, Histologie) Lebensqualität Nebenwirkungen/Schäden	Keine Einschränkungen
Patienten mit lokal fortgeschrittenem Prostatakarzinom ($\geq T3$)	Externe Strahlentherapie + neoadjuvante oder adjuvante Hormontherapie	Externe Strahlentherapie ohne neoadjuvante oder adjuvante Hormontherapie oder alleinige Hormontherapie	Mortalität (inkl. 5-Jahres Überleben, krankheitsfreies Überleben) Morbidity (PSA-Kinetik, Histologie) Lebensqualität Nebenwirkungen/Schäden	Keine Einschränkungen
Patienten mit lokal begrenztem oder lokal fortgeschrittenem Prostatakarzinom ($\leq T1-T4$)	Externe Hochdosisstrahlentherapie in Verbindung mit 3DCRT oder IMRT oder Normaler Bestrahlungsplanung	Externe Strahlentherapie mit konventionellen Dosierungen	Mortalität (inkl. 5-Jahres Überleben, krankheitsfreies Überleben) Morbidity (PSA-Kinetik, Histologie) Lebensqualität Nebenwirkungen/Schäden	Keine Einschränkungen

12.3.7.2. Recherche

Recherchestrategien für Fragen 1 und 2

Ausschlusskriterien für erste Relevanzsichtung:

A1: andere Erkrankung

A2: Methodik (Letter, Editorial u.ä.)

PubMed (10. März 2011)

Nr.	Suchfrage	Anzahl
#5	#1 AND #2 AND #3 Limits: English, German, Publication date from 2008/06	199
#4	#1 AND #2 AND #3	1288
#3	"locally advanced" OR T3 OR T4 (Details: "locally advanced"[All Fields] OR T3[All Fields] OR T4[All Fields])	58640
#2	radiotherapy OR radiation OR radiotherapeutic OR EBRT (Details: ("radiotherapy"[Subheading] OR "radiotherapy"[All Fields] OR "radiotherapy"[MeSH Terms]) OR ("radiation"[MeSH Terms] OR "radiation"[All Fields]) OR ("radiotherapy"[MeSH Terms] OR "radiotherapy"[All Fields] OR "radiotherapeutic"[All Fields]) OR EBRT[All Fields])	678589
#1	Prostate cancer (Details: "prostatic neoplasms"[MeSH Terms] OR ("prostatic"[All Fields] AND "neoplasms"[All Fields]) OR "prostatic neoplasms"[All Fields] OR ("prostate"[All Fields] AND "cancer"[All Fields]) OR "prostate cancer"[All Fields])	92213

Anzahl der Treffer: 199

Davon relevant: 183

Cochrane (10. März 2011)

Nr.	Suchfrage	Anzahl
#1	"prostate cancer in Title, Abstract or Keywords and radiotherapy or radiation or radiotherapeutic or EBRT in Title, Abstract or Keywords and locally advanced OR T3 OR T4 in Title, Abstract or Keywords, from 2008 to 2011	23

- Cochrane Database of Systematic Reviews (5)
- Database of Abstracts of Reviews of Effects (1)
- Cochrane Central Register of Controlled Trials (17)
- Cochrane Methodology Register (0)
- Health Technology Assessment Database (0)
- NHS Economic Evaluation Database (0)

Anzahl der Treffer: 23

Davon neu: 10

Davon relevant: 7

Recherchestrategien für Frage 3
PubMed (10. März 2011)

Nr.	Suchfrage	Anzahl
#6	#1 AND #2 AND #3 AND #4 Limits: English, German, Publication date from 2008	60
#5	#1 AND #2 AND #3 AND #4	242
#4	"locally advanced" OR T3 OR T4 OR localized OR T1 OR T2 (Details: "locally advanced"[All Fields] OR T3[All Fields] OR T4[All Fields] OR localized[All Fields] OR T1[All Fields] OR T2[All Fields])	2960 50
#3	dose escalation (Details: dose[All Fields] AND escalation[All Fields])	6549
#2	radiotherapy OR radiation OR radiotherapeutic OR EBRT (Details: ("radiotherapy"[Subheading] OR "radiotherapy"[All Fields] OR "radiotherapy"[MeSH Terms]) OR ("radiation"[MeSH Terms] OR "radiation"[All Fields]) OR ("radiotherapy"[MeSH Terms] OR "radiotherapy"[All Fields] OR "radiotherapeutic"[All Fields]) OR EBRT[All Fields])	6785 89
#1	Prostate cancer (Details: "prostatic neoplasms"[MeSH Terms] OR ("prostatic"[All Fields] AND "neoplasms"[All Fields]) OR "prostatic neoplasms"[All Fields] OR ("prostate"[All Fields] AND "cancer"[All Fields]) OR "prostate cancer"[All Fields])	9221 3

Anzahl der Treffer: 60

Cochrane (10. März 2011)

Nr.	Suchfrage	Anzahl
#1	"prostate cancer in Title, Abstract or Keywords and radiotherapy or radiation or radiotherapeutic or EBRT in Title, Abstract or Keywords and locally advanced or T3 or T4 or localized or T1 or T2 in Title, Abstract or Keywords and dose escalation in Title, Abstract or Keywords, from 2008 to 2011	7

- Cochrane Database of Systematic Reviews (0)
- Database of Abstracts of Reviews of Effects (0)
- Cochrane Central Register of Controlled Trials (7)
- Cochrane Methodology Register (0)
- Health Technology Assessment Database (0)
- NHS Economic Evaluation Database (0)

Anzahl der Treffer: 7

Davon neu: 0

12.3.7.3. Ein- und Ausschlusskriterien

Für Frage 1

Einschlussgründe	
E1 Zielgruppe	Patienten mit lokal fortgeschrittenem primären Prostatakarzinom (cT3-cT4)
E2 Publikationstyp	RCT oder systematischer Review, ggf. mit Metaanalyse aus RCTs oder Kohortenstudie
E3: Suchzeitraum	Publikationen seit August 2008 (letzte Recherche S3 Leitlinien-Gruppe)
E4: Sprachen	deutsch, englisch
E5 Intervention	Externe Strahlentherapie
Ausschlussgründe	
A1	andere Population
A2	Nicht Fragestellung (siehe oben)
A3	Anderer Publikationstyp (Editorial, Fallbericht, Brief etc.)
A4	Unsystematischer Review
A5	Doppelpublikation oder aktuellere Publikation vorhanden

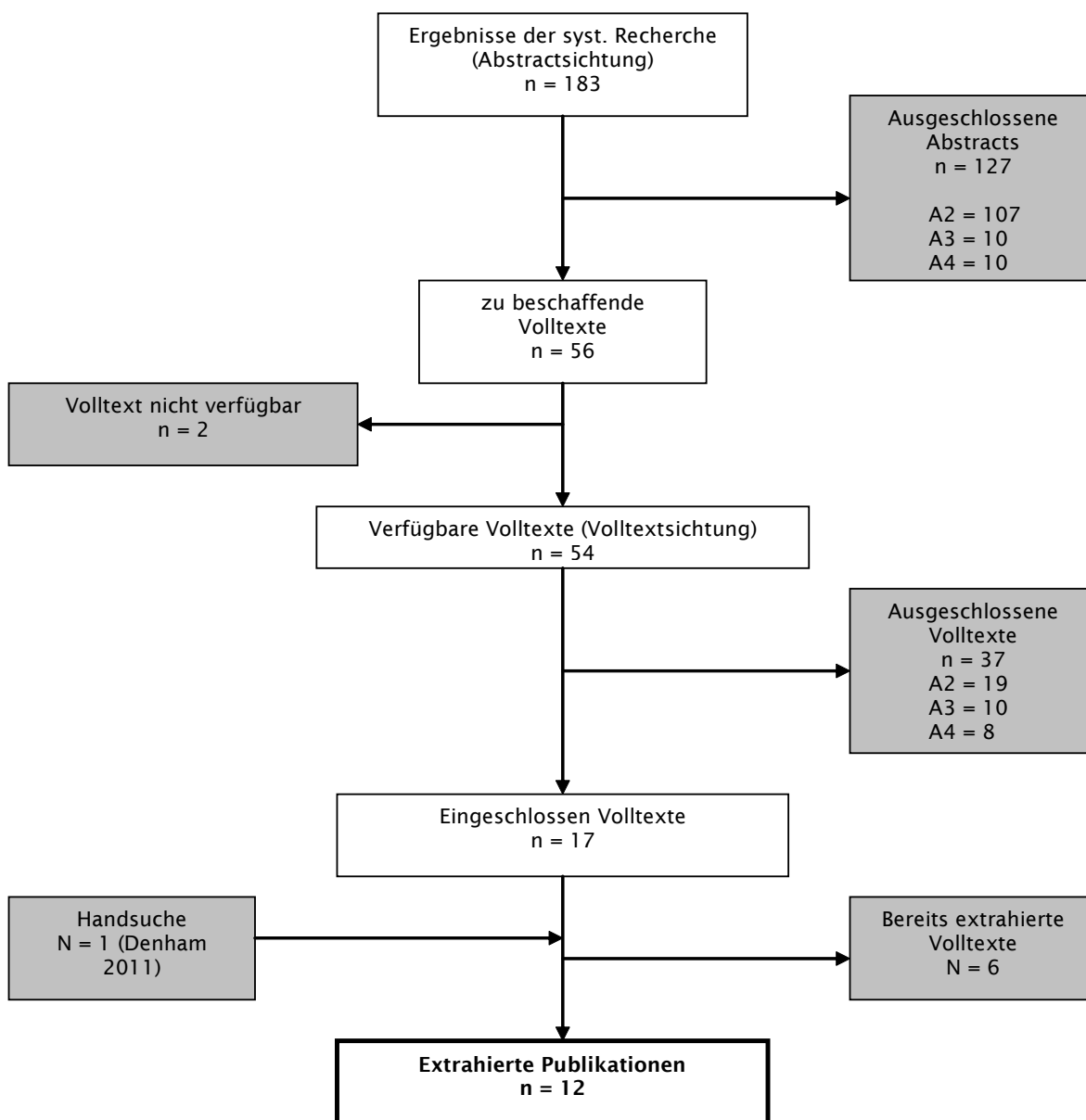
Für Frage 2

Einschlussgründe	
E1 Zielgruppe	Patienten mit lokal fortgeschrittenem primären Prostatakarzinom (cT3-cT4)
E2 Publikationstyp	RCT oder systematischer Review, ggf. mit Metaanalyse aus RCTs
E3: Suchzeitraum	Publikationen seit August 2008 (letzte Recherche S3 Leitlinien-Gruppe)
E4: Sprachen	deutsch, englisch
E5 Intervention	Externe Strahlentherapie + Hormontherapie
Ausschlussgründe	
A1	andere Population
A2	Nicht Fragestellung (siehe oben)
A3	Anderer Publikationstyp (Kohortenstudie, Fallserie, Editorial, Fallbericht, Brief etc.)
A4	Unsystematischer Review
A5	Doppelpublikation oder aktuellere Publikation vorhanden

Für Frage 3

Einschlussgründe	
E1 Zielgruppe	Patienten mit lokal begrenztem und lokal fortgeschrittenem primärem Prostatakarzinom (cT1-cT4)
E2 Publikationstyp	RCT oder systematischer Review, ggf. mit Metaanalyse aus RCTs
E3: Suchzeitraum	Publikationen seit August 2008 (letzte Recherche S3 Leitlinien-Gruppe)
E4: Sprachen	deutsch, englisch
E5 Intervention	Hochdosisstrahlentherapie +/- Hormontherapie
Ausschlussgründe	
A1	andere Population
A2	Nicht Fragestellung (siehe oben)
A3	Anderer Publikationstyp (Editorial, Fallbericht, Brief etc.)
A4	Unsystematischer Review
A5	Doppelpublikation oder aktuellere Publikation vorhanden

12.3.7.4. Ergebnisse der Recherche



12.3.7.4.1. Eingeschlossene Publikationen

1. Armstrong JG, Gillham CM, Dunne MT, Fitzpatrick DA, Finn MA, Cannon ME, Taylor JC, O'Shea CM, Buckney SJ, Thirion PG. A Randomized Trial (Irish Clinical Oncology Research Group 97-01) Comparing Short Versus Protracted Neoadjuvant Hormonal Therapy Before Radiotherapy for Localized Prostate Cancer. *Int J Radiat Oncol Biol Phys* 2010.
2. Bolla M, Van TG, Warde P, Dubois JB, Mirimanoff RO, Storme G, Bernier J, Kuten A, Sternberg C, Billiet I, Torcilla JL, Pfeffer R, Cutajar CL, Van der KT, Collette L. External irradiation with or without long-term androgen suppression for prostate cancer with high metastatic risk: 10-year results of an EORTC randomised study. *Lancet Oncol* 2010;11(11):1066-73.
3. Kuban DA, Levy LB, Cheung MR, Lee AK, Choi S, Frank S, Pollack A. Long-term Failure Patterns and Survival in a Randomized Dose-Escalation Trial for Prostate Cancer. *Who Dies of Disease?* *Int J Radiat Oncol Biol Phys* 2010.
4. Bolla M, de Reijke TM, Van TG, Van Den Bergh AC, Oddens J, Poortmans PM, Gez E, Kil P, Akdas A, Soete G, Kariakine O, van der Steen-Banasik EM, Musat E, Pierart M,

- Mauer ME, Collette L. Duration of androgen suppression in the treatment of prostate cancer. *N Engl J Med* 2009;360(24):2516-27.
5. Efsthathiou JA, Bae K, Shipley WU, Hanks GE, Pilepich MV, Sandler HM, Smith MR. Cardiovascular mortality after androgen deprivation therapy for locally advanced prostate cancer: RTOG 85-31. *J Clin Oncol* 2009;27(1):92-9.
 6. Shelley MD, Kumar S, Coles B, Wilt T, Staffurth J, Mason MD. Adjuvant hormone therapy for localised and locally advanced prostate carcinoma: a systematic review and meta-analysis of randomised trials. *Cancer Treat Rev* 2009;35(7):540-6.
 7. Shelley MD, Kumar S, Wilt T, Staffurth J, Coles B, Mason MD. A systematic review and meta-analysis of randomised trials of neo-adjuvant hormone therapy for localised and locally advanced prostate carcinoma. *Cancer Treat Rev* 2009;35(1):9-17.
 8. Widmark A, Klepp O, Solberg A, Damber JE, Angelsen A, Fransson P, Lund JA, Tasdemir I, Hoyer M, Wiklund F, Fossa SD. Endocrine treatment, with or without radiotherapy, in locally advanced prostate cancer (SPCG-7/SFUO-3): an open randomised phase III trial. *Lancet* 2009;373(9660):301-8.
 9. Efsthathiou JA, Bae K, Shipley WU, Hanks GE, Pilepich MV, Sandler HM, Smith MR. Cardiovascular mortality and duration of androgen deprivation for locally advanced prostate cancer: analysis of RTOG 92-02. *Eur Urol* 2008;54(4):816-23.
 10. Horwitz EM, Bae K, Hanks GE, Porter A, Grignon DJ, Brereton HD, Venkatesan V, Lawton CA, Rosenthal SA, Sandler HM, Shipley WU. Ten-year follow-up of radiation therapy oncology group protocol 92-02: a phase III trial of the duration of elective androgen deprivation in locally advanced prostate cancer. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology* 2008;26:2497-504.
 11. Kuban DA, Tucker SL, Dong L, Starkschall G, Huang EH, Cheung MR, Lee AK, Pollack A. Long-term results of the M. D. Anderson randomized dose-escalation trial for prostate cancer. *International journal of radiation oncology, biology, physics* 2008;70:67-74.
 12. Lawton CA, Bae K, Pilepich M, Hanks G, Shipley W. Long-term treatment sequelae after external beam irradiation with or without hormonal manipulation for adenocarcinoma of the prostate: analysis of radiation therapy oncology group studies 85-31, 86-10, and 92-02. *International journal of radiation oncology, biology, physics* 2008;70:437-41.
 13. Roach M, Bae K, Speight J, Wolkov HB, Rubin P, Lee RJ, Lawton C, Valicenti R, Grignon D, Pilepich MV. Short-term neoadjuvant androgen deprivation therapy and external-beam radiotherapy for locally advanced prostate cancer: long-term results of RTOG 8610. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology* 2008;26:585-91.
 14. Bria E, Cuppone F, Giannarelli D, Milella M, Ruggeri EM, Sperduti I, Pinnaro P, Terzoli E, Cognetti F, Carlini P. Does hormone treatment added to radiotherapy improve outcome in locally advanced prostate cancer?: meta-analysis of randomized trials. *Cancer* 2009;115(15):3446-56.
 15. Cuppone F, Bria E, Giannarelli D, Vaccaro V, Milella M, Nistico C, Ruggeri EM, Sperduti I, Bracarda S, Pinnaro P, Lanzetta G, Muti P, Cognetti F, Carlini P. Impact of hormonal treatment duration in combination with radiotherapy for locally advanced prostate cancer: meta-analysis of randomized trials. *BMC Cancer* 2010;10:675.
 16. Hummel S, Simpson EL, Hemingway P, Stevenson MD, Rees A. Intensity-modulated radiotherapy for the treatment of prostate cancer: a systematic review and economic evaluation. *Health Technol Assess* 2010;14(47):1-iv.
 17. Namiki S, Tochigi T, Ishidoya S, Ito A, Numata I, Arai Y. Long-term quality of life following primary treatment in men with clinical stage T3 prostate cancer. *Qual Life Res* 2011;20(1):111-8.

12.3.7.4.2. Ausgeschlossene Publikationen (Volltextscreening)

Ausschlussgrund A2: Anderes Thema (nicht Fragestellung)

18. Heidenreich A, Richter S, Thuer D, Pfister D. Prognostic parameters, complications, and oncologic and functional outcome of salvage radical prostatectomy for locally recurrent prostate cancer after 21st-century radiotherapy. *Eur Urol* 2010;57(3):437-43.

19. Nguyen PL, Chen MH, Beard CJ, Suh WW, Renshaw AA, Loffredo M, McMahon E, Kantoff PW, D'Amico AV. Radiation with or without 6 months of androgen suppression therapy in intermediate- and high-risk clinically localized prostate cancer: a postrandomization analysis by risk group. *Int J Radiat Oncol Biol Phys* 2010;77(4):1046-52.
20. Odratzka K, Dolezel M, Vanasek J, Vaculikova M, Zouhar M, Sefrova J, Paluska P, Vosmik M, Kohlova T, Kolarova I, Macingova Z, Navratil P, Brodak M, Prosvic P. Time course of late rectal toxicity after radiation therapy for prostate cancer. *Prostate Cancer Prostatic Dis* 2010;13(2):138-43.
21. Ojha RP, Fischbach LA, Zhou Y, Felini MJ, Singh KP, Thertulien R. Acute myeloid leukemia incidence following radiation therapy for localized or locally advanced prostate adenocarcinoma. *Cancer Epidemiol* 2010;34(3):274-8.
22. Schmitz MD, Padula GD, Chun PY, Davis AT. Normalization of prostate specific antigen in patients treated with intensity modulated radiotherapy for clinically localized prostate cancer. *Radiat Oncol* 2010;5:80.
23. Choo R, Danjoux C, Gardner S, Morton G, Szumacher E, Loblaw DA, Cheung P, Pearse M. Prospective study evaluating postoperative radiotherapy plus 2-year androgen suppression for post-radical prostatectomy patients with pathologic T3 disease and/or positive surgical margins. *Int J Radiat Oncol Biol Phys* 2009;75(2):407-12.
24. Da Pozzo LF, Cozzarini C, Briganti A, Suardi N, Salonia A, Bertini R, Gallina A, Bianchi M, Fantini GV, Bolognesi A, Fazio F, Montorsi F, Rigatti P. Long-term follow-up of patients with prostate cancer and nodal metastases treated by pelvic lymphadenectomy and radical prostatectomy: the positive impact of adjuvant radiotherapy. *Eur Urol* 2009;55(5):1003-11.
25. Fransson P, Lund JA, Damber JE, Klepp O, Wiklund F, Fossa S, Widmark A. Quality of life in patients with locally advanced prostate cancer given endocrine treatment with or without radiotherapy: 4-year follow-up of SPCG-7/SFUO-3, an open-label, randomised, phase III trial. *Lancet Oncol* 2009;10(4):370-80.
26. Koontz BF, Das S, Temple K, Bynum S, Catalano S, Koontz JI, Montana GS, Oleson JR. Dosimetric and radiobiologic comparison of 3D conformal versus intensity modulated planning techniques for prostate bed radiotherapy. *Med Dosim* 2009;34(3):256-60.
27. Lips IM, van Gils CH, van der Heide UA, Kruger AE, Van VM. Health-related quality of life 3 years after high-dose intensity-modulated radiotherapy with gold fiducial marker-based position verification. *BJU Int* 2009;103(6):762-7.
28. Sasaki T, Nakamura K, Ogawa K, Onishi H, Okamoto A, Koizumi M, Shioyama Y, Mitsumori M, Teshima T. Radiotherapy for patients with localized hormone-refractory prostate cancer: results of the Patterns of Care Study in Japan. *BJU Int* 2009;104(10):1462-6.
29. Schelin S, Madsen M, Palmqvist E, Makela E, Klintonberg C, Aus G. Long-term follow-up after triple treatment of prostate cancer stage pT3. *Scand J Urol Nephrol* 2009;43(3):186-91.
30. Chin JL, Ng CK, Touma NJ, Pus NJ, Hardie R, Abdelhady M, Rodrigues G, Radwan J, Venkatesan V, Moussa M, Downey DB, Bauman G. Randomized trial comparing cryoablation and external beam radiotherapy for T2C-T3B prostate cancer. *Prostate cancer and prostatic diseases* 2008;11:40-5.
31. Choo R, Pearse M, Danjoux C, Gardner S, Morton G, Szumacher E, Loblaw DA, Cheung P. Analysis of gastrointestinal and genitourinary morbidity of postoperative radiotherapy for pathologic T3 disease or positive surgical margins after radical prostatectomy using national cancer institute expanded common toxicity criteria. *Int J Radiat Oncol Biol Phys* 2008;72(4):989-95.
32. Fang FM, Wang YM, Wang CJ, Huang HY, Chiang PH. Comparison of the outcome and morbidity for localized or locally advanced prostate cancer treated by high-dose-rate brachytherapy plus external beam radiotherapy (EBRT) versus EBRT alone. *Jpn J Clin Oncol* 2008;38(7):474-9.
33. Ganswindt U, Stenzl A, Bamberg M, Belka C. Adjuvant radiotherapy for patients with locally advanced prostate cancer--a new standard? *Eur Urol* 2008;54(3):528-42.
34. Heidenreich A, Semrau R, Thuer D, Pfister D. [Radical salvage prostatectomy : Treatment of local recurrence of prostate cancer after radiotherapy]. *Urologe A* 2008;47(11):1441-6.

35. Morgan SC, Waldron TS, Eapen L, Mayhew LA, Winkquist E, Lukka H. Adjuvant radiotherapy following radical prostatectomy for pathologic T3 or margin-positive prostate cancer: a systematic review and meta-analysis. *Radiother Oncol* 2008;88(1):1-9.
36. Shelley M, Wilt T, Coles B, Mason M. Cryotherapy for localised prostate cancer. Shelley Mike , Wilt Timothy , Coles Bernadette , Mason Malcolm Cryotherapy for localised prostate cancer Cochrane Database of Systematic Reviews: Reviews 2007 Issue 3 John Wiley & Sons , Ltd Chichester, UK DOI : 10 1002 /14651858 CD005010 pub2 2007.

Ausschlussgrund A3: Anderer Publikationstyp (Editorial, Fallbericht, Brief etc.)

1. Engineer R, Bhutani R, Mahantshetty U, Murthy V, Shrivastava SK. From two-dimensional to three-dimensional conformal radiotherapy in prostate cancer: an Indian experience. *Indian J Cancer* 2010;47(3):332-8.
2. Krauss D, Kestin L, Ye H, Brabbins D, Ghilezan M, Gustafson G, Vicini F, Martinez A. Lack of Benefit for the Addition of Androgen Deprivation Therapy to Dose-Escalated Radiotherapy in the Treatment of Intermediate- and High-Risk Prostate Cancer. *Int J Radiat Oncol Biol Phys* 2010.
3. Liauw SL, Stadler WM, Correa D, Weichselbaum RR, Jani AB. Dose-escalated radiotherapy for high-risk prostate cancer: outcomes in modern era with short-term androgen deprivation therapy. *Int J Radiat Oncol Biol Phys* 2010;77(1):125-30.
4. Sakamoto M, Mizowaki T, Mitsumori M, Takayama K, Sasai K, Norihisa Y, Kamoto T, Nakamura E, Ogawa O, Hiraoka M. Long-term outcomes of three-dimensional conformal radiation therapy combined with neoadjuvant hormonal therapy in Japanese patients with locally advanced prostate cancer. *Int J Clin Oncol* 2010;15(6):571-7.
5. Lim TS, Cheung PC, Loblaw DA, Morton G, Sixel KE, Pang G, Basran P, Zhang L, Tirona R, Szumacher E, Danjoux C, Choo R, Thomas G. Hypofractionated accelerated radiotherapy using concomitant intensity-modulated radiotherapy boost technique for localized high-risk prostate cancer: acute toxicity results. *Int J Radiat Oncol Biol Phys* 2008;72(1):85-92.
6. Yamazaki H, Nishiyama K, Tanaka E, Maeda O, Meguro N, Kinouchi T, Usami M, Kakimoto K, Ono Y, Nishimura T. Reduction of irradiation volume and toxicities with 3-D radiotherapy planning over conventional radiotherapy for prostate cancer treated with long-term hormonal therapy. *Anticancer Res* 2008;28(6B):3913-20.
7. Gryn S, Winkquist E. Effects of the duration of androgen deprivation therapy for localized or locally advanced prostate cancer in patients treated with radiotherapy. Gryn Steven , Winkquist Eric Effects of the duration of androgen deprivation therapy for localized or locally advanced prostate cancer in patients treated with radiotherapy Cochrane Database of Systematic Reviews: Protocols 2007 Issue 4 John Wiley & Sons 2007.
8. Souhami L, Bae K, Pilepich M, Sandler H. Impact of the duration of adjuvant hormonal therapy in patients with locally advanced prostate cancer treated with radiotherapy: a secondary analysis of RTOG 85-31. *J Clin Oncol* 2009;27(13):2137-43.

Ausschlussgrund A4: Unsystematischer Review

1. Sanfilippo N, Hardee ME, Wallach J. Review of chemoradiotherapy for high-risk prostate cancer. *Rev Recent Clin Trials* 2011;6(1):64-8.
2. Sumey C, Flaig TW. Adjuvant medical therapy for prostate cancer. *Expert Opin Pharmacother* 2011;12(1):73-84.
3. Staffurth J. A review of the clinical evidence for intensity-modulated radiotherapy. *Clin Oncol (R Coll Radiol)* 2010;22(8):643-57.
4. Verhagen PC, Schroder FH, Collette L, Bangma CH. Does local treatment of the prostate in advanced and/or lymph node metastatic disease improve efficacy of androgen-deprivation therapy? A systematic review. *Eur Urol* 2010;58(2):261-9.
5. Herfarth K, Sterzing F. [Radiotherapy for locally advanced prostate cancer]. *Urologe A* 2008;47(11):1424-30.
6. Kollmeier MA, Zelefsky MJ. What is the role of androgen deprivation therapy in the treatment of locally advanced prostate cancer? *Nat Clin Pract Urol* 2008;5(11):584-5.

7. Miller K, Lein M, Schostak M, Schrader M. [Adjuvant and neoadjuvant drug therapy for prostate cancer]. Urologe A 2008;47(11):1460-4.
8. Palisaar RJ, Noldus J. [The role of surgery in locally advanced prostate cancer]. Urologe A 2008;47(11):1417-23.

12.3.8. Recherchen zum Thema Protonentherapie

12.3.8.1. Fragestellungen

Population	Intervention	Kontrolle	Outcomes	Time aspects
Patienten mit lokal begrenztem oder lokal fortgeschrittenem Prostatakarzinom (cT1-cT4)	Externe Strahlentherapie mit Protonen oder Kombination von Photonen und Protonen	Externe Strahlentherapie mit Photonen	Mortalität (inkl. 5-Jahres Überleben, krankheitsfreies Überleben) Morbidity (PSA-Kinetik, Histologie) Lebensqualität Nebenwirkungen/Schäden	Keine Einschränkungen

12.3.8.2. Recherchen

12.3.8.2.1. Recherchestrategien für Fragen 1 und 2

Ausschlusskriterien der ersten Relevanzsichtung:

A1: andere Erkrankung

A2: Methodik (Letter, Editorial u.ä.)

PubMed (10. März 2011)

Nr.	Suchfrage	Anzahl
#5	#1 AND #2 AND #3 Limits: English, German, Publication date from 2008/06	199
#4	#1 AND #2 AND #3	1288
#3	"locally advanced" OR T3 OR T4 (Details: "locally advanced"[All Fields] OR T3[All Fields] OR T4[All Fields])	58640
#2	radiotherapy OR radiation OR radiotherapeutic OR EBRT (Details: ("radiotherapy"[Subheading] OR "radiotherapy"[All Fields] OR "radiotherapy"[MeSH Terms]) OR ("radiation"[MeSH Terms] OR "radiation"[All Fields]) OR ("radiotherapy"[MeSH Terms] OR "radiotherapy"[All Fields] OR "radiotherapeutic"[All Fields]) OR EBRT[All Fields])	678589
#1	Prostate cancer (Details: "prostatic neoplasms"[MeSH Terms] OR ("prostatic"[All Fields] AND "neoplasms"[All Fields]) OR "prostatic neoplasms"[All Fields] OR ("prostate"[All Fields] AND "cancer"[All Fields]) OR "prostate cancer"[All Fields])	92213

Anzahl der Treffer: 199

Davon relevant: 183

Cochrane (10. März 2011)

Nr.	Suchfrage	Anzahl
#1	"prostate cancer" in Title, Abstract or Keywords and radiotherapy or radiation or radiotherapeutic or EBRT in Title, Abstract or Keywords and locally advanced OR T3 OR T4 in Title, Abstract or Keywords, from 2008 to 2011	23
	<ul style="list-style-type: none"> • Cochrane Database of Systematic Reviews (5) • Database of Abstracts of Reviews of Effects (1) • Cochrane Central Register of Controlled Trials (17) • Cochrane Methodology Register (0) • Health Technology Assessment Database (0) • NHS Economic Evaluation Database (0) 	

Anzahl der Treffer: 23

Davon neu: 10

Davon relevant: 7

12.3.8.2.2. Recherchestrategien für Frage 3

PubMed (10. März 2011)

Nr.	Suchfrage	Anzahl
#6	#1 AND #2 AND #3 AND #4 Limits: English, German, Publication date from 2008	60
#5	#1 AND #2 AND #3 AND #4	242
#4	"locally advanced" OR T3 OR T4 OR localized OR T1 OR T2 (Details: "locally advanced"[All Fields] OR T3[All Fields] OR T4[All Fields] OR localized[All Fields] OR T1[All Fields] OR T2[All Fields])	296050
#3	dose escalation (Details: dose[All Fields] AND escalation[All Fields])	6549
#2	radiotherapy OR radiation OR radiotherapeutic OR EBRT (Details: ("radiotherapy"[Subheading] OR "radiotherapy"[All Fields] OR "radiotherapy"[MeSH Terms]) OR ("radiation"[MeSH Terms] OR "radiation"[All Fields]) OR ("radiotherapy"[MeSH Terms] OR "radiotherapy"[All Fields] OR "radiotherapeutic"[All Fields]) OR EBRT[All Fields])	678589
#1	Prostate cancer (Details: "prostatic neoplasms"[MeSH Terms] OR ("prostatic"[All Fields] AND "neoplasms"[All Fields]) OR "prostatic neoplasms"[All Fields] OR ("prostate"[All Fields] AND "cancer"[All Fields]) OR "prostate cancer"[All Fields])	92213

Anzahl der Treffer: 60

Cochrane (10. März 2011)

Nr.	Suchfrage	Anzahl
#1	"prostate cancer in Title, Abstract or Keywords and radiotherapy or radiation or radiotherapeutic or EBRT in Title, Abstract or Keywords and locally advanced or T3 or T4 or localized or T1 or T2 in Title, Abstract or Keywords and dose escalation in Title, Abstract or Keywords, from 2008 to 2011	7
	<ul style="list-style-type: none"> • Cochrane Database of Systematic Reviews (0) • Database of Abstracts of Reviews of Effects (0) • Cochrane Central Register of Controlled Trials (7) 	

- Cochrane Methodology Register (0)
- Health Technology Assessment Database (0)
- NHS Economic Evaluation Database (0)

Anzahl der Treffer: 7

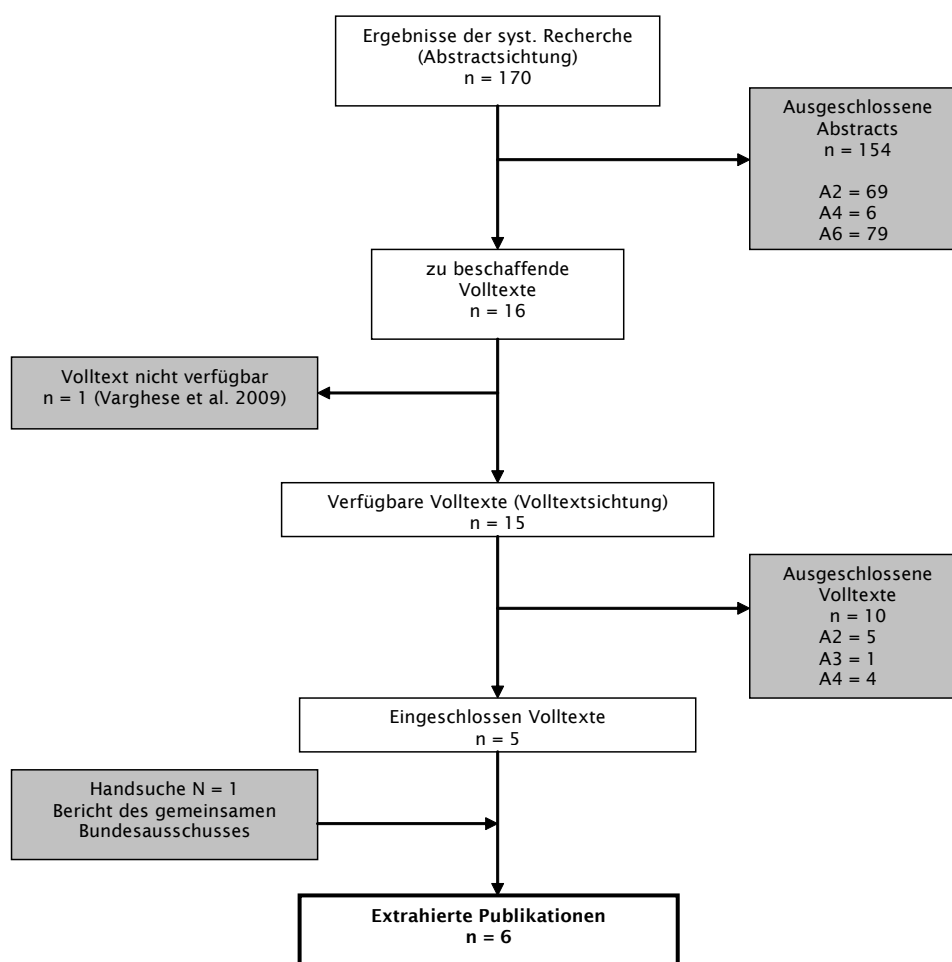
Davon neu: 0

12.3.8.3. Ein- und Ausschlusskriterien

Für Frage 1

Einschlussgründe	
E1 Zielgruppe	Patienten mit lokal begrenztem und lokal fortgeschrittenem primärem Prostatakarzinom (cT1-cT4)
E2 Publikationstyp	Klinische Studien inklusive Fallserien ($n \geq 50$) oder systematischer Review/HTA-Bericht (mit oder ohne Metaanalyse)
E3: Suchzeitraum	Publikationen seit 2008 (letzte Recherche des Gemeinsamen Bundesausschuss bei der Bewertung der Protonentherapie)
E4: Sprachen	deutsch, englisch
E5 Intervention	Externe Strahlentherapie mit Protonen oder einer Kombination aus Protonen und Photonen
Ausschlussgründe	
A1	andere Population
A2	Nicht Fragestellung (siehe oben)
A3	Anderer Publikationstyp (Editorial, Fallbericht, Brief etc.)
A4	Unsystematischer Review
A5	Doppelpublikation oder aktuellere Publikation vorhanden
A6	Publikationszeitpunkt innerhalb des Recherchezeitraums der Recherche des G-BA (06.05.2008)

12.3.8.4. Ergebnisse der Recherche



12.3.8.4.1. Eingeschlossene Publikationen

1. Mendenhall NP, Li Z, Hoppe BS, Marcus RB, Jr., Mendenhall WM, Nichols RC, Morris CG, Williams CR, Costa J, Henderson R. Early Outcomes from Three Prospective Trials of Image-guided Proton Therapy for Prostate Cancer. *Int J Radiat Oncol Biol Phys* 2010.
2. Nihei K, Ogino T, Onozawa M, Murayama S, Fuji H, Murakami M, Hishikawa Y. Multi-Institutional Phase II Study of Proton Beam Therapy for Organ-Confined Prostate Cancer Focusing on the Incidence of Late Rectal Toxicities. *Int J Radiat Oncol Biol Phys* 2010.
3. Brada M, Pijls-Johannesma M, De RD. Current clinical evidence for proton therapy. *Cancer J* 2009;15(4):319-24.
4. Terasawa T, Dvorak T, Ip S, Raman G, Lau J, Trikalinos TA. Systematic review: charged-particle radiation therapy for cancer. *Ann Intern Med* 2009;151(8):556-65.
5. Ollendorf DA, Hayes J, McMahon P, Kuba M, Tramontano A, Pearson SD. Brachytherapy/proton beam therapy for clinically localized, low-risk prostate cancer (Structured abstract). Boston : Institute for Clinical and Economic Review 2008;114.

12.3.8.4.2. Ausgeschlossene Publikationen (Volltextscreening)

Ausschlussgrund A2: Anderes Thema (nicht Fragestellung)

1. Fontenot JD, Bloch C, Followill D, Titt U, Newhauser WD. Estimate of the uncertainties in the relative risk of secondary malignant neoplasms following proton therapy and intensity-modulated photon therapy. *Phys Med Biol* 2010;55(23):6987-98.
2. Jabbari S, Weinberg VK, Shinohara K, Speight JL, Gottschalk AR, Hsu IC, Pickett B, McLaughlin PW, Sandler HM, Roach M, III. Equivalent biochemical control and improved prostate-specific antigen nadir after permanent prostate seed implant brachytherapy versus high-dose three-dimensional conformal radiotherapy and high-dose conformal proton beam radiotherapy boost. *Int J Radiat Oncol Biol Phys* 2010;76(1):36-42.
3. Talcott JA, Rossi C, Shipley WU, Clark JA, Slater JD, Niemierko A, Zietman AL. Patient-reported long-term outcomes after conventional and high-dose combined proton and photon radiation for early prostate cancer. *JAMA* 2010;303(11):1046-53.
4. Yoon M, Ahn SH, Kim J, Shin DH, Park SY, Lee SB, Shin KH, Cho KH. Radiation-induced cancers from modern radiotherapy techniques: intensity-modulated radiotherapy versus proton therapy. *Int J Radiat Oncol Biol Phys* 2010;77(5):1477-85.
5. Zietman AL, Bae K, Slater JD, Shipley WU, Efsthathiou JA, Coen JJ, Bush DA, Lunt M, Spiegel DY, Skowronski R, Jabola BR, Rossi CJ. Randomized trial comparing conventional-dose with high-dose conformal radiation therapy in early-stage adenocarcinoma of the prostate: long-term results from proton radiation oncology group/american college of radiology 95-09. *J Clin Oncol* 2010;28(7):1106-11.

Ausschlussgrund A3: Anderer Publikationstyp (Editorial, Fallbericht, Brief etc.)

1. Fontenot JD, Lee AK, Newhauser WD. Risk of secondary malignant neoplasms from proton therapy and intensity-modulated x-ray therapy for early-stage prostate cancer. *Int J Radiat Oncol Biol Phys* 2009;74(2):616-22

Ausschlussgrund A4: Unsystematischer Review

1. Kagan AR, Schulz RJ. Proton-beam therapy for prostate cancer. *Cancer J* 2010;16(5):405-9.
2. Printz C. "Boost" of proton therapy helps reduce prostate cancer recurrence. *Cancer* 2010;116(7):1619.
3. Proton beam therapy for prostate cancer. *Johns Hopkins Med Lett Health After 50* 2009;21(2):3, 7.
4. Efsthathiou JA, Trofimov AV, Zietman AL. Life, liberty, and the pursuit of protons: an evidence-based review of the role of particle therapy in the treatment of prostate cancer. *Cancer J* 2009;15(4):312-8.

12.3.9. Recherchen zum Thema HIFU

12.3.9.1. Fragestellungen

Population	Intervention	Control	Outcomes	Time aspects
Patienten mit lokal begrenztem, primärem, Prostatakarzinom (T1-T2, N0-Nx, M0)	Hochintensiver Fokussierter Ultraschall (HIFU)	Active Surveillance, radikale Prostatektomie, Strahlentherapie, interstitielle Brachytherapie	Mortalität (inkl. 5-Jahres Überleben, krankheitsfreies Überleben) Morbidity (PSA-Kinetik, Histologie) Lebensqualität	Keine Einschränkungen

Patienten mit lokal fortgeschrittenem, primärem, Prostatakarzinom (T3-T4, N0-Nx, M0)	Hochintensive r Fokussierter Ultraschall (HIFU)	Active Surveillance, radikale Prostatektomie, Strahlentherapie, interstitielle Brachytherapie,	Mortalität (inkl. 5-Jahres Überleben, krankheitsfreies Überleben) Morbidity (PSA-Kinetik, Histologie) Lebensqualität	Keine Einschränkungen
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12.3.9.2. Recherchen

Ausschlusskriterien für erste Relevanzsichtung:

A1: andere Erkrankung

A2: Methodik (Letter, Editorial u.ä.)

PubMed (03. Januar 2011)

Nr.	Suchfrage	Anzahl
#4	#1 AND #2 Limits: English, German, Publication date from 2008/08	107
#3	#1 AND #2	315
#2	HIFU (Details: "high-intensity focused ultrasound ablation"[MeSH Terms] OR ("high-intensity"[All Fields] AND "focused"[All Fields] AND "ultrasound"[All Fields] AND "ablation"[All Fields]) OR "high-intensity focused ultrasound ablation"[All Fields] OR "hifu"[All Fields])	1002
#1	Prostate cancer (Details: "prostatic neoplasms"[MeSH Terms] OR ("prostatic"[All Fields] AND "neoplasms"[All Fields]) OR "prostatic neoplasms"[All Fields] OR ("prostate"[All Fields] AND "cancer"[All Fields]) OR "prostate cancer"[All Fields])	90835

Anzahl der Treffer: 107

Davon relevant: 94

Cochrane (03. Januar 2011)

Nr.	Suchfrage	Anzahl
#1	"prostate cancer in Title, Abstract or Keywords and hifu OR high-intensity focused ultrasound in Title, Abstract or Keywords, from 2008 to 2011	6

- Cochrane Database of Systematic Reviews (1)
- Database of Abstracts of Reviews of Effects (0)
- Cochrane Central Register of Controlled Trials (3)
- Cochrane Methodology Register (0)
- Health Technology Assessment Database (2)
- NHS Economic Evaluation Database (0)

Anzahl der Treffer: 6

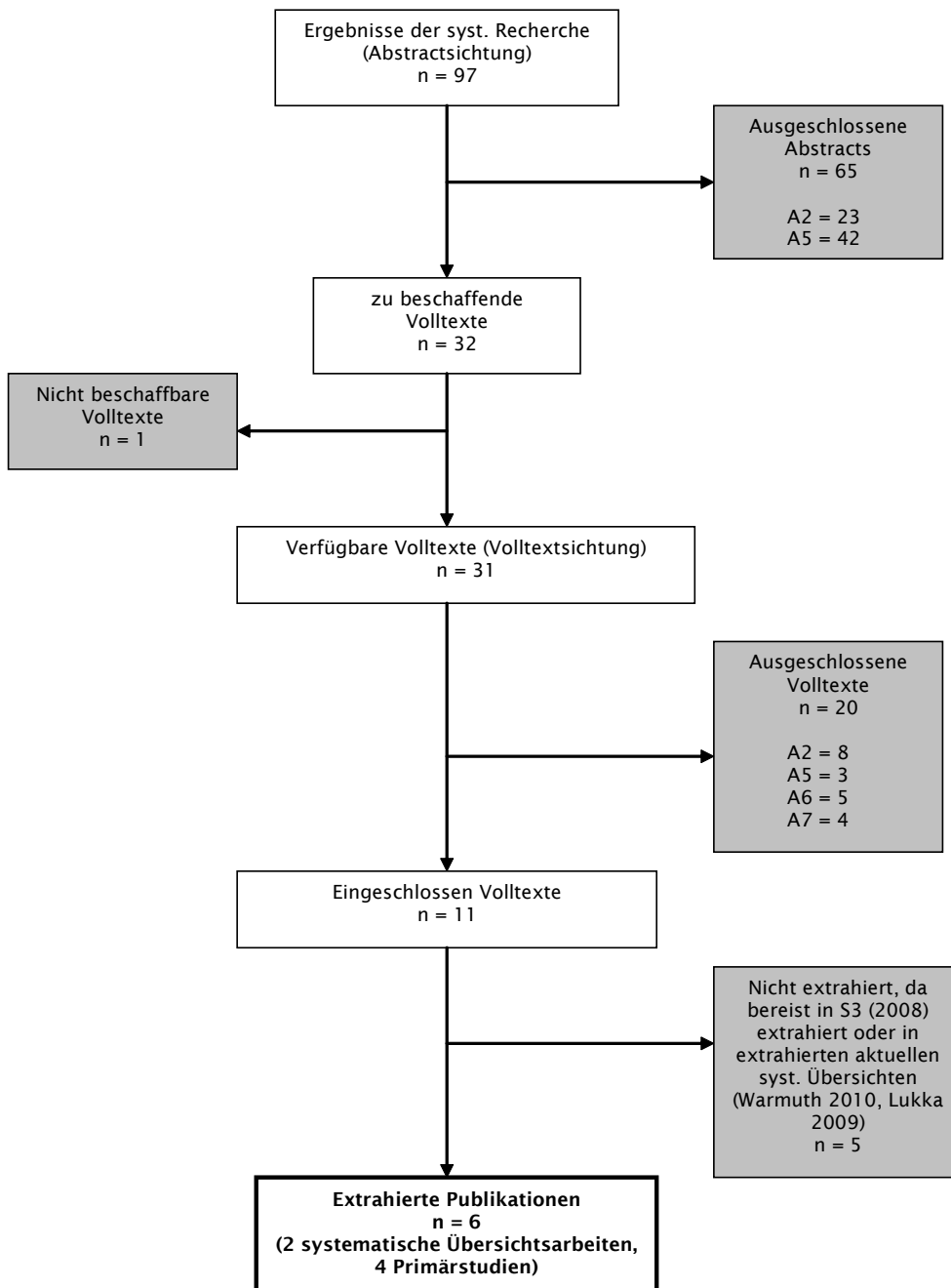
Davon neu: 4

Davon relevant: 3

12.3.9.3. Ein- und Ausschlusskriterien

Einschlussgründe	
E1 Zielgruppe	Patienten mit lokal begrenztem oder lokal fortgeschrittenem primären Prostatakarzinom oder Patienten mit Lokalrezidiv nach Prostatektomie oder Strahlentherapie
E2 Publikationstyp	Klinische Studien inklusive Fallserien oder systematischer Review/HTA-Bericht (mit oder ohne Metaanalyse)
E3: Suchzeitraum	Publikationen seit August 2008 (letzte Recherche S3 Leitlinien-Gruppe)
E4: Sprachen	deutsch, englisch
E5 Intervention	HIFU, auch nicht-kontrollierte Studien werden berücksichtigt
Ausschlussgründe	
A1	Nicht Zielgruppe
A2	Keine klinische Studie oder systematischer Review (mit oder ohne Metaanalyse)
A3	Publikation vor August 2008 erschienen
A4	Sprache nicht englisch oder deutsch
A5	Nicht Fragestellung: HIFU zur Therapie des Prostatakarzinoms

12.3.9.4. Ergebnisse der Recherche



12.3.9.4.1. Eingeschlossene Publikationen

Eingeschlossene Publikationen	Einschluss in Warmuth 2010	Einschluss in Lukka 2009
Ahmed HU, Zacharakis E, Dudderidge T, Armitage JN, Scott R, Calleary J, Illing R, Kirkham A, Freeman A, Ogden C, Allen C, Emberton M. High-intensity-focused ultrasound in the treatment of primary prostate cancer: the first UK series. Br J Cancer 2009;101(1):19-26.	X	
Blana A, Rogenhofer S, Ganzer R, Lunz JC, Schostak M, Wieland WF, Walter B. Eight years' experience with high-intensity focused ultrasonography for treatment of localized prostate cancer. Urology 2008;72(6):1329-33.	Diese Arbeit wurde im Rahmen der Konsultationsphase der Version 2008 identifiziert und ist in der jetzigen Version der S3-Leitlinie bereits extrahiert.	
Crouzet S, Rebillard X, Chevallier D, Rischmann P, Pasticier G, Garcia G, Rouviere O, Chapelon JY, Gelet A. Multicentric oncologic outcomes of high-intensity focused ultrasound for localized prostate cancer in 803 patients. Eur Urol 2010;58(4):559-66.	Wurde extrahiert	
Li LY, Lin Z, Yang M, Gao X, Xia TL, Ding T. Comparison of penile size and erectile function after high-intensity focused ultrasound and targeted cryoablation for localized prostate cancer: a prospective pilot study. J Sex Med 2010;7(9):3135-42.	Ergebnisse für HIFU wurden extrahiert	
Lukka H, Waldron T, Chin J, Mayhew L, Warde P, Winkvist E, Rodrigues G, Shayegan B. High-intensity Focused Ultrasound for Prostate Cancer: a Systematic Review. Clin Oncol (R Coll Radiol) 2010.	Wurde extrahiert	
Mearini L, D'Urso L, Collura D, Zucchi A, Costantini E, Formiconi A, Bini V, Muto G, Porena M. Visually directed transrectal high intensity focused ultrasound for the treatment of prostate cancer: a preliminary report on the Italian experience. J Urol 2009;181(1):105-11.		X
Netsch C, Pfeiffer D, Gross AJ. Development of bladder outlet obstruction after a single treatment of prostate cancer with high-intensity focused ultrasound: experience with 226 patients. J Endourol 2010;24(9):1399-403.	Wurde extrahiert	
Shoji S, Nakano M, Nagata Y, Usui Y, Terachi T, Uchida T. Quality of life following high-intensity focused ultrasound for the treatment of localized prostate cancer: a prospective study. Int J Urol 2010;17(8):715-9.	Wurde extrahiert	

Uchida T, Shoji S, Nakano M, Hongo S, Nitta M, Murota A, Nagata Y. Transrectal high-intensity focused ultrasound for the treatment of localized prostate cancer: eight-year experience. <i>Int J Urol</i> 2009;16(11):881-6.	X	
Warmuth M, Johansson T, Mad P. Systematic Review of the Efficacy and Safety of High-Intensity Focussed Ultrasound for the Primary and Salvage Treatment of Prostate Cancer. <i>Eur Urol</i> 2010.	Wurde extrahiert	
Obyn C, Mambourg F. Assessment of high intensity focused ultrasound for the treatment of prostate cancer. <i>Acta Chir Belg</i> 2009;109(5):581-6.	X	X

12.3.9.4.2. Ausgeschlossene Publikationen (Volltextscreening)

Ausschlussgrund A2 (Keine klinische Studie oder systematischer Review (mit oder ohne Metaanalyse))

1. Ahmed HU, Emberton M. Active surveillance and radical therapy in prostate cancer: can focal therapy offer the middle way? *World J Urol* 2008;26(5):457-67.
2. Abdel-Wahab M, Pollack A. Prostate cancer: Defining biochemical failure in patients treated with HIFU. *Nat Rev Urol* 2010;7(4):186-7.
3. Chaussy C, Thuroff S. High-intensity focused ultrasound in the management of prostate cancer. *Expert Rev Med Devices* 2010;7(2):209-17.
4. Kimura M, Mouraviev V, Tsivian M, Mayes JM, Satoh T, Polascik TJ. Current salvage methods for recurrent prostate cancer after failure of primary radiotherapy. *BJU Int* 2010;105(2):191-201.
5. Lukka H, Waldron T, Chin J, Mayhew L, Warde P, Winquist E, Rodrigues G, Shayegan B. High-intensity focused ultrasound for prostate cancer: a practice guideline. *Can Urol Assoc J* 2010;4(4):232-6.
6. Mazzucchelli R, Scarpelli M, Cheng L, Lopez-Beltran A, Galosi AB, Kirkali Z, Montironi R. Pathology of prostate cancer and focal therapy ('male lumpectomy'). *Anti-cancer Res* 2009;29(12):5155-61.
7. Ward JF. Prostate cancer: HIFU is effective, but associated morbidity still remains unclear. *Nat Rev Urol* 2010;7(11):597-8.
8. Ward JF. Contemporary outcomes of focal therapy in prostate cancer: what do we know so far.. *World J Urol* 2010;28(5):593-7.

Ausschlussgrund A5 (Nicht Fragestellung: HIFU zur Therapie des Prostatakarzinoms)

1. Biermann K, Montironi R, Lopez-Beltran A, Zhang S, Cheng L. Histopathological findings after treatment of prostate cancer using high-intensity focused ultrasound (HIFU). *Prostate* 2010;70(11):1196-200.
2. Blana A, Brown SC, Chaussy C, Conti GN, Eastham JA, Ganzer R, Murat FJ, Pasticier G, Rebillard X, Rewcastle JC, Robertson CN, Thuroff S, Ward JF. High-intensity focused ultrasound for prostate cancer: comparative definitions of biochemical failure. *BJU Int* 2009;104(8):1058-62.
3. Li LY, Yang M, Gao X, Zhang HB, Li JF, Xu WF, Lin Z, Zhou XL. Prospective comparison of five mediators of the systemic response after high-intensity focused ultrasound and targeted cryoablation for localized prostate cancer. *BJU Int* 2009;104(8):1063-7.

Ausschlussgrund A6 (n < 50)

1. Berge V, Baco E, Karlsen SJ. A prospective study of salvage high-intensity focused ultrasound for locally radiorecurrent prostate cancer: early results. *Scand J Urol Nephrol* 2010;44(4):223-7.

2. Challacombe BJ, Murphy DG, Zakri R, Cahill DJ. High-intensity focused ultrasound for localized prostate cancer: initial experience with a 2-year follow-up. *BJU Int* 2009;104(2):200-4.
3. Maestroni U, Ziveri M, Azzolini N, Dinale F, Ziglioli F, Campaniello G, Frattini A, Ferretti S. High Intensity Focused Ultrasound (HIFU): a useful alternative choice in prostate cancer treatment. Preliminary results. *Acta Biomed* 2008;79(3):211-6.
4. Murota-Kawano A, Nakano M, Hongo S, Shoji S, Nagata Y, Uchida T. Salvage high-intensity focused ultrasound for biopsy-confirmed local recurrence of prostate cancer after radical prostatectomy. *BJU Int* 2010;105(12):1642-5.
5. Zacharakis E, Ahmed HU, Ishaq A, Scott R, Illing R, Freeman A, Allen C, Emberton M. The feasibility and safety of high-intensity focused ultrasound as salvage therapy for recurrent prostate cancer following external beam radiotherapy. *BJU Int* 2008;102(7):786-92.

Ausschlussgrund A7 (restrospektive Auswertung)

1. Misrai V, Roupret M, Chartier-Kastler E, Comperat E, Renard-Penna R, Haertig A, Bitker MO, Richard F, Conort P. Oncologic control provided by HIFU therapy as single treatment in men with clinically localized prostate cancer. *World J Urol* 2008;26(5):481-5.
2. Murat FJ, Poissonnier L, Rabilloud M, Belot A, Bouvier R, Rouviere O, Chapelon JY, Gelet A. Mid-term results demonstrate salvage high-intensity focused ultrasound (HIFU) as an effective and acceptably morbid salvage treatment option for locally radiorecurrent prostate cancer. *Eur Urol* 2009;55(3):640-7.
3. Ripert T, Azemar MD, Menard J, Barbe C, Messaoudi R, Bayoud Y, Pierrelvelcin J, Duval F, Staerman F. Six years' experience with high-intensity focused ultrasonography for prostate cancer: oncological outcomes using the new 'Stuttgart' definition for biochemical failure. *BJU Int* 2010.
4. Ripert T, Azemar MD, Menard J, Bayoud Y, Messaoudi R, Duval F, Staerman F. Transrectal high-intensity focused ultrasound (HIFU) treatment of localized prostate cancer: review of technical incidents and morbidity after 5 years of use. *Prostate Cancer Prostatic Dis* 2010;13(2):132-7.

12.3.10. Recherchen zum Thema Therapie von Knochenmetastasen

12.3.10.1. Fragestellungen

Population	Intervention	Control	Outcomes	Time aspects
Pat. mit kurativ behandeltem PCa	Präventive Gabe von Bis-phosphonaten	-	Auftreten von Knochenmetastasen	-
Pat mit PCa und Knochenmetastasen	Perkutane Radiotherapie, Radioisotope, operative Interventionen, Spezifische Medikamente zur Behandlung von Knochenmetastasen	Placebo/Goldstandard	Auftreten von Skeletal related events Schmerzreduktion Nebenwirkungen Gesamtüberleben	-

12.3.10.2. Recherchen

1. Recherche zu Prävention von Knochenmetastasen
(ab 1/2000 – 10.3.2011)

Pubmed

Nr.	Suchfrage	Anzahl
#5	#1 AND #2 AND #3 Limits: English, German	153
#4	#1 AND #2 AND #3	165
#3	prevention (Details: "prevention and control"[Subheading] OR ("prevention"[All Fields] AND "control"[All Fields]) OR "prevention and control"[All Fields] OR "prevention"[All Fields])	1038408
#2	bone metastasis (Details: ("bone and bones"[MeSH Terms] OR ("bone"[All Fields] AND "bones"[All Fields]) OR "bone and bones"[All Fields] OR "bone"[All Fields]) AND ("neoplasm metastasis"[MeSH Terms] OR ("neoplasm"[All Fields] AND "metastasis"[All Fields]) OR "neoplasm metastasis"[All Fields] OR "metastasis"[All Fields]))	21188
#1	Prostate cancer (Details: "prostatic neoplasms"[MeSH Terms] OR ("prostatic"[All Fields] AND "neoplasms"[All Fields]) OR "prostatic neoplasms"[All Fields] OR ("prostate"[All Fields] AND "cancer"[All Fields]) OR "prostate cancer"[All Fields])	92213

Anzahl der Treffer: 153

Davon relevant: 150

Cochrane

Nr.	Suchfrage	Anzahl
#1	"prostate cancer in Title, Abstract or Keywords and bone metastasis in Title, Abstract or Keywords and prevention in Title, Abstract or Keywords	33

- Cochrane Database of Systematic Reviews (2)
- Database of Abstracts of Reviews of Effects (0)
- Cochrane Central Register of Controlled Trials (29)
- Cochrane Methodology Register (0)
- Health Technology Assessment Database (1)
- NHS Economic Evaluation Database (1)

Anzahl der Treffer: 33

Davon neu: 26

Davon relevant: 26

2. Recherche zu Behandlung von Knochenmetastasen
(2/2009-8.6.2011)

Pubmed

Nr.	Suchfrage	Anzahl
#9	#4 AND #7 Limits: English, German; Publication Date from 2009	36
#8	#4 AND #7	275
#7	#5 OR #6	2297626
#6	(randomized controlled trial [pt] OR controlled clinical trial [pt] OR randomized [tiab] OR placebo [tiab] OR drug therapy [sh] OR randomly [tiab] OR trial [tiab] OR groups [tiab]) AND humans [mh]	2194815
#5	systematic[sb]	156356
#4	#1 AND #2 AND #3	687
#3	("Radioisotopes"[Mesh]) OR radionuclide*[tiab] OR "Radiotherapy"[Mesh] OR radiation OR radiotherapy OR ("Diphosphonates"[Mesh])	900425
#2	bone metastasis	21468
#1	Prostate cancer	94089

Anzahl der Treffer: 36

Davon relevant: 34

Cochrane

Nr.	Suchfrage	Anzahl
#1	"prostate cancer in Title, Abstract or Keywords and bone metastasis in Title, Abstract or Keywords in Title, Abstract or Keywords from 2009 to 2011	9

- Cochrane Database of Systematic Reviews (4)
- Database of Abstracts of Reviews of Effects (0)
- Cochrane Central Register of Controlled Trials (15)
- Cochrane Methodology Register (0)
- Health Technology Assessment Database (1)
- NHS Economic Evaluation Database (0)

Davon relevant: 2

12.3.10.3. Ein – und Ausschlusskriterien

Einschlussgründe	
E1 Zielgruppe	Patienten mit kurativ behandeltem PCa Patienten mit KNochenmetastasen
E2 Publikations- typ	Therapie: Randomisierte kontrollierte Studien Phase III Unerwünschte Wirkungen: Fallserien mit v.a. PCa, mind, n=11
E3: Suchzeit- raum	Prävention: ab 2000 Behandlung : ab 2009
E4: Sprachen	Deutsch, Englisch
E5 Intervention	Prävention: Medikation Behandlung: Medikation (Bisphosphonate, Denosumab) , perkutane Strahlentherapie, Therapie mit Radioisotopen, operative Therapie

Ausschlusskriterien für erste Relevanzsichtung der Volltexte

A1: Methodik (Letter, Editorial, experimentelle Phase I - Studie, Phase II-Studie, Nebenwirkungen Fallberichte <10)

A2: andere Erkrankung bzw. nicht v.a. PCa

A3: kein Fokus auf Prävention oder Behandlung von Knochenmetastasen bei Prostatakarzinompatienten

A4: unsystematische Übersichtsarbeit

12.3.10.4. Ergebnisse der Recherche

12.3.10.4.1. Recherche zu Prävention

Abstracts:

Pubmed: 153, Cochrane: n= 26, Referenzlisten:1

Volltexte: 12

Nach Volltextsichtung eingeschlossene Texte

1. (nur im Hintergrund zitiert, nicht extrahiert) Mason MD, Sydes MR, Glaholm J, Langley RE, Huddart RA, Sokal M, Stott M, Robinson AC, James ND, Parmar MK, Dearnaley DP. Oral sodium clodronate for nonmetastatic prostate cancer--results of a randomized double-blind placebo-controlled trial: Medical Research Council PR04 (ISRCTN61384873). *J Natl Cancer Inst* 2007;99(10):765-76.
2. Morgan G, Lipton A. Antitumor effects and anticancer applications of bisphosphonates. *Semin Oncol* 2010;37 Suppl 2:S30-S40.
3. Smith MR, Kabbavar F, Saad F, Hussain A, Gittelman MC, Bilhartz DL, Wynne C, Murray R, Zinner NR, Schulman C, Linnartz R, Zheng M, Goessl C, Hei YJ, Small EJ, Cook R, Higano CS. Natural history of rising serum prostate-specific antigen in men with castrate nonmetastatic prostate cancer. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology* 2005;23(13):2918-25. (siehe Evidenztabelle, aus Referenzliste)
4. (nur im Hintergrund zitiert, nicht extrahiert) Witjes W, Tammela T, Wirth M. Effectiveness of zoledronic acid for the prevention of bone metastases in high risk pros-

tate cancer patients: A randomised, open label, multicenter study of the European Association of Urology (EAU) in cooperation with the Scandinavian Prostate Cancer Group (SPCG) and the Arbeitsgemeinschaft Urologische Onkologie (AUO). An initial report of the "ZEUS" study. *Journal of Clinical Oncology: ASCO annual meeting proceedings* 2006;24(18S):14644.

Ausgeschlossene Volltexte

A3 nicht Fokus Prävention von Knochenmetastasen bei PCa:

1. Ryan CW, Huo D, Bylow K, Demers LM, Stadler WM, Henderson TO, Vogelzang NJ. Suppression of bone density loss and bone turnover in patients with hormone-sensitive prostate cancer and receiving zoledronic acid. *BJU Int* 2007;100(1):70-5. (Prävention Osteoporose)
2. Smith MR, McGovern FJ, Zietman AL, Fallon MA, Hayden DL, Schoenfeld DA, Kantoff PW, Finkelstein JS. Pamidronate to prevent bone loss during androgen-deprivation therapy for prostate cancer. *The New England journal of medicine* 2001;345(13):948-55. (Prävention Osteoporose)
3. Smith MR, Eastham J, Gleason DM, Shasha D, Tchekmedyan S, Zinner N. Randomized controlled trial of zoledronic acid to prevent bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer. *Journal of Urology* 2003;169(6):2008-12. (Prävention Osteoporose)
4. Taxel P, Fall PM, Albertsen PC, Dowsett RD, Trahiotis M, Zimmerman J, Ohannesian C, Raisz LG. The effect of micronized estradiol on bone turnover and calcitropic hormones in older men receiving hormonal suppression therapy for prostate cancer. *J Clin Endocrinol Metab* 2002;87(11):4907-13. (Prävention Osteoporose)

A4 nicht systematischer Review:

1. Body JJ. Bisphosphonates for malignancy-related bone disease: current status, future developments. *Support Care Cancer* 2006;14(5):408-18.
2. Chen TC, Holick MF. Vitamin D and prostate cancer prevention and treatment. *Trends Endocrinol Metab* 2003;14(9):423-30.
3. Coleman R, Gnani M. New results from the use of bisphosphonates in cancer patients. *Curr Opin Support Palliat Care* 2009;3(3):213-8.
4. Gnani M. Bisphosphonates in the prevention of disease recurrence: current results and ongoing trials. *Curr Cancer Drug Targets* 2009;9(7):824-33.
5. Lattouf JB, Saad F. Preservation of bone health in prostate cancer. *Curr Opin Support Palliat Care* 2007;1(3):192-7.
6. Saad F, McKiernan J, Eastham J. Rationale for zoledronic acid therapy in men with hormone-sensitive prostate cancer with or without bone metastasis. *Urol Oncol* 2006;24(1):4-12.
7. Santini D, Galluzzo S, Vincenzi B, Schiavon G, Fratto E, Pantano F, Tonini G. New developments of aminobisphosphonates: the double face of Janus. *Ann Oncol* 2007;18 Suppl 6:vi164-vi167.

12.3.10.4.2. Recherche zu Behandlung

Abstracts nach Ausschluss von Dubletten:

Pubmed: 37 Cochrane Reviews: 4, Referenzlisten, Handsuche 2 (Walter, Rades); Volltexte: 15

12.3.10.4.3. Einschluss nach Volltextscreening

1. Aragon-Ching JB, Ning YM, Chen CC, Latham L, Guadagnini JP, Gulley JL, Arlen PM, Wright JJ, Parnes H, Figg WD, Dahut WL. Higher incidence of Osteonecrosis of the Jaw (ONJ) in patients with metastatic castration resistant prostate cancer treated with anti-angiogenic agents. *Cancer Invest* 2009;27(2):221-6.
2. Fizazi K, Carducci M, Smith M, Damiao R, Brown J, Karsh L, Milecki P, Shore N, Rader M, Wang H, Jiang Q, Tadros S, Dansey R, Goessl C. Denosumab versus zoledronic acid in patients with hormone-sensitive metastatic prostate cancer: a randomised, double-blind, phase 3 trial. *Lancet* 2012;380(9845):603-11.

- dronic acid for treatment of bone metastases in men with castration-resistant prostate cancer: a randomised, double-blind study. *Lancet* 2011;377(9768):813-22.
3. George R, Jeba J, Ramkumar G, Chacko AG, Leng M, Tharyan P. Interventions for the treatment of metastatic extradural spinal cord compression in adults. *Cochrane Database Syst Rev* 2010;(1):CD006716.
 4. Walter C, Al-Nawas B, Grotz KA, Thomas C, Thuroff JW, Zinser V, Gamm H, Beck J, Wagner W. Prevalence and risk factors of bisphosphonate-associated osteonecrosis of the jaw in prostate cancer patients with advanced disease treated with zoledronate. *Eur Urol* 2008;54(5):1066-72.
 5. Sze WM, Shelley M, Held I, Mason M. Palliation of metastatic bone pain: single fraction versus multifraction radiotherapy - a systematic review of the randomised trials. *Cochrane Database Syst Rev* 2011;(5):CD004721. (aus Referenzliste)

Zusätzlich aus Handsuche:

1. Chow E. , Metaanalyse zur Einzeit vs. Mehrzeitbestrahlung von Knochenmetastasen, *JCO* 2007 (Zitat wird ergänzt)
2. Dearnaley D.P. et al, 2009 Adjuvant therapy with oral sodium clodronate in locally advanced and metastatic prostate cancer...(Zitat wird ergänzt)

12.3.10.4.4. Ausgeschlossene Volltexte

A1 (Methodik):

1. Chaturvedi P, Pai PS, Chaukar DA, Gupta S, D'cruz AK. Bisphosphonate induced osteonecrosis of the jaw masquerading as tumor: a word of caution for oral surgeons and oncologists. *Eur J Surg Oncol* 2010;36(6):541-5. Fallberichte Kiefernekrose n=6
2. Frei M, Bornstein MM, Schaller B, Reichart PA, Weimann R, Iizuka T. Bisphosphonate-related osteonecrosis of the jaw combined with jaw metastasis of prostate adenocarcinoma: report of a case. *J Oral Maxillofac Surg* 2010;68(4):863-7. Fallbericht Kiefernekrose
3. Hatoum HT, Lin SJ, Guo A, Lipton A, Smith MR. Zoledronic acid therapy impacts risk and frequency of skeletal complications and follow-up duration in prostate cancer patients with bone metastasis. *Curr Med Res Opin* 2011;27(1):55-62. retrospektive Registerauswertung zu Zoledronsäure
4. Krishnan A, Arslanoglu A, Yildirm N, Silbergleit R, Aygun N. Imaging findings of bisphosphonate-related osteonecrosis of the jaw with emphasis on early magnetic resonance imaging findings. *J Comput Assist Tomogr* 2009;33(2):298-304. Fallberichte Kiefernekrose n=6
5. Rades D, Huttenlocher S, Dunst J, Bajrovic A, Karstens JH, Rudat V, Schild SE. Matched pair analysis comparing surgery followed by radiotherapy and radiotherapy alone for metastatic spinal cord compression. *J Clin Oncol* 2010;28(22):3597-604. retrospektive Matched Pair Studie zu Rückenmarkskompressionstherapie (radiotherapie vs. Radiotherapie+operat. Dekompression, n.s.) (aus Handsuche)
6. Saad F, Eastham J. Zoledronic Acid improves clinical outcomes when administered before onset of bone pain in patients with prostate cancer. *Urology* 2010;76(5):1175-81. retrospektive exploratische Analyse eines RCT zu Zoledronsäure
7. Velde NV, Wu EQ, Guo A, Lu M, Yu AP, Sharma H, Liu J, Fan CP, Shi L. The benefits of timely intervention with zoledronic acid in patients with metastatic prostate cancer to bones: a retrospective study of the US Veterans Affairs population. *Prostate Cancer Prostatic Dis* 2011;14(1):79-84. retrospektive Auswertung zu Zoledronsäure

A2 nicht vorwiegend PCa:

1. Junquera L, Gallego L, Cuesta P, Pelaz A, de Vicente JC. Clinical experiences with bisphosphonate-associated osteonecrosis of the jaws: analysis of 21 cases. *Am J Otolaryngol* 2009;30(6):390-5. Fallserie Kiefernekrosen (nur 10% Pat mit PCa (2/21))

A3 nicht Fokus Behandlung von Knochenmetastasen bei PCa:

1. Gnant M. Bisphosphonates in the prevention of disease recurrence: current results and ongoing trials. *Curr Cancer Drug Targets* 2009;9(7):824-33. Prävention von Knochenmetastasen

A4 nicht systematischer Review:

1. Buijs JT, Kuijpers CC, van der PG. Targeted therapy options for treatment of bone metastases; beyond bisphosphonates. *Curr Pharm Des* 2010;16(27):3015-27.
2. Tu SM, Lin SH, Podoloff DA, Logothetis CJ. Multimodality therapy: bone-targeted radioisotope therapy of prostate cancer. *Clin Adv Hematol Oncol* 2010;8(5):341-51.

12.3.11. Recherche zum Thema Behandlung des kastrationsresistenten Prostatakarzinoms**12.3.11.1. Fragestellungen**

	Population	Intervention	Control	Outcomes	Time aspects
1	Patienten mit kastrationsresistentem Prostatakarzinom (ohne Einschränkung)	Systemtherapie (nicht spezifisch für Knochenmetastasen)	Placebo/Goldstandard	Überleben, Nebenwirkungen, Lebensqualität	-

12.3.11.2. Recherchen

PubMed (06. Juni 2011)

Nr.	Suchfrage	Anzahl
#8	#3 AND #6, Limits English, German, Publication Date from 2008/08	679
#7	#3 AND #6	3767
#6	#4 OR #5	2296269
#5	(randomized controlled trial [pt] OR controlled clinical trial [pt] OR randomized [tiab] OR placebo [tiab] OR drug therapy [sh] OR randomly [tiab] OR trial [tiab] OR groups [tiab]) AND humans [mh]	2193575
#4	systematic[sb]	156150
#3	#1 AND #2	6498
#2	"hormone-refractory" OR "hormone refractory" OR chemotherapy[tiab] OR docetaxel[tiab] OR prednisolone[tiab] OR mitoxantrone[tiab] OR dexamethasone OR ketoconazole OR hydrocortisone OR thalidomide OR doxorubicin OR paclitaxel OR carboplatin OR estramustine OR vinblastine OR Abirateron	382071

#1	prostate AND cancer	81449
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Anzahl der Treffer: 679

Davon relevant: 620

Cochrane (06. Juni 2011)

Nr.	Suchfrage	Anzahl
#4	#1 And #2, from 2008 to 2011	85
#3	#1 AND #2	629
#2	"hormone?refractory" OR chemotherapy OR docetaxel OR prednisolone OR mitoxantrone OR dexamethasone OR ketoconazole OR hydrocortisone OR thalidomide OR doxorubicin OR paclitaxel OR carboplatin OR estramustine OR vinblastine OR Abirateron:ti,ab,kw	38897
#1	(prostate):ti,ab,kw and (cancer):ti,ab,kw	3060

- Cochrane Database of Systematic Reviews (3)
- Database of Abstracts of Reviews of Effects (0)
- Cochrane Central Register of Controlled Trials (80)
- Cochrane Methodology Register (0)
- Health Technology Assessment Database (1)
- NHS Economic Evaluation Database (1)

Anzahl der Treffer: 85

Davon neu: 45

Davon relevant: 42

12.3.11.3. Ein – und Ausschlusskriterien

Ausschlussgründe

A1: andere Erkrankung

A2: nicht Fragestellung (siehe oben)

A3: Methodik (keine Phase III RCTs oder systematische Übersichten)

A4: unsystematische Übersichtsarbeit

A5: Doppelpublikation oder Volltext nicht erhältlich

12.3.11.4. Ergebnisse der Recherche

12.3.11.4.1. Nach Volltextsichtung eingeschlossene Texte

1. de Bono JS, Logothetis CJ, Molina A, Fizazi K, North S, Chu L et al. Abiraterone and increased survival in metastatic prostate cancer. N Engl J Med 2011 May 26;364(21):1995-2005.
1. Shamash J, Powles T, Sarker SJ, Protheroe A, Mithal N, Mills R et al. A multi-centre randomised phase III trial of Dexamethasone vs Dexamethasone and diethylstilbe-

- strol in castration-resistant prostate cancer: immediate vs deferred Diethylstilbestrol. *Br J Cancer* 2011 February 15;104(4):620-8.
2. Chao HH, Mayer T, Concato J, Rose MG, Uchio E, Kelly WK. Prostate cancer, comorbidity, and participation in randomized controlled trials of therapy. *J Investig Med* 2010 March;58(3):566-8.
 3. Colloca G, Venturino A, Checcaglini F. Patient-reported outcomes after cytotoxic chemotherapy in metastatic castration-resistant prostate cancer: a systematic review. *Cancer Treat Rev* 2010 October;36(6):501-6.
 4. de Bono JS, Oudard S, Ozguroglu M, Hansen S, Machiels JP, Kocak I et al. Prednisone plus cabazitaxel or mitoxantrone for metastatic castration-resistant prostate cancer progressing after docetaxel treatment: a randomised open-label trial. *Lancet* 2010 October 2;376(9747):1147-54.
 5. Kantoff PW, Higano CS, Shore ND, Berger ER, Small EJ, Penson DF et al. Sipuleucel-T immunotherapy for castration-resistant prostate cancer. *N Engl J Med* 2010 July 29;363(5):411-22.
 6. Higano CS, Schellhammer PF, Small EJ, Burch PA, Nemunaitis J, Yuh L et al. Integrated data from 2 randomized, double-blind, placebo-controlled, phase 3 trials of active cellular immunotherapy with sipuleucel-T in advanced prostate cancer. *Cancer* 2009 August 15;115(16):3670-9.
 7. Steinberg M. Degarelix: a gonadotropin-releasing hormone antagonist for the management of prostate cancer. *Clin Ther* 2009;31 Pt 2:2312-31.
 8. Beer TM, Ryan CW, Venner PM, Petrylak DP, Chatta GS, Ruether JD et al. Intermittent chemotherapy in patients with metastatic androgen-independent prostate cancer: results from ASCENT, a double-blinded, randomized comparison of high-dose capecitabine plus docetaxel with placebo plus docetaxel. *Cancer* 2008;112:326-30.
 9. Berthold DR, Pond GR, Soban F, de WR, Eisenberger M, Tannock IF. Docetaxel plus prednisone or mitoxantrone plus prednisone for advanced prostate cancer: updated survival in the TAX 327 study. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology* 2008;26:242-5.
 10. Machiels JP, Mazzeo F, Clausse M, Filleul B, Marcelis L, Honhon B et al. Prospective randomized study comparing docetaxel, estramustine, and prednisone with docetaxel and prednisone in metastatic hormone-refractory prostate cancer. *J Clin Oncol* 2008 November 10;26(32):5261-8.
 11. Nelson JB, Love W, Chin JL, Saad F, Schulman CC, Sleep DJ et al. Phase 3, randomized, controlled trial of abiraterone in patients with nonmetastatic, hormone-refractory prostate cancer. *Cancer* 2008 November 1;113(9):2478-87.

12.3.11.4.2. Ausgeschlossene Volltexte

A2 (nicht Fragestellung)

1. Armstrong AJ, Halabi S, de WR, Tannock IF, Eisenberger M. The relationship of body mass index and serum testosterone with disease outcomes in men with castration-resistant metastatic prostate cancer. *Prostate Cancer Prostatic Dis* 2009;12(1):88-93.
2. Haidar A, Jonler M, Folkmar TB, Lund L. Bisphosphonate (zoledronic acid)-induced osteonecrosis of the jaw. *Scand J Urol Nephrol* 2009;43(6):442-4.
3. Inoue T, Segawa T, Kamba T, Yoshimura K, Nakamura E, Nishiyama H et al. Prevalence of skeletal complications and their impact on survival of hormone refractory prostate cancer patients in Japan. *Urology* 2009 May;73(5):1104-9.
4. Millikan RE, Wen S, Pagliaro LC, Brown MA, Moomey B, Do KA et al. Phase III trial of androgen ablation with or without three cycles of systemic chemotherapy for advanced prostate cancer. *J Clin Oncol* 2008 December 20;26(36):5936-42.
5. Walter C, Al-Nawas B, Grotz KA, Thomas C, Thuroff JW, Zinser V et al. Prevalence and risk factors of bisphosphonate-associated osteonecrosis of the jaw in prostate cancer patients with advanced disease treated with zoledronate. *Eur Urol* 2008 November;54(5):1066-72.

A3 (Methodik)

1. Picus J, Halabi S, Kelly WK, Vogelzang NJ, Whang YE, Kaplan EB et al. A phase 2 study of estramustine, docetaxel, and bevacizumab in men with castrate-resistant

- prostate cancer: results from Cancer and Leukemia Group B Study 90006. *Cancer* 2011 February 1;117(3):526-33.
2. Smith TJ, Dow LA, Virago EA, Khatcheressian J, Matsuyama R, Lyckholm LJ. A pilot trial of decision aids to give truthful prognostic and treatment information to chemotherapy patients with advanced cancer. *J Support Oncol* 2011 March;9(2):79-86.
 3. Antonarakis ES, Carducci MA, Eisenberger MA. Novel targeted therapeutics for metastatic castration-resistant prostate cancer. *Cancer Lett* 2010 May 1;291(1):1-13.
 4. Azuma H, Inamoto T, Takahara K, Ibuki N, Koyama K, Utimoto S et al. Combination therapy with VP16 and ethinylestradiol for hormone-refractory prostate cancer: good response with tolerability. *Anticancer Res* 2010 September;30(9):3737-45.
 5. Caffo O, Sava T, Comploj E, Giampaolo MA, Segati R, Valduga F et al. Estramustine plus docetaxel as second-line therapy in patients with hormone-refractory prostate cancer resistant to docetaxel alone. *Urol Oncol* 2010 March;28(2):152-6.
 6. Eymard JC, Oudard S, Gravis G, Ferrero JM, Theodore C, Joly F et al. Docetaxel reintroduction in patients with metastatic castration-resistant docetaxel-sensitive prostate cancer: a retrospective multicentre study. *BJU Int* 2010 October;106(7):974-8.
 7. Kaliks RA, Santi P, Cardoso AP, Giglio AD. Complete androgen blockade safely allows for delay of cytotoxic chemotherapy in castration refractory prostate cancer. *Int Braz J Urol* 2010 May;36(3):300-7.
 8. Keisner SV, Shah SR, Jean GW, Ussery SM, Dowell JE. Retrospective analysis of the consequences of acid suppressive therapy on ketoconazole efficacy in advanced castration-resistant prostate cancer. *Ann Pharmacother* 2010 October;44(10):1538-44.
 9. Lorient Y, Massard C, Gross-Goupil M, Di PM, Escudier B, Bossi A et al. The interval from the last cycle of docetaxel-based chemotherapy to progression is associated with the efficacy of subsequent docetaxel in patients with prostate cancer. *Eur J Cancer* 2010 July;46(10):1770-2.
 10. Miura N, Numata K, Kusuhara Y, Shirato A, Hashine K, Sumiyoshi Y. Docetaxel-prednisolone combination therapy for Japanese patients with hormone-refractory prostate cancer: a single institution experience. *Jpn J Clin Oncol* 2010 November;40(11):1092-8.
 11. Nakabayashi M, Oh WK, Jacobus S, Regan MM, Taplin ME, Kantoff PW et al. Activity of ketoconazole after taxane-based chemotherapy in castration-resistant prostate cancer. *BJU Int* 2010 May;105(10):1392-6.
 12. Nakagami Y, Ohori M, Sakamoto N, Koga S, Hamada R, Hatano T et al. Safety and efficacy of docetaxel, estramustine phosphate and hydrocortisone in hormone-refractory prostate cancer patients. *Int J Urol* 2010 July;17(7):629-34.
 13. Regan MM, O'Donnell EK, Kelly WK, Halabi S, Berry W, Urakami S et al. Efficacy of carboplatin-taxane combinations in the management of castration-resistant prostate cancer: a pooled analysis of seven prospective clinical trials. *Ann Oncol* 2010 February;21(2):312-8.
 14. Reuter CW, Morgan MA, Ivanyi P, Fenner M, Ganser A, Grunwald V. Carboplatin plus weekly docetaxel as salvage chemotherapy in docetaxel-resistant and castration-resistant prostate cancer. *World J Urol* 2010 June;28(3):391-8.
 15. Rousseau F, Retornaz F, Joly F, Esterni B, badie-Lacourtoisie S, Fargeot P et al. Impact of an all-oral capecitabine and vinorelbine combination regimen on functional status of elderly patients with advanced solid tumours: A multicentre pilot study of the French geriatric oncology group (GERICO). *Crit Rev Oncol Hematol* 2010 October;76(1):71-8.
 16. Shamash J, Stebbing J, Sweeney C, Sonpavde G, Harland S, Dawkins G et al. A validated prognostic index predicting response to dexamethasone and diethylstilbestrol in castrate-resistant prostate cancer. *Cancer* 2010 August 1;116(15):3595-602.
 17. Sonpavde G, Periman PO, Bernold D, Weckstein D, Fleming MT, Galsky MD et al. Sunitinib malate for metastatic castration-resistant prostate cancer following docetaxel-based chemotherapy. *Ann Oncol* 2010 February;21(2):319-24.
 18. Alamarai S, Charpidou AG, Matthay RA, Confeld D, Syrigos KN, Saif MW. Pneumonitis related to docetaxel: case report and review of the literature. *In Vivo* 2009 July;23(4):635-7.
 19. Bellmunt J, Carles J, Albanell J. Predictive modelling in hormone-refractory prostate cancer (HRPC). *Clin Transl Oncol* 2009 February;11(2):82-5.

20. Curigliano G, Spitaleri G, De CO, Scardino E, Sbanotto A, de BF. Health-related quality of life in patients with hormone refractory prostate cancer receiving gefitinib. *Urol Int* 2009;82(2):196-202.
21. Fontana A, Galli L, Fioravanti A, Orlandi P, Galli C, Landi L et al. Clinical and pharmacodynamic evaluation of metronomic cyclophosphamide, celecoxib, and dexamethasone in advanced hormone-refractory prostate cancer. *Clin Cancer Res* 2009 August 1;15(15):4954-62.
22. Italiano A, Ortholan C, Oudard S, Pouessel D, Gravis G, Beuzebec P et al. Docetaxel-based chemotherapy in elderly patients (age 75 and older) with castration-resistant prostate cancer. *Eur Urol* 2009 June;55(6):1368-75.
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A4 (unsystematische Übersichtsarbeit)

1. Galsky MD, Vogelzang NJ. Docetaxel-based combination therapy for castration-resistant prostate cancer. *Ann Oncol* 2010 November;21(11):2135-44.
2. Kohli M, Tindall DJ. New developments in the medical management of prostate cancer. *Mayo Clin Proc* 2010 January;85(1):77-86.
3. Wallerand H, Robert G, Bernhard JC, Ravaud A, Patard JJ. Tyrosine-kinase inhibitors in the treatment of muscle invasive bladder cancer and hormone refractory prostate cancer. *Arch Esp Urol* 2010 November;63(9):773-87.
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A5 (Doppelpublikation oder Volltext nicht erhältlich)

1. Sission TM, Danesi R, Kirkland CT, Baum CE, Ockers SB, Stein EV et al. Estrogen receptor alpha and aromatase polymorphisms affect risk, prognosis, and therapeutic outcome in men with castration-resistant prostate cancer treated with docetaxel-based therapy. J Clin Endocrinol Metab 2011 February;96(2):E368-E372.
2. Sonpavde G, Attard G, Bellmunt J, Mason MD, Malavaud B, Tombal B et al. The Role of Abiraterone Acetate in the Management of Prostate Cancer: A Critical Analysis of the Literature. Eur Urol 2011 April 2

12.4. Methodik und Ergebnisse der Recherchen zur 2. Aktualisierung 2014

12.4.1. Recherche zum Thema Früherkennung/Screening (Kapitel 3.1 der Leitlinie)

12.4.1.1. Fragestellung

Fragestellung /Themenbereich	Population	Intervention	Kontrolle	Outcome	Evidenzgrundlage
Früherkennung „intelligent“: risikoadaptierte Zeitabstände, Altersbeginn der Früherkennung (PSA, Nomogramm, digital-rektale Tastuntersuchung) Börgermann, Rübben, Egidi	Männer (1) Alter >= 40 bis Lebenserwartung <10 Jahre und PSA <1 ng/ml baseline, low risk? (2) Alter >= 40 bis Lebenserwartung <10 Jahre und PSA >1 <3 ng/ml baseline, mittleres Risiko? (3) Alter >= 40 bis Lebenserwartung <10 Jahre und PSA >3 ng/ml baseline high risk?	Jährliche PSA- Kontrolle	Andere Zeitabstände: (A) Keine PSA - Kontrolle (B) zweijährliche PSA Kontrolle (C) dreijährliche PSA Kontrolle (D) vierjährliche PSA Kontrolle	PCa-spezifische Mortalität, Gesamtüberleben, Histo	Aggregierte Evidenz (Systematischer Review, Leitlinienadaptation) + RCT, prospektive Kohortenstudien

12.4.1.2. Recherchestrategien

Ausschlusskriterien für Relevanzsichtung:

A1: andere Erkrankung (nicht PCa)

A2: Methodik (Letter, Editorial, News, Comment)

A3: Dubletten durch Suche in verschiedenen Datenbanken

A4: Publikationen vor 2011 und nicht deutsch oder englisch (Cochrane Library)

PubMed (10. April 2013)

Suchstrategie:

Nr.	Suchfrage	Anzahl
#5	#1 AND #2 AND #3 Limits: English, German, Publication date from 2011/01/01	674
#4	#1 AND #2 AND #3	4198
#3	("prostate-specific antigen"[MeSH Terms] OR ("prostate-specific"[All Fields] AND "antigen"[All Fields]) OR "prostate-specific antigen"[All Fields] OR ("prostate"[All Fields] AND "specific"[All Fields] AND "antigen"[All Fields]) OR "prostate specific antigen"[All Fields]) OR PSA[All Fields]	32371
#2	"screening"[All Fields] OR "mass screening"[MeSH Terms] OR "early detection of cancer"[MeSH Terms] OR "early detection of cancer"[All Fields]	360428
#1	"prostatic neoplasms"[MeSH Terms] OR ("prostatic"[All Fields] AND "neoplasms"[All Fields]) OR "prostatic neoplasms"[All Fields] OR ("prostate"[All Fields] AND "cancer"[All Fields]) OR "prostate cancer"[All Fields]	107976

Anzahl der Treffer: 674;

Davon relevant: 594

Cochrane (10. April 2013)

Suchstrategie:

Nr.	Suchfrage	Anzahl
#4	#1 AND #2 from 2011 to 2013, in Cochrane Reviews (Reviews only), Other Reviews, Trials, Methods Studies, Technology Assessment and Economic Evaluations	51
#3	#1 AND #2	536
#2	screening OR early detection:ti,ab,kw	17312
#1	(prostatic OR prostate) AND (neoplasm OR neoplasms OR cancer):ti,ab,kw	4111

- Cochrane Database of Systematic Reviews (4)
- Database of Abstracts of Reviews of Effects (4)
- Cochrane Central Register of Controlled Trials (41)
- Cochrane Methodology Register (0)
- Health Technology Assessment Database (1)

- NHS Economic Evaluation Database (1)

Anzahl der Treffer: 51

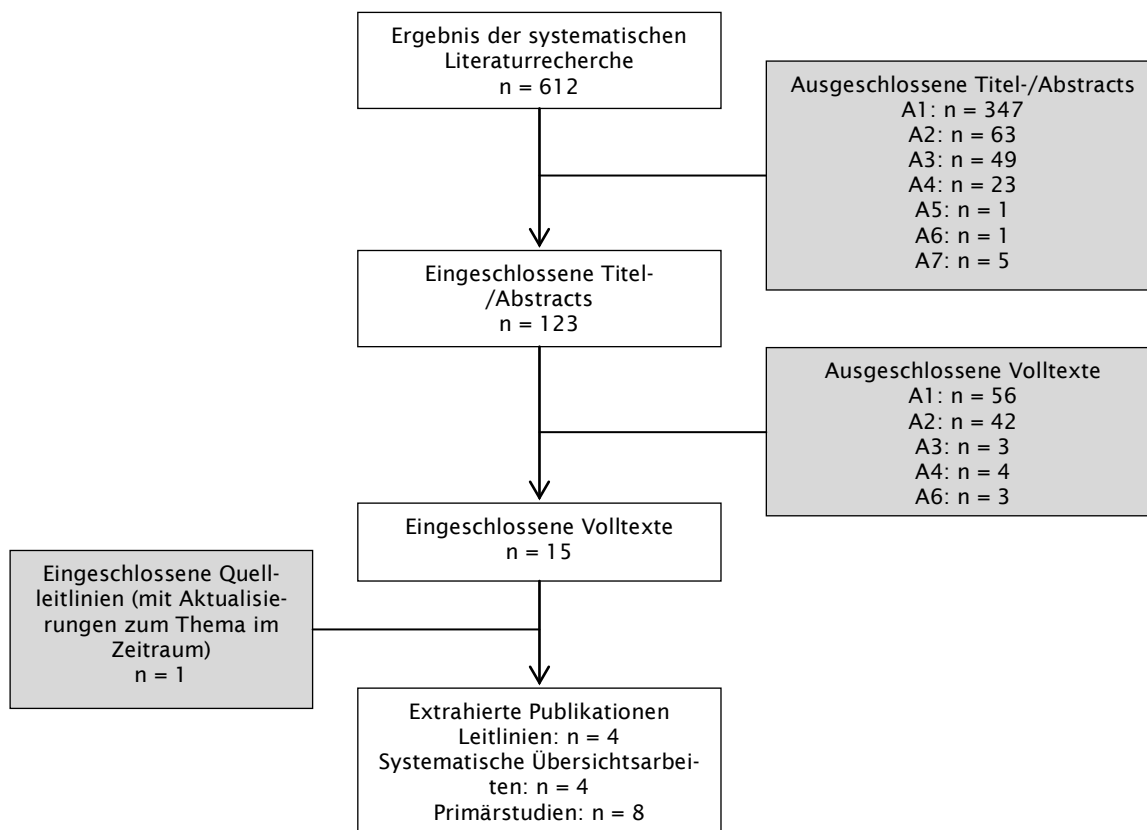
Davon neu: 25

Davon relevant: 18

12.4.1.3. Ein- und Ausschlusskriterien

Ausschlussgründe (Mehrfachnennungen möglich)	
A1	andere Erkrankung, andere Fragestellung, anderes Thema (analog Festlegung in PICO-Tabelle – Auszug s.u.)
A2	anderer Publikationstyp (z.B. Fallberichte, Fall-Kontroll-Studien, Editorial u.ä.) als a priori für die Fragestellung definiert (hier: Systematischer Review, RCT, prospektive Kohortenstudien)
A3	unsystematischer Review oder Review <u>ohne</u> Einschluss von RCT und/ oder prospektiven Kohortenstudien)
A4	retrospektive Kohortenstudie
A5	n < 25
A6	Doppelpublikation oder nicht erhältlich
A7	Sonstiges (z.B. Sprache, Publikation außerhalb des Suchzeitraums etc.)
Einschlussgründe	
E1	Systematischer Review (aus RCTs und / oder prospektiven Kohortenstudien) (wahrscheinlich) passend zur Fragestellung analog PICO-Tabelle
E2	RCT, prospektive Kohortenstudien (wahrscheinlich) passend zur Fragestellung analog PICO-Tabelle

12.4.1.4. Ergebnisse der Recherche



12.4.1.4.1. Extrahierte Publikationen

Eingeschlossene Volltexte (nach Volltextsichtung)

1. Ilic D, Neuberger MM, Djulbegovic M, Dahm P. Screening for prostate cancer. *Cochrane Database Syst Rev* 2013;1:CD004720 PM:23440794, DOI: 10.1002/14651858.CD004720.pub3.
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3. Basch E, Oliver TK, Vickers A, Thompson I, Kantoff P, Parnes H, Loblaw DA, Roth B, Williams J, Nam RK. Screening for prostate cancer with prostate-specific antigen testing: American Society of Clinical Oncology Provisional Clinical Opinion. *J Clin Oncol* 2012;30(24):3020-5 PM:22802323, DOI: JCO.2012.43.3441 [pii];10.1200/JCO.2012.43.3441 .
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5. Moyer VA. Screening for prostate cancer: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med* 2012;157(2):120-34 PM:22801674, DOI: 1216568 [pii];10.7326/0003-4819-157-2-201207170-00459.
6. Zhu X, Albertsen PC, Andriole GL, Roobol MJ, Schroder FH, Vickers AJ. Risk-based prostate cancer screening. *Eur Urol* 2012;61(4):652-61 PM:22134009, DOI: S0302-2838(11)01269-3 [pii];10.1016/j.eururo.2011.11.029.
7. Lin K, Croswell JM, Koenig H, Lam C, Maltz A. Prostate-Specific Antigen-Based Screening for Prostate Cancer: An Evidence Update for the U.S. Preventive Services Task Force. *Internet* 2011; PM:22171385, DOI: NBK82303 [bookaccession].

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10. Andriole GL, Crawford ED, Grubb RL, III, Buys SS, Chia D, Church TR, Fouad MN, Isaacs C, Kvale PA, Reding DJ, Weissfeld JL, Yokochi LA, O'Brien B, Ragard LR, Clapp JD, Rathmell JM, Riley TL, Hsing AW, Izmirlian G, Pinsky PF, Kramer BS, Miller AB, Gohagan JK, Prorok PC. Prostate cancer screening in the randomized Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial: mortality results after 13 years of follow-up. *J Natl Cancer Inst* 2012;104(2):125-32 PM:22228146, DOI: djr500 [pii];10.1093/jnci/djr500.
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12. van Leeuwen PJ, Roobol MJ, Kranse R, Zappa M, Carlsson S, Bul M, Zhu X, Bangma CH, Schroder FH, Hugosson J. Towards an optimal interval for prostate cancer screening. *Eur Urol* 2012;61(1):171-6 PM:21840117, DOI: S0302-2838(11)00862-1 [pii];10.1016/j.eururo.2011.08.002.
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15. Sandblom G, Varenhorst E, Rosell J, Lofman O, Carlsson P. Randomised prostate cancer screening trial: 20 year follow-up. *BMJ* 2011;342:d1539 PM:21454449.

Extrahierte Quelleitlinie

Carter HB, Albertsen PC, Barry MJ, Etzioni R, Freedland SJ, Greene KL, Holmberg L, Kantoff P, Konety BR, Murad MH, Penson DF, Zietman AL. Early Detection of Prostate Cancer: AUA Guideline. *Journal of Urology* 2013

12.4.1.4.2. Ausgeschlossene Volltexte (nach Volltextsichtung)

A1: Andere Erkrankung, andere Fragestellung, anderes Thema (analog Festlegung in PICO-Tabelle siehe oben)

1. Barocas DA, Grubb R, III, Black A, Penson DF, Fowke JH, Andriole G, Crawford ED. Association between race and follow-up diagnostic care after a positive prostate cancer screening test in the Prostate, Lung, Colorectal, and Ovarian cancer screening Atrial. *Cancer* 2013; PM:23559420, DOI: 10.1002/cncr.28042.
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4. Kim JH, Shim JS, Bae JH, Park HS, Moon dG, Kwon SS, Park JY. Association between percent-free prostate-specific antigen and glomerular filtration rate in transrectal ultrasound-guided biopsy-proven patients with prostate-specific antigen levels ranging from 4 to 10 ng/ml. *World J Urol* 2013;31(2):313-8 PM:23283411, DOI: 10.1007/s00345-012-1012-0.

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9. Ankerst DP, Boeck A, Freedland SJ, Thompson IM, Cronin AM, Roobol MJ, Hugoson J, Stephen JJ, Kattan MW, Klein EA, Hamdy F, Neal D, Donovan J, Parekh DJ, Klocker H, Horninger W, Benchikh A, Salama G, Villers A, Moreira DM, Schroder FH, Lilja H, Vickers AJ. Evaluating the PCPT risk calculator in ten international biopsy cohorts: results from the Prostate Biopsy Collaborative Group. *World J Urol* 2012;30(2):181-7 PM:22210512, DOI: 10.1007/s00345-011-0818-5.
10. Avery KN, Metcalfe C, Vedhara K, Lane JA, Davis M, Neal DE, Hamdy FC, Donovan JL, Blazeby JM. Predictors of attendance for prostate-specific antigen screening tests and prostate biopsy. *Eur Urol* 2012;62(4):649-55 PM:22244151, DOI: S0302-2838(12)00002-4 [pii];10.1016/j.eururo.2011.12.059.
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14. Casey RG, Hegarty PK, Conroy R, Rea D, Butler MR, Grainger R, McDermott T, Thornhill JA. The Distribution of PSA Age-Specific Profiles in Healthy Irish Men between 20 and 70. *ISRN Oncol* 2012;2012:832109 PM:22919517, DOI: 10.5402/2012/832109.
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18. Consedine NS. Are we worrying about the right men and are the right men feeling worried? Conscious but not unconscious prostate anxiety predicts screening among men from three ethnic groups. *Am J Mens Health* 2012;6(1):37-50 PM:21862565, DOI: 1557988311415513 [pii];10.1177/1557988311415513.
19. Demichelis F, Setlur SR, Banerjee S, Chakravarty D, Chen JY, Chen CX, Huang J, Beltran H, Oldridge DA, Kitabayashi N, Stenzel B, Schaefer G, Horninger W, Bektic J, Chinnaiyan AM, Goldenberg S, Siddiqui J, Regan MM, Kearney M, Soong TD, Rickman DS, Elemento O, Wei JT, Scherr DS, Sanda MA, Bartsch G, Lee C, Klocker H, Rubin MA. Identification of functionally active, low frequency copy number

- variants at 15q21.3 and 12q21.31 associated with prostate cancer risk. *Proc Natl Acad Sci U S A* 2012;109(17):6686-91 PM:22496589, DOI: 10.1073/pnas.1117405109 [pii];10.1073/pnas.1117405109.
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 31. Khan S, Jutzy JM, Valenzuela MM, Turay D, Aspe JR, Ashok A, Mirshahidi S, Mercola D, Lilly MB, Wall NR. Plasma-derived exosomal survivin, a plausible biomarker for early detection of prostate cancer. *PLoS One* 2012;7(10):e46737 PM:23091600, DOI: 10.1371/journal.pone.0046737 [doi];PONE-D-12-09870 [pii].
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A2: anderer Publikationstyp (z.B. Fallberichte, Fall-Kontroll-Studien, Editorial u.ä.) als a priori für die Fragestellung definiert (hier: Systematischer Review, RCT, prospektive Kohortenstudien)

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A3: unsystematischer Review oder Review ohne Einschluss von RCT und/ oder prospektiven Kohortenstudien)

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A4: retrospektive Kohortenstudie

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A6: Doppelpublikation oder nicht erhältlich

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12.4.1.4.3. Ausgeschlossene Titel-/Abstracts (nach Titel-/Abstractscreening durchgeführt von Rübber/Börgermann)

A1: Andere Erkrankung, andere Fragestellung, anderes Thema (analog Festlegung in PICO-Tabelle siehe oben)

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A4: retrospektive Kohortenstudie

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A5: Eingeschlossene Patienten n < 25

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A6: Doppelpublikation oder nicht erhältlich

1. 66. Roobol MJ, Carlsson SV. Risk stratification in prostate cancer screening. *Nat Rev Urol* 2013;10(1):38-48 PM:23247693, DOI: nrur.2012.225 [pii];10.1038/nrur.2012.225.

A7: Sonstiges (z.B. Sprache, Publikation außerhalb des Suchzeitraums etc.)

1. 26. Greene KL, Albertsen PC, Babaian RJ, Carter HB, Gann PH, Han M, Kuban DA, Sartor AO, Stanford JL, Zietman A, Carroll P. Prostate specific antigen best practice statement: 2009 update. *J Urol* 2013;189(1 Suppl):S2-S11 PM:23234625, DOI: S0022-5347(12)05479-1 [pii];10.1016/j.juro.2012.11.014.
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3. 420. Ennis R, Jotkowitz A. Good ethics begins with sound medicine: prostate cancer screening and chemoprevention. *Am J Bioeth* 2011;11(12):26-7 PM:22146026, DOI: 10.1080/15265161.2011.568583.
4. 488. Krizkova S, Ryvolova M, Gumulec J, Masarik M, Adam V, Majzlik P, Hubalek J, Provaznik I, Kizek R. Electrophoretic fingerprint metallothionein analysis as a potential prostate cancer biomarker. *Electrophoresis* 2011;32(15):1952-61 PM:21557258, DOI: 10.1002/elps.201000519.
5. 516. Moltzahn F, Olshen AB, Baehner L, Peek A, Fong L, Stoppler H, Simko J, Hilton JF, Carroll P, Blesloch R. Microfluidic-based multiplex qRT-PCR identifies diagnostic and prognostic microRNA signatures in the sera of prostate cancer pa-

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12.4.2. Recherche zum Thema PET-CT/MRT beim PSA-Rezidiv (Empfehlung 3.19 der Leitlinie)

12.4.2.1. Fragestellung

Fragestellung/The men-bereich	Population	Intervention	Kontrolle	Outcome	Evidenz-grundlage
Diagnostik und Therapie des Rezidivs nach Operationen / nach Strahlentherapie: Ist ein PET-CT/MRT beim PSA-Rezidiv nach radikaler Prostatektomie/Strahlentherapie in Korrelation zum PSA-Wert indiziert? Wiegel, Miller, Kotzerke	Patienten mit PCa nach radikaler Prostatektomie und / oder Strahlentherapie mit PSA Rezidiv	PET CT PET MRT	Kein PET (Referenz: Histologie)	Sensitivität, Spezifität, PPW (Testgüte), Likelihood-Ratio, Mortalität, therapeutische Konsequenzen	Aggregierte Evidenz (Systematischer Review) + RCT + prospektive Kohortenstudien

12.4.2.2. Recherchestrategien

Ausschlusskriterien für Relevanzsichtung:

A1: Dubletten aufgrund Suche in mehreren Datenbanken

A2: Methodik (Letter, Editorial u.ä.)

PubMed (08. Mai 2013)

Suchstrategie:

Nr.	Suchfrage	Anzahl
#9	Search #1 AND #7 Limits: English, German, Publication date from 2008/01/01	369
#8	#1 AND #7	594
#7	#5 OR #6	31572
#6	#3 AND #4	27226
#5	#2 AND #4	10736
#4	"positron-emission tomography"[MeSH Terms] OR ("positron-emission"[All Fields] AND "tomography"[All Fields]) OR "positron-emission tomography"[All Fields] OR ("positron"[All Fields] AND "emission"[All Fields] AND "tomography"[All Fields]) OR "positron emission tomography"[All Fields]	47672

Nr.	Suchfrage	Anzahl
#3	"tomography, x-ray computed"[MeSH Terms] OR ("tomography"[All Fields] AND "x-ray"[All Fields] AND "computed"[All Fields]) OR "x-ray computed tomography"[All Fields] OR ("computed"[All Fields] AND "tomography"[All Fields]) OR "computed tomography"[All Fields]	369781
#2	"magnetic resonance imaging"[MeSH Terms] OR ("magnetic"[All Fields] AND "resonance"[All Fields] AND "imaging"[All Fields]) OR "magnetic resonance imaging"[All Fields]	328644
#1	"prostatic neoplasms"[MeSH Terms] OR ("prostatic"[All Fields] AND "neoplasms"[All Fields]) OR "prostatic neoplasms"[All Fields] OR ("prostate"[All Fields] AND "cancer"[All Fields]) OR "prostate cancer"[All Fields]	108586

Anzahl der Treffer: 369

Davon relevant: 351

Cochrane (08. Mai 2013)

Suchstrategie:

Nr.	Suchfrage	Anzahl
#9	#1 AND #7 from 2008 to 2013, in Cochrane Reviews (Reviews only), Other Reviews, Trials, Methods Studies, Technology Assessment and Economic Evaluations	4
#8	#1 AND #7	8
#7	#5 OR #6	811
#6	#3 AND #4	700
#5	#2 AND #4	208
#4	positron emission tomography:ti,ab,kw	1532
#3	computed tomography:ti,ab,kw	6078
#2	magnetic resonance imaging:ti,ab,kw	5832
#1	(prostatic OR prostate) AND (neoplasm OR neoplasms OR cancer):ti,ab,kw	4162

- Cochrane Database of Systematic Reviews (0)
- Database of Abstracts of Reviews of Effects (0)
- Cochrane Central Register of Controlled Trials (3)
- Cochrane Methodology Register (0)
- Health Technology Assessment Database (1)
- NHS Economic Evaluation Database (0)

Anzahl der Treffer: 4

Davon neu: 2

Davon relevant: 1

12.4.2.3. Ein- und Ausschlusskriterien

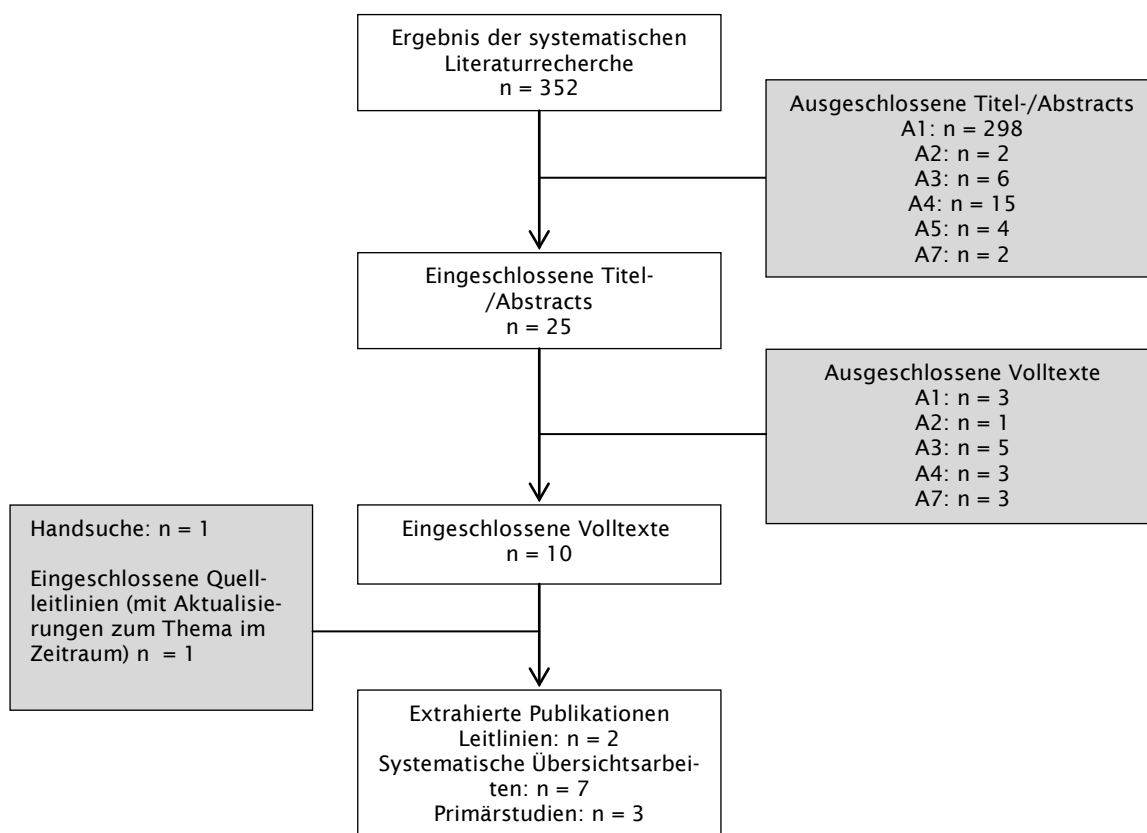
Ausschlussgründe (Mehrfachnennungen möglich)

A1	andere Erkrankung, andere Fragestellung, anderes Thema (analog Festlegung in PICO-Tabelle – Auszug s.u.)
A2	anderer Publikationstyp (z.B. Fallberichte, Fall-Kontroll-Studien, Editorial u.ä.) als a priori für die Fragestellung definiert (hier: Systematischer Review, RCT, prospektive Kohortenstudien)
A3	unsystematischer Review oder Review <u>ohne</u> Einschluss von RCT und/ oder prospektiven Kohortenstudien)
A4	retrospektive Kohortenstudie
A5	n < 25
A6	Doppelpublikation oder nicht erhältlich
A7	Sonstiges (z.B. Sprache, Publikation außerhalb des Suchzeitraums etc.)

Einschlussgründe

E1	Systematischer Review (aus RCTs und / oder prospektiven Kohortenstudien) (wahrscheinlich) passend zur Fragestellung analog PICO-Tabelle
E2	RCT, prospektive Kohortenstudien (wahrscheinlich) passend zur Fragestellung analog PICO-Tabelle

12.4.2.4. Ergebnisse der Recherche



12.4.2.4.1. Extrahierte Publikationen

Eingeschlossene Volltexte (nach Volltextsichtung)

1. 22. Umbehr MH, Muntener M, Hany T, Sulser T, Bachmann LM. The Role of 11C-Choline and 18F-Fluorocholine Positron Emission Tomography (PET) and PET/CT in Prostate Cancer: A Systematic Review and Meta-analysis. Eur Urol 2013; PM:23628493, DOI: S0302-2838(13)00382-5 [pii];10.1016/j.eururo.2013.04.019.
2. 29. Bauman G, Belhocine T, Kovacs M, Ward A, Beheshti M, Rachinsky I. 18F-fluorocholine for prostate cancer imaging: a systematic review of the literature. Prostate Cancer Prostatic Dis 2012;15(1):45-55 PM:21844889, DOI: pcan201135 [pii];10.1038/pcan.2011.35.
3. 88. Panebianco V, Sciarra A, Lisi D, Galati F, Buonocore V, Catalano C, Gentile V, Laghi A, Passariello R. Prostate cancer: 1HMRS-DCEMR at 3T versus [(18)F]choline PET/CT in the detection of local prostate cancer recurrence in men with biochemical progression after radical retropubic prostatectomy (RRP). Eur J Radiol 2012;81(4):700-8 PM:21330082, DOI: S0720-048X(11)00145-8 [pii];10.1016/j.ejrad.2011.01.095.
4. 115. Zengerling F, Schrader AJ, Schrader M, Jentzmik F. [Diagnostic relevance of choline-PET / CT in patients with prostate cancer]. Aktuelle Urol 2012;43(1):49-54 PM:21769763, DOI: 10.1055/s-0031-1271553.
5. 120. Beer AJ, Eiber M, Souvatzoglou M, Schwaiger M, Krause BJ. Radionuclide and hybrid imaging of recurrent prostate cancer. Lancet Oncol 2011;12(2):181-91 PM:20599424, DOI: S1470-2045(10)70103-0 [pii];10.1016/S1470-2045(10)70103-0.
6. 158. Martino P, Scattoni V, Galosi AB, Consonni P, Trombetta C, Palazzo S, Macagnano C, Liguori G, Valentino M, Battaglia M, Barozzi L. Role of imaging and biopsy to assess local recurrence after definitive treatment for prostate carcinoma (surgery, radiotherapy, cryotherapy, HIFU). World J Urol 2011;29(5):595-605 PM:21553276, DOI: 10.1007/s00345-011-0687-y.

7. 163. Mottet N, Bellmunt J, Bolla M, Joniau S, Mason M, Matveev V, Schmid HP, Van der Kwast T, Wiegel T, Zattoni F, Heidenreich A. EAU guidelines on prostate cancer. Part II: Treatment of advanced, relapsing, and castration-resistant prostate cancer. *Eur Urol* 2011;59(4):572-83 PM:21315502, DOI: S0302-2838(11)00046-7 [pii];10.1016/j.eururo.2011.01.025.
8. 168. Picchio M, Briganti A, Fanti S, Heidenreich A, Krause BJ, Messa C, Montorsi F, Reske SN, Thalmann GN. The role of choline positron emission tomography/computed tomography in the management of patients with prostate-specific antigen progression after radical treatment of prostate cancer. *Eur Urol* 2011;59(1):51-60 PM:20869161, DOI: S0302-2838(10)00859-6 [pii];10.1016/j.eururo.2010.09.004.
9. 198. Beresford MJ, Gillatt D, Benson RJ, Ajithkumar T. A systematic review of the role of imaging before salvage radiotherapy for post-prostatectomy biochemical recurrence. *Clin Oncol (R Coll Radiol)* 2010;22(1):46-55 PM:19948393, DOI: S0936-6555(09)00368-9 [pii];10.1016/j.clon.2009.10.015.
10. 243. Richter JA, Rodriguez M, Rioja J, Penuelas I, Marti-Climent J, Garrastachu P, Quincoces G, Zudaire J, Garcia-Velloso MJ. Dual tracer 11C-choline and FDG-PET in the diagnosis of biochemical prostate cancer relapse after radical treatment. *Mol Imaging Biol* 2010;12(2):210-7 PM:19543774, DOI: 10.1007/s11307-009-0243-y.

Extrahierte Quelleitlinie

1. Heidenreich A, Bolla M, Joniau S, Mason MD, Matveev V, Mottet N, Schmid HP, van der Kwast TH, Wiegel T, Zattoni F. EAU guidelines on prostate cancer. 2013

Eingeschlossene Volltexte (Handsuche)

1. Beheshti M, Haim S, Zakavi R, Steinmair M, Waldenberger P, Kunit T, Nader M, Langsteger W, Loidl W. Impact of 18F-Choline PET/CT in Prostate Cancer Patients with Biochemical Recurrence: Influence of Androgen Deprivation Therapy and Correlation with PSA Kinetics. *J Nucl Med* 2013;54(6):833-40

12.4.2.4.2. Ausgeschlossene Volltexte (nach Volltextsichtung)

A1: Andere Erkrankung, andere Fragestellung, anderes Thema (analog Festlegung in PICO-Tabelle siehe oben)

1. 44. Fortuin AS, Deserno WM, Meijer HJ, Jager GJ, Takahashi S, Debats OA, Reske SN, Schick C, Krause BJ, van O, I, Witjes AJ, Hoogeveen YL, van Lin EN, Barentsz JO. Value of PET/CT and MR lymphography in treatment of prostate cancer patients with lymph node metastases. *Int J Radiat Oncol Biol Phys* 2012;84(3):712-8 PM:22417806, DOI: S0360-3016(11)03819-3 [pii];10.1016/j.ijrobp.2011.12.093.
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A2: anderer Publikationstyp (z.B. Fallberichte, Fall-Kontroll-Studien, Editorial u.ä.) als a priori für die Fragestellung definiert (hier: Systematischer Review, RCT, prospektive Kohortenstudien)

1. 37. Desai B, Gross ME, Jadvar H. Multimodality imaging in biochemical recurrence of prostate cancer: utility of (18)F-NaF PET/CT in early detection of metastasis. *Rev Esp Med Nucl Imagen Mol* 2012;31(4):231-2 PM:22980132, DOI: S2253-654X(12)00097-2 [pii];10.1016/j.remnm.2012.03.008.

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3. 86. Olbert PJ, Heinis J, Hofmann R, Hegele A. [Choline PET/CT in the diagnosis of primary and recurrent prostate cancer. Are there evidence-based indications?]. *Urologe A* 2012;51(6):843-7 PM:22476740, DOI: 10.1007/s00120-012-2830-9.
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A4: retrospektive Kohortenstudie

1. 4. Detti B, Scoccianti S, Franceschini D, Cipressi S, Cassani S, Villari D, Gacci M, Pupi A, Vaggelli L, Saieva C, Pertici M, Livi L, Ceroti M, Nicita G, Carini M, Biti G. Predictive factors of [18F]-Choline PET/CT in 170 patients with increasing PSA after primary radical treatment. *J Cancer Res Clin Oncol* 2013;139(3):521-8 PM:23183655, DOI: 10.1007/s00432-012-1354-4.
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A7: Sonstiges (z.B. Sprache, Publikation außerhalb des Suchzeitraums etc.)

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12.4.2.4.3. Ausgeschlossene Titel-/Abstracts (nach Titel-/Abstractscreening)

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2. 2. Balogova S, Talbot JN, Nataf V, Michaud L, Huchet V, Kerrou K, Montravers F. (18)F-Fluorodihydroxyphenylalanine vs other radiopharmaceuticals for imaging neuroendocrine tumours according to their type. *Eur J Nucl Med Mol Imaging* 2013;40(6):943-66 PM:23417499, DOI: 10.1007/s00259-013-2342-x.
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292. 344. Schiavina R, Scattoni V, Castellucci P, Picchio M, Corti B, Briganti A, Franceschelli A, Sanguedolce F, Bertaccini A, Farsad M, Giovacchini G, Fanti S, Grigioni WF, Fazio F, Montorsi F, Rigatti P, Martorana G. 11C-choline positron emission tomography/computerized tomography for preoperative lymph-node staging in intermediate-risk and high-risk prostate cancer: comparison with clinical staging nomograms. *Eur Urol* 2008;54(2):392-401 PM:18456393, DOI: S0302-2838(08)00474-0 [pii];10.1016/j.eururo.2008.04.030.

293. 346. Sharma R, Katz JK. Taxotere chemosensitivity evaluation in mice prostate tumor: validation and diagnostic accuracy of quantitative measurement of tumor characteristics by MRI, PET, and histology of mice tumor. *Technol Cancer Res Treat* 2008;7(3):175-85 PM:18473489, DOI: d=3032&c=4257&p=16596&do=detail [pii].
294. 347. Terauchi T, Murano T, Daisaki H, Kanou D, Shoda H, Kakinuma R, Hamashima C, Moriyama N, Kakizoe T. Evaluation of whole-body cancer screening using 18F-2-deoxy-2-fluoro-D-glucose positron emission tomography: a preliminary report. *Ann Nucl Med* 2008;22(5):379-85 PM:18600415, DOI: 10.1007/s12149-008-0130-7.
295. 349. Vetsch G, Baumann CK, Klay M, Leupin N, Rentsch C, Mueller-Garamvolgyi E, Burgi U, Schiemann U. [Malignant lymphoma of the prostate--diagnosis on the second biopsy]. *Med Klin (Munich)* 2008;103(4):245-8 PM:18484209, DOI: 10.1007/s00063-008-1034-y.
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297. 351. Wolff I, Grimm MO, Wirth M. [Value of lymphadenectomy for limited nodal recurrence of prostate cancer after local therapy with curative intent]. *Urologe A* 2008;47(11):1436-40 PM:18813903, DOI: 10.1007/s00120-008-1723-4.
298. 352. Zhang M, Huang M, Le C, Zanzonico PB, Claus F, Kolbert KS, Martin K, Ling CC, Koutcher JA, Humm JL. Accuracy and reproducibility of tumor positioning during prolonged and multi-modality animal imaging studies. *Phys Med Biol* 2008;53(20):5867-82 PM:18827321, DOI: S0031-9155(08)82935-1 [pii];10.1088/0031-9155/53/20/021.

A2: anderer Publikationstyp (z.B. Fallberichte, Fall-Kontroll-Studien, Editorial u.ä.) als a priori für die Fragestellung definiert (hier: Systematischer Review, RCT, prospektive Kohortenstudien)

1. 3. Barrett JA, Coleman RE, Goldsmith SJ, Vallabhajosula S, Petry NA, Cho S, Armor T, Stubbs JB, Maresca KP, Stabin MG, Joyal JL, Eckelman WC, Babich JW. First-in-man evaluation of 2 high-affinity PSMA-avid small molecules for imaging prostate cancer. *J Nucl Med* 2013;54(3):380-7 PM:23303962, DOI: jnumed.112.111203 [pii];10.2967/jnumed.112.111203.
2. 342. Scher B, Seitz M. PET/CT imaging of recurrent prostate cancer. *Eur J Nucl Med Mol Imaging* 2008;35(1):5-8 PM:17985129, DOI: 10.1007/s00259-007-0633-9.

A3: unsystematischer Review oder Review ohne Einschluss von RCT und/ oder prospektiven Kohortenstudien)

1. 13. Kitajima K, Murphy RC, Nathan MA. Choline PET/CT for imaging prostate cancer: an update. *Ann Nucl Med* 2013; PM:23632880, DOI: 10.1007/s12149-013-0731-7.
2. 41. Farsad M, Schwarzenbock S, Krause BJ. PET/CT and choline: diagnosis and staging. *Q J Nucl Med Mol Imaging* 2012;56(4):343-53 PM:23013664, DOI: R39122492 [pii].
3. 234. Mease RC. Radionuclide based imaging of prostate cancer. *Curr Top Med Chem* 2010;10(16):1600-16 PM:20583988, DOI: BSP/CTMC/E-Pub/-0102-10-16 [pii].
4. 250. Weidner A, Michaely HJ, Pelzer A, Michel MS, Wenz F, Schoenberg SO, Dinter DJ. [Imaging of prostate cancer by diagnostic radiology and nuclear medicine]. *Aktuelle Urol* 2010;41(1):35-42 PM:20101785, DOI: 10.1055/s-0029-1224730.
5. 256. Bouchelouche K, Capala J, Oehr P. Positron emission tomography/computed tomography and radioimmunotherapy of prostate cancer. *Curr Opin Oncol* 2009;21(5):469-74 PM:19535981, DOI: 10.1097/CCO.0b013e32832d56e4.
6. 283. Picchio M, Crivellaro C, Giovacchini G, Gianolli L, Messa C. PET-CT for treatment planning in prostate cancer. *Q J Nucl Med Mol Imaging* 2009;53(2):245-68 PM:19293771.

A4: retrospektive Kohortenstudie

1. 10. Giovacchini G, Picchio M, Garcia-Parra R, Mapelli P, Briganti A, Montorsi F, Gianolli L, Messa C. [11C]choline positron emission tomography/computerized tomography for early detection of prostate cancer recurrence in patients with low increasing prostate specific antigen. *J Urol* 2013;189(1):105-10 PM:23164385, DOI: S0022-5347(12)04813-6 [pii];10.1016/j.juro.2012.09.001.
2. 46. Fuccio C, Castellucci P, Schiavina R, Guidalotti PL, Gavaruzzi G, Montini GC, Nanni C, Marzola MC, Rubello D, Fanti S. Role of 11C-choline PET/CT in the restaging of prostate cancer patients with biochemical relapse and negative results at bone scintigraphy. *Eur J Radiol* 2012;81(8):e893-e896 PM:22621862, DOI: S0720-048X(12)00202-1 [pii];10.1016/j.ejrad.2012.04.027.
3. 49. Giovacchini G, Picchio M, Parra RG, Briganti A, Gianolli L, Montorsi F, Messa C. Prostate-specific antigen velocity versus prostate-specific antigen doubling time for prediction of 11C choline PET/CT in prostate cancer patients with biochemical failure after radical prostatectomy. *Clin Nucl Med* 2012;37(4):325-31 PM:22391699, DOI: 10.1097/RLU.0b013e31823363b0 [doi];00003072-201204000-00001 [pii].
4. 90. Picchio M, Spinapolice EG, Fallanca F, Crivellaro C, Giovacchini G, Gianolli L, Messa C. [11C]Choline PET/CT detection of bone metastases in patients with PSA progression after primary treatment for prostate cancer: comparison with bone scintigraphy. *Eur J Nucl Med Mol Imaging* 2012;39(1):13-26 PM:21932120, DOI: 10.1007/s00259-011-1920-z.
5. 101. Soyka JD, Muster MA, Schmid DT, Seifert B, Schick U, Miralbell R, Jorcano S, Zaugg K, Seifert HH, Veit-Haibach P, Strobel K, Schaefer NG, Husarik DB, Hany TF. Clinical impact of 18F-choline PET/CT in patients with recurrent prostate cancer. *Eur J Nucl Med Mol Imaging* 2012;39(6):936-43 PM:22415598, DOI: 10.1007/s00259-012-2083-2.
6. 122. Bertagna F, Abuhilal M, Bosio G, Simeone C, Rossini P, Pizzocaro C, Orlando E, Finamanti M, Biasiotto G, Rodella C, Cosciani CS, Giubbini R. Role of (1)(1)C-choline positron emission tomography/computed tomography in evaluating patients affected by prostate cancer with suspected relapse due to prostate-specific antigen elevation. *Jpn J Radiol* 2011;29(6):394-404 PM:21786095, DOI: 10.1007/s11604-011-0570-1.
7. 179. Souvatzoglou M, Krause BJ, Purschel A, Thamm R, Schuster T, Buck AK, Zimmermann F, Molls M, Schwaiger M, Geinitz H. Influence of (11)C-choline PET/CT on the treatment planning for salvage radiation therapy in patients with biochemical recurrence of prostate cancer. *Radiother Oncol* 2011;99(2):193-200 PM:21620494, DOI: S0167-8140(11)00197-6 [pii];10.1016/j.radonc.2011.05.005.
8. 212. Fuccio C, Castellucci P, Schiavina R, Santi I, Allegri V, Pettinato V, Boschi S, Martorana G, Al-Nahhas A, Rubello D, Fanti S. Role of 11C-choline PET/CT in the restaging of prostate cancer patients showing a single lesion on bone scintigraphy. *Ann Nucl Med* 2010;24(6):485-92 PM:20544323, DOI: 10.1007/s12149-010-0390-x.
9. 213. Giovacchini G, Picchio M, Coradeschi E, Bettinardi V, Gianolli L, Scattoni V, Cozzarini C, Di MN, Rigatti P, Fazio F, Messa C. Predictive factors of [(11)C]choline PET/CT in patients with biochemical failure after radical prostatectomy. *Eur J Nucl Med Mol Imaging* 2010;37(2):301-9 PM:19756592, DOI: 10.1007/s00259-009-1253-3.
10. 214. Giovacchini G, Picchio M, Briganti A, Cozzarini C, Scattoni V, Salonia A, Landoni C, Gianolli L, Di MN, Rigatti P, Montorsi F, Messa C. [11C]choline positron emission tomography/computerized tomography to restage prostate cancer cases with biochemical failure after radical prostatectomy and no disease evidence on conventional imaging. *J Urol* 2010;184(3):938-43 PM:20643445, DOI: S0022-5347(10)03519-6 [pii];10.1016/j.juro.2010.04.084.
11. 215. Giovacchini G, Picchio M, Scattoni V, Garcia PR, Briganti A, Gianolli L, Montorsi F, Messa C. PSA doubling time for prediction of [(11)C]choline PET/CT findings in prostate cancer patients with biochemical failure after radical prostatectomy. *Eur J Nucl Med Mol Imaging* 2010;37(6):1106-16 PM:20306038, DOI: 10.1007/s00259-010-1403-7.
12. 257. Castellucci P, Fuccio C, Nanni C, Santi I, Rizzello A, Lodi F, Franceschelli A, Martorana G, Manferrari F, Fanti S. Influence of trigger PSA and PSA kinetics on 11C-Choline PET/CT detection rate in patients with biochemical relapse after radi-

- cal prostatectomy. *J Nucl Med* 2009;50(9):1394-400 PM:19690023, DOI: jnu-med.108.061507 [pii];10.2967/jnumed.108.061507.
13. 289. Rinnab L, Simon J, Hautmann RE, Cronauer MV, Hohl K, Buck AK, Reske SN, Mottaghy FM. [(11)C]choline PET/CT in prostate cancer patients with biochemical recurrence after radical prostatectomy. *World J Urol* 2009;27(5):619-25 PM:19234708, DOI: 10.1007/s00345-009-0371-7.
 14. 296. Steiner C, Vees H, Zaidi H, Wissmeyer M, Berrebi O, Kossovsky MP, Khan HG, Miralbell R, Ratib O, Buchegger F. Three-phase 18F-fluorocholine PET/CT in the evaluation of prostate cancer recurrence. *Nuklearmedizin* 2009;48(1):1-9 PM:19212605, DOI: 09010001 [pii].
 15. 345. Schilling D, Schlemmer HP, Wagner PH, Bottcher P, Merseburger AS, Aschoff P, Bares R, Pfannenbergl C, Ganswindt U, Corvin S, Stenzl A. Histological verification of 11C-choline-positron emission/computed tomography-positive lymph nodes in patients with biochemical failure after treatment for localized prostate cancer. *BJU Int* 2008;102(4):446-51 PM:18410442, DOI: BJU7592 [pii];10.1111/j.1464-410X.2008.07592.x.

A5: Eingeschlossene Patienten n < 25

1. 176. Savir-Baruch B, Schuster DM, Jarkas N, Master VA, Nieh PT, Halkar RK, Nye JA, Lewis MM, Crowe RJ, Voll RJ, Camp VM, Bellamy LM, Roberts DL, Goodman MM. Pilot evaluation of anti-1-amino-2-[18F] fluorocyclopentane-1-carboxylic acid (anti-2-[18F] FACPC) PET-CT in recurrent prostate carcinoma. *Mol Imaging Biol* 2011;13(6):1272-7 PM:20976627, DOI: 10.1007/s11307-010-0445-3.
2. 195. Beauregard JM, Williams SG, Degrado TR, Roselt P, Hicks RJ. Pilot comparison of F-fluorocholine and F-fluorodeoxyglucose PET/CT with conventional imaging in prostate cancer. *J Med Imaging Radiat Oncol* 2010;54(4):325-32 PM:20718912, DOI: ARA2178 [pii];10.1111/j.1754-9485.2010.02178.x.
3. 251. Winter A, Uphoff J, Henke RP, Wawroschek F. First results of [11C]choline PET/CT-guided secondary lymph node surgery in patients with PSA failure and single lymph node recurrence after radical retropubic prostatectomy. *Urol Int* 2010;84(4):418-23 PM:20299773, DOI: 000296298 [pii];10.1159/000296298.
4. 301. Winter A, Uphoff J, Henke RP, Wawroschek F. [First results of PET / CT-guided secondary lymph node surgery on patients with a PSA relapse after radical prostatectomy]. *Aktuelle Urol* 2009;40(5):294-9 PM:19533582, DOI: 10.1055/s-0028-1098914.

A7: Sonstiges (z.B. Sprache, Publikation außerhalb des Suchzeitraums etc.)

1. 129. Castellucci P, Fuccio C, Rubello D, Schiavina R, Santi I, Nanni C, Allegri V, Montini GC, Ambrosini V, Boschi S, Martorana G, Marzola MC, Fanti S. Is there a role for (1)(1)C-choline PET/CT in the early detection of metastatic disease in surgically treated prostate cancer patients with a mild PSA increase <1.5 ng/ml? *Eur J Nucl Med Mol Imaging* 2011;38(1):55-63 PM:20848281, DOI: 10.1007/s00259-010-1604-0.
2. 348. Tuncel M, Souvatzoglou M, Herrmann K, Stofffuss J, Schuster T, Weirich G, Wester HJ, Schwaiger M, Krause BJ. [(11)C]Choline positron emission tomography/computed tomography for staging and restaging of patients with advanced prostate cancer. *Nucl Med Biol* 2008;35(6):689-95 PM:18678354, DOI: S0969-8051(08)00114-5 [pii];10.1016/j.nucmedbio.2008.05.006.

12.4.3. Recherche zum Thema DNA-Zytometrie (Empfehlung 4.20 der Leitlinie)

12.4.3.1. Fragestellung

Fragestellung/Themenbereich	Population	Intervention	Kontrolle	Outcome	Evidenzgrundlage
Stellenwert der DNA-Zytometrie (de novo-Recherche): Bringt die DNA-Zytometrie zusätzliche Informationen gegenüber den etablierten Prognosefaktoren / prädiktive Faktoren (Gleason-Score), die für die Therapieentscheidung (active surveillance) relevant sind? <u>Dietz, Böcking, Wernert, Kristiansen, Weißbach</u>	Pat mit PCa unter Active surveillance	Histo Gleason-Score 6 3+4 und 4+3. DNA Zytometrie, PSA und Follow up	Histo Gleason 6 3+4 und 4+3, PSA und Follow up	Prostata-spezifische Mortalität (primär), PSA-Progress (sekundär)	Leitlinien-adaptation: Übernahme eines Satzes, ggf. modifiziert, aus der Pathologischen „Anleitung zur pathologisch-anatomischen Diagnostik von Prostatatumoren des Bundesverbandes Deutscher Pathologen e. V. und der Deutschen Gesellschaft für Pathologie e. V.“

12.4.3.2. Recherchestrategie

In der LL-Gruppe wurde zu Beginn festgelegt, dass für diese Fragestellung keine systematische Recherche durchgeführt werden soll. Es wurde festgelegt, dass die nachfolgende Leitlinie als Referenz berücksichtigt wird. Diese Leitlinie wurde mit Hilfe von DELBI bewertet (dabei ist 0 der niedrigste und 1 der höchste zu erreichende Wert).

Bundesverband Deutscher Pathologen (BDP), Deutsche Gesellschaft für Pathologie (DGP). Anleitung zur pathologisch-anatomischen Diagnostik von Prostatatumoren. Version 2.0 des Bundesverbandes Deutscher Pathologen und der Deutschen Gesellschaft für Pathologie. 2011

Domäne 1: Geltungsbereich und Zweck	Domäne 2: Beteiligung von Interessengruppen	Domäne 3: Methodische Exaktheit der Leitlinienentwicklung	Domäne 4: Klarheit und Gestaltung	Domäne 5: Generelle Anwendbarkeit	Domäne 6: Redaktionelle Unabhängigkeit	Domäne 7: Anwendbarkeit im deutschen Gesundheitssystem
0,33	0,08	0,10	0,25	0,00	0,00	0,11

12.4.4. Recherche zum Thema immunhistochemische Untersuchungen (Kapitel 4.3 der Leitlinie)

12.4.4.1. Fragestellung

Fragestellung /Themenbereich	Population	Intervention	Kontrolle	Outcome	Evidenzgrundlage
Pathomorphologische Untersuchungen: Welche immunhistochemischen Zusatzuntersuchungen sind notwendig? <u>Wernert, Kristiansen, Weißbach</u>	Patienten mit histologischem Verdacht auf PCa (Primärdiagnose), der konventionell-morphologisch nicht zweifelsfrei gesichert werden kann	Immunhistochemische Zusatzuntersuchung: Basalzellmarker (z.B. p63, 34betaE12, CK5/6). Optional: AMACR. Ggf. weitere Marker zur Differentialdiagnose	Ohne jeweilige Zusatzuntersuchung Referenz: Histologie	Sensitivität, Spezifität (Testgüteparameter)	Aggregierte Evidenz (Systematischer Review, Leitlinienadaption)

12.4.4.2. Recherchestrategien

Ausschlusskriterien für Relevanzsichtung:

A1: Methodik (Letter, Editorial u.ä.)

A2: andere Erkrankung

PubMed (08. Mai 2013)

Nr.	Suchfrage	Anzahl
#8	#5 AND #6 Limits: English, German, Publication date from 2008/01/01	19
#7	#5 AND #6	33
#6	systematic[sb]	202356
#5	#1 AND #4	6340
#4	#2 AND #3	451536
#3	"diagnosis"[Subheading] OR "diagnosis"[All Fields] OR "diagnosis"[MeSH Terms]	8070583
#2	"immunohistochemistry"[MeSH Terms] OR "immunohistochemistry"[All Fields]	539454
#1	"prostatic neoplasms"[MeSH Terms] OR ("prostatic"[All Fields] AND "neoplasms"[All Fields]) OR "prostatic neoplasms"[All Fields] OR ("prostate"[All	108586

Nr.	Suchfrage	Anzahl
	Fields] AND "cancer"[All Fields]) OR "prostate cancer"[All Fields]	

Anzahl der Treffer: 19

Cochrane (08. Mai 2013)

Suchstrategie:

Nr.	Suchfrage	Anzahl
#6	#1 AND #4 from 2008 to 2013, in Cochrane Reviews (Reviews only), Other Reviews, Trials, Methods Studies, Technology Assessment and Economic Evaluations	0
#5	#1 AND #4	4
#4	#2 AND #3	104
#3	diagnosis:ti,ab,kw	24252
#2	immunohistochemistry:ti,ab,kw	1543
#1	(prostatic OR prostate) AND (neoplasm OR neoplasms OR cancer):ti,ab,kw	4162

- Cochrane Database of Systematic Reviews (0)
- Database of Abstracts of Reviews of Effects (0)
- Cochrane Central Register of Controlled Trials (0)
- Cochrane Methodology Register (0)
- Health Technology Assessment Database (0)
- NHS Economic Evaluation Database (0)

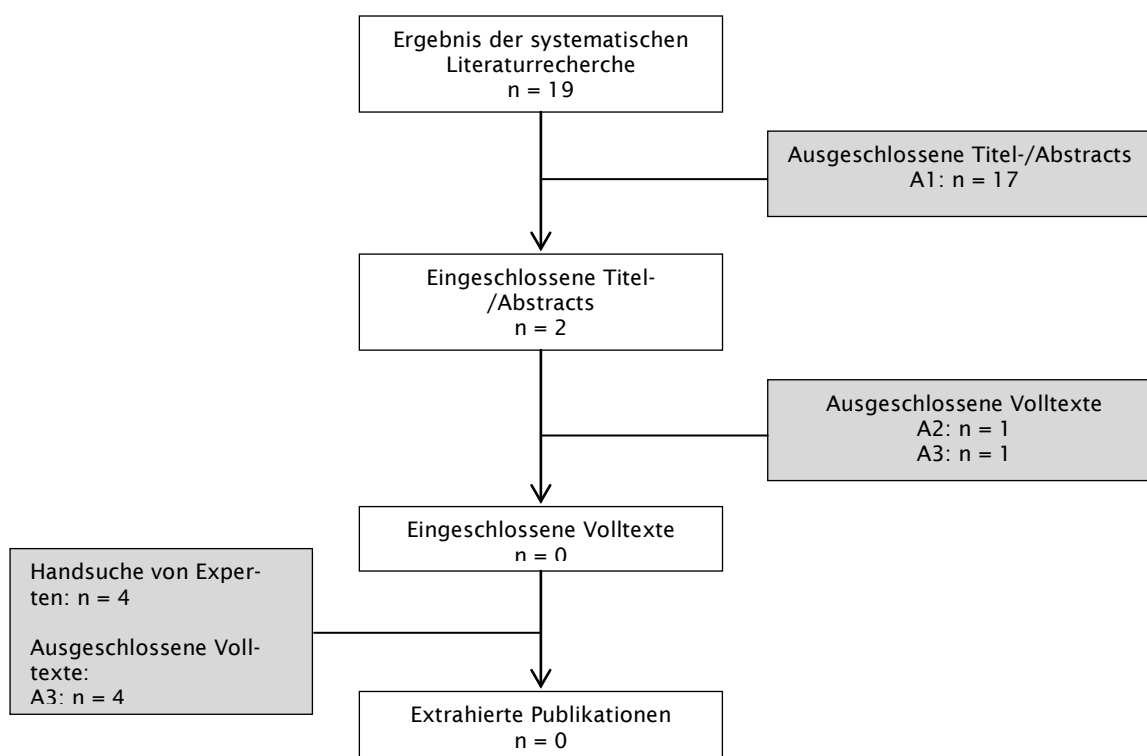
Anzahl der Treffer: 0

12.4.4.3. Ein- und Ausschlusskriterien

Ausschlusskriterien für erste Relevanzsichtung:	
A1:	andere Erkrankung, andere Fragestellung, anderes Thema (analog Festlegung in PICO-Tabelle – Auszug s.u.)
A2:	anderer Publikationstyp (z.B. RCT, Kohortenstudien, Fallberichte, Fall-Kontroll-Studien, Editorial u.ä.) als a priori für die Fragestellung definiert (hier: Systematischer Review, Leitlinien)
A3:	unsystematischer Review oder Review <u>ohne</u> Einschluss von RCT und/ oder prospektiven Kohortenstudien)
A4:	retrospektive Kohortenstudie
A5:	n < 25

A6:	Doppelpublikation oder nicht erhältlich
A7:	Sonstiges (z.B. Sprache, Publikation außerhalb des Suchzeitraums etc.)
Einschlusskriterien für erste Relevanzsichtung:	
E1:	Systematischer Review (aus RCTs und / oder prospektiven Kohortenstudien) (wahrscheinlich) oder Leitlinien passend zur Fragestellung analog PICO-Tabelle

12.4.4.4. Ergebnisse der Recherche



12.4.4.4.1. Ausgeschlossene Volltexte (Handsuche von Experten)

A3: unsystematischer Review oder Review ohne Einschluss von RCT und/ oder prospektiven Kohortenstudien)

1. Kristiansen G. Diagnostic and prognostic molecular biomarkers for prostate cancer. *Histopathology* 2012;60(1):125-41
<http://www.ncbi.nlm.nih.gov/pubmed/22212082>, DOI: 10.1111/j.1365-2559.2011.04083.x.
2. Brimo F, Epstein JI. Selected common diagnostic problems in urologic pathology: perspectives from a large consult service in genitourinary pathology. *Arch Pathol Lab Med* 2012;136(4):360-71 <http://www.ncbi.nlm.nih.gov/pubmed/22458899>, DOI: 10.5858/arpa.2011-0187-RA.
3. Brimo F, Epstein JI. Immunohistochemical pitfalls in prostate pathology. *Hum Pathol* 2012;43(3):313-24 <http://www.ncbi.nlm.nih.gov/pubmed/22325142>, DOI: 10.1016/j.humpath.2011.11.005.
4. Paner GP, Aron M, Hansel DE, Amin MB. Non-epithelial neoplasms of the prostate. *Histopathology* 2012;60(1):166-86
<http://www.ncbi.nlm.nih.gov/pubmed/22212085>, DOI: 10.1111/j.1365-2559.2011.04020.x.

12.4.4.4.2. Ausgeschlossene Volltexte (nach Volltextscreening)

A2: anderer Publikationstyp (z.B. Fallberichte, Fall-Kontroll-Studien, Editorial u.ä.) als a priori für die Fragestellung definiert (hier: Systematischer Review, Leitlinien-adaptation)

1. 9. Minner S, Enodien M, Sirma H, Luebke AM, Krohn A, Mayer PS, Simon R, Tennstedt P, Muller J, Scholz L, Brase JC, Liu AY, Schluter H, Pantel K, Schumacher U, Bokemeyer C, Steuber T, Graefen M, Sauter G, Schlomm T. ERG status is unrelated to PSA recurrence in radically operated prostate cancer in the absence of andihormonal therapy. *Clin Cancer Res* 2011;17(18):5878-88 PM:21791629, DOI: 1078-0432.CCR-11-1251 [pii];10.1158/1078-0432.CCR-11-1251.

A3: unsystematischer Review oder Review ohne Einschluss von RCT und/ oder prospektiven Kohortenstudien)

1. 16. Paner GP, Luthringer DJ, Amin MB. Best practice in diagnostic immunohistochemistry: prostate carcinoma and its mimics in needle core biopsies. *Arch Pathol Lab Med* 2008;132(9):1388-96 PM:18788849, DOI: 2008-0261-CPR [pii];10.1043/1543-2165(2008)132[1388:BPIDIP]2.0.CO;2.

12.4.4.4.3. Ausgeschlossene Titel-/Abstracts (nach Titel-/Abstractscreening durchgeführt von Kristiansen)

A1: Andere Erkrankung, andere Fragestellung, anderes Thema (analog Festlegung in PICO-Tabelle siehe oben)

1. 1. Yi Y, Breau RH, Witiuk K, Neuberger MM, Dahm P. Diagnostic tests in urology: percentage of free prostate-specific antigen (PSA). *BJU Int*
2. 2. Abern MR, Tsivian M, Polascik TJ. Focal therapy of prostate cancer: evidence-based analysis for modern selection criteria. *Curr Urol Rep* 2012;13(2):160-9 PM:22298223, DOI: 10.1007/s11934-012-0241-5.
3. 3. Ashida S, Orloff MS, Bebek G, Zhang L, Zheng P, Peehl DM, Eng C. Integrated analysis reveals critical genomic regions in prostate tumor microenvironment associated with clinicopathologic phenotypes. *Clin Cancer Res* 2012;18(6):1578-87 PM:22275508, DOI: 1078-0432.CCR-11-2535 [pii];10.1158/1078-0432.CCR-11-2535.
4. 4. Katafigiotis I, Tyritzis SI, Stravodimos KG, Alamanis C, Pavlakis K, Vlahou A, Makridakis M, Katafigioti A, Garbis SD, Constantinides CA. Zinc alpha2-glycoprotein as a potential novel urine biomarker for the early diagnosis of prostate cancer. *BJU Int* 2012;110(11 Pt B):E688-E693 PM:23020913, DOI: 10.1111/j.1464-410X.2012.11501.x .
5. 5. Wang EC, Kwah YC, Tan WP, Lee JS, Tan SH. Extramammary Paget disease: Immunohistochemistry is critical to distinguish potential mimickers. *Dermatol Online J* 2012;18(9):4 PM:23031371.
6. 6. Zumsteg ZS, Zelefsky MJ. Short-term androgen deprivation therapy for patients with intermediate-risk prostate cancer undergoing dose-escalated radiotherapy: the standard of care? *Lancet Oncol* 2012;13(6):e259-e269 PM:22652234, DOI: S1470-2045(12)70084-0 [pii];10.1016/S1470-2045(12)70084-0.
7. 7. Ficarra E, Di CS, Acquaviva A, Macii E. Automated segmentation of cells with IHC membrane staining. *IEEE Trans Biomed Eng* 2011;58(5):1421-9 PM:21245003, DOI: 10.1109/TBME.2011.2106499.
8. 8. Grifantini R, Pagani M, Pierleoni A, Grandi A, Parri M, Campagnoli S, Pileri P, Cattaneo D, Canidio E, Pontillo A, De CE, Bresciani A, Marinoni F, Pedrazzoli E, Nogarotto R, Abrignani S, Viale G, Sarmientos P, Grandi G. A novel polyclonal antibody library for expression profiling of poorly characterized, membrane and secreted human proteins. *J Proteomics* 2011;75(2):532-47 PM:21920474, DOI: S1874-3919(11)00433-7 [pii];10.1016/j.jprot.2011.08.018.
9. 10. Stovsky M, Ponsky L, Vourganti S, Stuhldreher P, Siroky MB, Kipnis V, Fedotoff O, Mikheeva L, Zaslavsky B, Chait A, Jones JS. Prostate-specific antigen/solvent interaction analysis: a preliminary evaluation of a new assay concept for detecting prostate cancer using urinary samples. *Urology* 2011;78(3):601-5

- PM:21783231, DOI: S0090-4295(11)00567-X [pii];10.1016/j.urology.2011.03.071.
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 16. 18. Tomlins SA, Rhodes DR, Yu J, Varambally S, Mehra R, Perner S, Demichelis F, Helgeson BE, Laxman B, Morris DS, Cao Q, Cao X, Andren O, Fall K, Johnson L, Wei JT, Shah RB, Al-Ahmadie H, Eastham JA, Eggener SE, Fine SW, Hotakainen K, Stenman UH, Tsodikov A, Gerald WL, Lilja H, Reuter VE, Kantoff PW, Scardino PT, Rubin MA, Bjartell AS, Chinnaiyan AM. The role of SPINK1 in ETS rearrangement-negative prostate cancers. *Cancer Cell* 2008;13(6):519-28 PM:18538735, DOI: S1535-6108(08)00152-9 [pii];10.1016/j.ccr.2008.04.016.
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12.4.5. Recherche zum Thema Prognosescore für das frühe Prostatakarzinom (de novo Recherche)

12.4.5.1. Fragestellung

Fragestellung/ Themenbereich	Population	Intervention	Comparison	Outcome	Evidenzgrundlage / Zusatzinformation
Bestimmung und Umgang mit der Komorbidität der Betroffenen: Welche Klassifikation/ Score (Prognosescore) kann die Therapieentscheidung	Pat mit frühem PCa, die kurativ behandelbar wären (=Patienten vor Behandlung)	Score, Klassifikation [ASA, Charlson Score, Body Mass, Kombination von Scores]	Keine	Validierung der Scores, Prognostische Güte: 10-Jahres-Überlebensraten, konkurrierende Sterblichkeit = (Gesamtmortalität minus pros-	Kohortenstudien, RCT

Fragestellung/ Themenbereich	Population	Intervention	Com- pariso n	Outcome	Evidenz- grundlage / Zusatz- information
idung beim frü- hen Prostatakar- zinom am wirk- samsten unter- stützen? <u>Wirth, Fröhner,</u> <u>Wedding</u>				tataspezifische Mortalität), Al- ters- und/oder Komorbiditäts- grenzen für eine kurative Thera- pie	

12.4.5.2. Recherchestrategien

12.4.5.2.1. Recherche

Ausschlusskriterien für Relevanzsichtung:

A1: andere Erkrankung (nicht PCa)

A2: Methodik (Letter, Editorial, News, Comment)

A3: Dubletten durch Suche in verschiedenen Datenbanken

A4: Publikationen vor 2003 und nicht deutsch oder englisch (Cochrane Library)

PubMed (18. April 2013)

Nr.	Suchfrage	Anzahl
#6	#3 AND #4 Limits: English, German, Publication date from 2003/01/01	1428
#5	#3 AND #4	2240
#4	"prognosis"[All Fields] OR "therapy decision"[All Fields] OR "treatment decision"[All Fields] OR "therapy plan*"[All Fields] OR "treatment plan*"[All Fields]	466981
#3	#1 AND #2	10494
#2	"classification"[All Fields] OR score[All Fields] OR scores[All Fields]	973865
#1	"prostatic neoplasms"[MeSH Terms] OR ("prostatic"[All Fields] AND "neoplasms"[All Fields]) OR "prostatic neoplasms"[All Fields] OR ("prostate"[All Fields] AND "cancer"[All Fields]) OR "prostate cancer"[All Fields]	108143

Anzahl der Treffer: 1428

Davon relevant: 1389

Cochrane (18. April 2013)

Suchstrategie:

Nr.	Suchfrage	Anzahl
#6	#3 AND #4 from 2003 to 2013, in Cochrane Reviews (Reviews only), Other Reviews, Trials, Methods Studies, Technology Assessment and Economic Evaluations	85
#5	#3 AND #4	125
#4	prognosis OR ((treatment OR therapy) AND (decision OR plan)):ti,ab,kw	22786
#3	#1 AND #2	636
#2	classification OR score:ti,ab,kw	71200
#1	(prostatic OR prostate) AND (neoplasm OR neoplasms OR cancer):ti,ab,kw	4111

- Cochrane Database of Systematic Reviews (2)
- Database of Abstracts of Reviews of Effects (0)
- Cochrane Central Register of Controlled Trials (82)
- Cochrane Methodology Register (1)
- Health Technology Assessment Database (0)
- NHS Economic Evaluation Database (0)

Anzahl der Treffer: 85

Davon neu: 47

Davon relevant: 45

12.4.5.2.2. Recherche: Nomogramm

Ausschlusskriterien für Relevanzsichtung:

A1: andere Erkrankung (nicht PCa)

A2: Methodik (Letter, Editorial, News, Comment)

A3: Dubletten durch Suche in verschiedenen Datenbanken

A4: Publikationen vor 2008 und nicht deutsch oder englisch (Cochrane Library)

A5: Dubletten aus Recherche vom 18. April zu klassifikation-score

PubMed (14. Mai 2013)

Nr.	Suchfrage	Anzahl
#4	#1 AND #2 Limits: English, German, Publication date from 2008/01/01	113
#3	#1 AND #2	690

Nr.	Suchfrage	Anzahl
#2	"nomograms"[MeSH Terms] OR "nomograms"[All Fields] OR "nomogram"[All Fields]	4652
#1	"prostatic neoplasms"[MeSH Terms] OR ("prostatic"[All Fields] AND "neoplasms"[All Fields]) OR "prostatic neoplasms"[All Fields] OR ("prostate"[All Fields] AND "cancer"[All Fields]) OR "prostate cancer"[All Fields]	108657

Anzahl der Treffer: 113

Davon relevant: 77

Cochrane (14. Mai 2013)

Suchstrategie:

Nr.	Suchfrage	Anzahl
#4	#1 AND #2 from 2008 to 2013, in Cochrane Reviews (Reviews only), Other Reviews, Trials, Methods Studies, Technology Assessment and Economic Evaluations	8
#3	#1 AND #2	17
#2	nomogram OR nomograms:ti,ab,kw	192
#1	(prostatic OR prostate) AND (neoplasm OR neoplasms OR cancer):ti,ab,kw	4162

- Cochrane Database of Systematic Reviews (0)
- Database of Abstracts of Reviews of Effects (1)
- Cochrane Central Register of Controlled Trials (7)
- Cochrane Methodology Register (0)
- Health Technology Assessment Database (0)
- NHS Economic Evaluation Database (0)

Anzahl der Treffer: 8

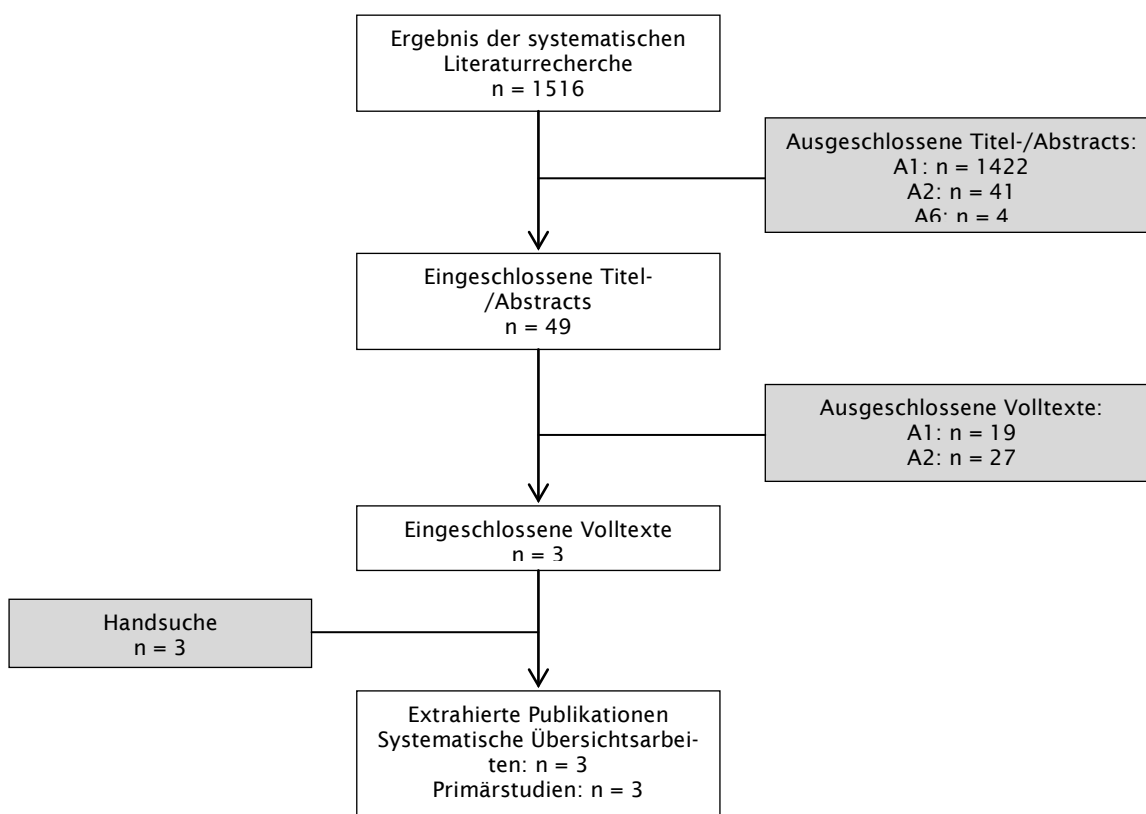
Davon relevant: 5

12.4.5.3. Ein- und Ausschlusskriterien

Ausschlusskriterien	
A1:	andere Erkrankung, andere Fragestellung, anderes Thema (analog Festlegung in PICO-Tabelle – Auszug s.u.)
A2:	anderer Publikationstyp (z.B. Fallberichte, Fall-Kontroll-Studien, Editorial u.ä.) als a priori für die Fragestellung definiert (hier: RCT + Kohortenstudien)
A3:	unsystematischer Review oder Review <u>ohne</u> Einschluss von RCT und/ oder Kohortenstudien
A4:	Keine vergleichende Studie

Ausschlusskriterien	
A5:	n < 25
A6:	Doppelpublikation oder nicht erhältlich
A7:	Sonstiges (z.B. Sprache, Publikation außerhalb des Suchzeitraums etc.)
Einschlusskriterien	
E1:	Systematischer Review (aus RCTs und / oder Kohortenstudien) (wahrscheinlich) passend zur Fragestellung analog PICO-Tabelle
E2:	RCT, Kohortenstudien (wahrscheinlich) passend zur Fragestellung analog PICO-Tabelle

12.4.5.4. Ergebnisse der Recherche



12.4.5.4.1. Extrahierte Publikationen

Eingeschlossene Volltexte (nach Volltextsichtung)

- Walz J, Gallina A, Saad F, Montorsi F, Perrotte P, Shariat SF, Jeldres C, Graefen M, Benard F, McCormack M, Valiquette L, Karakiewicz PI. A nomogram predicting 10-year life expectancy in candidates for radical prostatectomy or radiotherapy for prostate cancer. J Clin Oncol 2007;25(24):3576-81

<http://www.ncbi.nlm.nih.gov/pubmed/17704404>, DOI: 10.1200/JCO.2006.10.3820.

2. Rodrigues G, Warde P, Pickles T, Crook J, Brundage M, Souhami L, Lukka H. Pre-treatment risk stratification of prostate cancer patients: A critical review. *Can Urol Assoc J* 2012;6(2):121-7 <http://www.ncbi.nlm.nih.gov/pubmed/22511420>, DOI: 10.5489/cuaj.11085.
3. Sutcliffe P, Hummel S, Simpson E, Young T, Rees A, Wilkinson A, Hamdy F, Clarke N, Staffurth J. Use of classical and novel biomarkers as prognostic risk factors for localised prostate cancer: a systematic review. *Health Technol Assess* 2009;13(5):iii, xi-iiixiii PM:19128541, DOI: 10.3310/hta13050.

Eingeschlossene Volltexte (nach Handsuche)

1. Daskivich TJ, Fan KH, Koyama T, Albertsen PC, Goodman M, Hamilton AS, Hoffman RM, Stanford JL, Stroup AM, Litwin MS, Penson DF. Effect of age, tumor risk, and comorbidity on competing risks for survival in a U.S. population-based cohort of men with prostate cancer. *Ann Intern Med* 2013;158(10):709-17 <http://www.ncbi.nlm.nih.gov/pubmed/23689764>, DOI: 10.7326/0003-4819-158-10-201305210-00005.

12.4.5.4.2. Ausgeschlossene Volltexte (nach Volltextsichtung)

A1: Andere Erkrankung, andere Fragestellung, anderes Thema (analog Festlegung in PICO-Tabelle siehe oben)

1. Froehner M, Koch R, Litz R, Oehlschlaeger S, Noack B, Manseck A, Albrecht DM, Wirth MP. Preoperative cardiopulmonary risk assessment as predictor of early noncancer and overall mortality after radical prostatectomy. *Urology* 2003;61(3):596-600 <http://www.ncbi.nlm.nih.gov/pubmed/12639654>.
2. Ritvo P, Irvine J, Naglie G, Tomlinson G, Bezjak A, Matthew A, Trachtenberg J, Krahn M. Reliability and validity of the PORPUS, a combined psychometric and utility-based quality-of-life instrument for prostate cancer. *J Clin Epidemiol* 2005;58(5):466-74 <http://www.ncbi.nlm.nih.gov/pubmed/15845333>, DOI: 10.1016/j.jclinepi.2004.08.019.
3. Froehner M, Koch R, Litz RJ, Haase M, Klenk U, Oehlschlaeger S, Baretton GB, Wirth MP. Comparison of tumor- and comorbidity-related predictors of mortality after radical prostatectomy. *Scand J Urol Nephrol* 2005;39(6):449-54 <http://www.ncbi.nlm.nih.gov/pubmed/16303719>, DOI: 10.1080/00365590510031174.
4. Froehner M, Koch R, Litz RJ, Hakenberg OW, Oehlschlaeger S, Wirth MP. Comorbidity is poor predictor of survival in patients undergoing radical prostatectomy after 70 years of age. *Urology* 2006;68(3):583-6 <http://www.ncbi.nlm.nih.gov/pubmed/16979740>, DOI: 10.1016/j.urology.2006.03.050.
5. Walz J, Gallina A, Perrotte P, Jeldres C, Trinh QD, Hutterer GC, Traumann M, Ramirez A, Shariat SF, McCormack M, Perreault JP, Benard F, Valiquette L, Saad F, Karakiewicz PI. Clinicians are poor raters of life-expectancy before radical prostatectomy or definitive radiotherapy for localized prostate cancer. *BJU Int* 2007;100(6):1254-8 <http://www.ncbi.nlm.nih.gov/pubmed/17979925>, DOI: 10.1111/j.1464-410X.2
6. Gallina A, Chun FK, Briganti A, Shariat SF, Montorsi F, Salonia A, Erbersdobler A, Rigatti P, Valiquette L, Huland H, Graefen M, Karakiewicz PI. Development and split-sample validation of a nomogram predicting the probability of seminal vesicle invasion at radical prostatectomy. *Eur Urol* 2007;52(1):98-105 <http://www.ncbi.nlm.nih.gov/pubmed/17267098>, DOI: 10.1016/j.eururo.2007.01.060.
7. Froehner M, Koch R, Litz RJ, Oehlschlaeger S, Twelker L, Hakenberg OW, Wirth MP. Detailed analysis of Charlson comorbidity score as predictor of mortality after radical prostatectomy. *Urology* 2008;72(6):1252-7 <http://www.ncbi.nlm.nih.gov/pubmed/18723211>, DOI: 10.1016/j.urology.2008.05.037.
8. Thanigasalam R, Rasiah KK, Stricker PD, Haynes AM, Sutherland SI, Sutherland RL, Henshall SM, Horvath LG. Stage migration in localized prostate cancer has no ef-

- fect on the post-radical prostatectomy Kattan nomogram. *BJU Int* 2010;105(5):642-7 <http://www.ncbi.nlm.nih.gov/pubmed/19751263>, DOI: 10.1111/j.1464-410X.2009.08842.x.
9. Ohori M, Kattan MW, Yu C, Matsumoto K, Satoh T, Ishii J, Miyakawa A, Irie A, Iwamura M, Tachibana M. Nomogram to predict seminal vesicle invasion using the status of cancer at the base of the prostate on systematic biopsy. *Int J Urol* 2010;17(6):534-40 <http://www.ncbi.nlm.nih.gov/pubmed/20370843>, DOI: 10.1111/j.1442-2042.2010.02513.x.
 10. Lai JS, Bode R, Wee HL, Eton D, Cella D. A brief assessment of physical functioning for prostate cancer patients. *Patient Relat Outcome Meas* 2010;1:51-6 <http://www.ncbi.nlm.nih.gov/pubmed/22915952>.
 11. Tamblyn DJ, Chopra S, Yu C, Kattan MW, Pinnock C, Kopsaftis T. Comparative analysis of three risk assessment tools in Australian patients with prostate cancer. *BJU Int* 2011;108 Suppl 2:51-6 <http://www.ncbi.nlm.nih.gov/pubmed/22085129>, DOI: 10.1111/j.1464-410X.2011.10687.x.
 12. Ploussard G, Masson-Lecomte A, Beauval JB, Ouzzane A, Bonniol R, Buge F, Fadli S, Roupret M, Rebillard X, Gaschignard N, Pfister C, Villers A, Soulie M, Salomon L. Radical prostatectomy for high-risk prostate cancer defined by preoperative criteria: oncologic follow-up in national multicenter study in 813 patients and assessment of easy-to-use prognostic substratification. *Urology* 2011;78(3):607-13 <http://www.ncbi.nlm.nih.gov/pubmed/21783233>, DOI: 10.1016/j.urology.2011.05.021.
 13. Oon SF, Watson RW, O'Leary JJ, Fitzpatrick JM. Epstein criteria for insignificant prostate cancer. *BJU Int* 2011;108(4):518-25 <http://www.ncbi.nlm.nih.gov/pubmed/21320276>, DOI: 10.1111/j.1464-410X.2011.09979.x.
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 15. Cooperberg MR, Hilton JF, Carroll PR. The CAPRA-S score: A straightforward tool for improved prediction of outcomes after radical prostatectomy. *Cancer* 2011;117(22):5039-46 <http://www.ncbi.nlm.nih.gov/pubmed/21647869>, DOI: 10.1002/cncr.26169.
 16. Shukla-Dave A, Hricak H, Akin O, Yu C, Zakian KL, Udo K, Scardino PT, Eastham J, Kattan MW. Preoperative nomograms incorporating magnetic resonance imaging and spectroscopy for prediction of insignificant prostate cancer. *BJU Int* 2012;109(9):1315-22 <http://www.ncbi.nlm.nih.gov/pubmed/21933336>, DOI: 10.1111/j.1464-410X.2011.10612.x.
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 18. van Vugt HA, Roobol MJ, van der Poel HG, van Muilekom EH, Busstra M, Kil P, Oomens EH, Leliveld A, Bangma CH, Korfage I, Steyerberg EW. Selecting men diagnosed with prostate cancer for active surveillance using a risk calculator: a prospective impact study. *BJU Int* 2012;110(2):180-7 [PM:22112199](http://www.ncbi.nlm.nih.gov/pubmed/22112199), DOI: 10.1111/j.1464-410X.2011.10679.x.
 19. Guzzo TJ, Dluzniewski P, Orosco R, Platz EA, Partin AW, Han M. Prediction of mortality after radical prostatectomy by Charlson comorbidity index. *Urology* 2010;76(3):553-7 [PM:20627284](http://www.ncbi.nlm.nih.gov/pubmed/20627284), DOI: S0090-4295(10)00420-6 [pii];10.1016/j.urology.2010.02.069.

A2: anderer Publikationstyp (z.B. Fallberichte, Fall-Kontroll-Studien, Editorial u.ä.) als a priori für die Fragestellung definiert (hier: Systematischer Review, RCT, prospektive Kohortenstudien)

1. Kattan MW. Nomograms are superior to staging and risk grouping systems for identifying high-risk patients: preoperative application in prostate cancer. *Curr Opin Urol* 2003;13(2):111-6 <http://www.ncbi.nlm.nih.gov/pubmed/12584470>, DOI: 10.1097/01.mou.0000058631.64616.54.

2. Ramsden AR, Chodak G. An analysis of risk factors for biochemical progression in patients with seminal vesicle invasion: validation of Kattan's nomogram in a pathological subgroup. *BJU Int* 2004;93(7):961-4
<http://www.ncbi.nlm.nih.gov/pubmed/15142143>, DOI: 10.1111/j.1464-410X.2003.04760.x.
3. Poulakis V, Witzsch U, de VR, Emmerlich V, Meves M, Altmannsberger HM, Becht E. Preoperative neural network using combined magnetic resonance imaging variables, prostate specific antigen, and Gleason score to predict prostate cancer recurrence after radical prostatectomy. *Eur Urol* 2004;46(5):571-8
<http://www.ncbi.nlm.nih.gov/pubmed/15474265>, DOI: 10.1016/j.eururo.2004.07.010.
4. Froehner M, Koch R, Litz R, Oehlschlaeger S, Wirth MP. Which conditions contributing to the Charlson score predict survival after radical prostatectomy? *Journal of Urology* 2004;171(2 Pt 1):697-9
<http://www.ncbi.nlm.nih.gov/pubmed/14713789>, DOI: 10.1097/01.ju.0000108138.36333.09.
5. Kefi A, Irer B, Ozdemir I, Tuna B, Goktay Y, Yorukoglu K, Esen A. Predictive value of the international prostate symptom score for positive prostate needle biopsy in the low-intermediate prostate-specific antigen range. *Urol Int* 2005;75(3):222-6
<http://www.ncbi.nlm.nih.gov/pubmed/16215309>, DOI: 10.1159/000087798.
6. Froehner M, Koch R, Litz RJ, Oehlschlaeger S, Hakenberg OW, Wirth MP. Feasibility and limitations of comorbidity measurement in patients undergoing radical prostatectomy. *Eur Urol* 2005;47(2):190-5
<http://www.ncbi.nlm.nih.gov/pubmed/15661413>, DOI: 10.1016/j.eururo.2004.07.031.
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<http://www.ncbi.nlm.nih.gov/pubmed/17084158>, DOI: 10.1016/j.juro.2006.06.081.
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<http://www.ncbi.nlm.nih.gov/pubmed/16770340>, DOI: 10.1038/sj.pcan.4500889.
9. Epstein JI. What's new in prostate cancer disease assessment in 2006? *Curr Opin Urol* 2006;16(3):146-51
<http://www.ncbi.nlm.nih.gov/pubmed/16679850>, DOI: 10.1097/01.mou.0000193389.31727.9b.
10. Cooperberg MR, Freedland SJ, Pasta DJ, Elkin EP, Presti JC, Jr., Amling CL, Terris MK, Aronson WJ, Kane CJ, Carroll PR. Multiinstitutional validation of the UCSF cancer of the prostate risk assessment for prediction of recurrence after radical prostatectomy. *Cancer* 2006;107(10):2384-91
<http://www.ncbi.nlm.nih.gov/pubmed/17039503>, DOI: 10.1002/cncr.22262.
11. Chun FK, Steuber T, Erbersdobler A, Currlin E, Walz J, Schlomm T, Haese A, Heinzer H, McCormack M, Huland H, Graefen M, Karakiewicz PI. Development and internal validation of a nomogram predicting the probability of prostate cancer Gleason sum upgrading between biopsy and radical prostatectomy pathology. *Eur Urol* 2006;49(5):820-6
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<http://www.ncbi.nlm.nih.gov/pubmed/17868719>, DOI: 10.1016/j.juro.2007.07.043.
13. Chun FK, Karakiewicz PI, Briganti A, Walz J, Kattan MW, Huland H, Graefen M. A critical appraisal of logistic regression-based nomograms, artificial neural networks, classification and regression-tree models, look-up tables and risk-group stratification models for prostate cancer. *BJU Int* 2007;99(4):794-800
<http://www.ncbi.nlm.nih.gov/pubmed/17378842>, DOI: 10.1111/j.1464-410X.2006.06694.x.
14. Roupret M, Hupertan V, Comperat E, Drouin SJ, Phe V, Xylinas E, Demanse D, Sibony M, Richard F, Cussenot O. Cross-cultural validation of a prognostic tool: ex-

- ample of the Kattan preoperative nomogram as a predictor of prostate cancer recurrence after radical prostatectomy. *BJU Int* 2009;104(6):813-7
<http://www.ncbi.nlm.nih.gov/pubmed/19254280>, DOI: 10.1111/j.1464-410X.2009.08473.x.
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12.4.5.4.3. Ausgeschlossene Titel-/Abstracts (nach Titel-/Abstractscreening)

A1: Andere Erkrankung, andere Fragestellung, anderes Thema (analog Festlegung in PICO-Tabelle siehe oben)

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A6: Doppelpublikation oder nicht erhältlich

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12.4.6. Recherche zum Thema Active Surveillance, Behandlung des Low-Risk PCa (Kapitel 5.1 und 5.2 der Leitlinie)

12.4.6.1. Fragestellung

Fragestellung/ Themenbereich	Population	Intervention	Comparison	Outcome	Evidenzgrundlage/Zusatzinformation
Low-risk-Karzinom (lokal begrenzt): kurativ Fröhner, Börgermann	Patienten mit Low risk Karzinom (lokal begrenzt) PSA-Wert max. 10 ng/ml, Gleason Score max. 6 und 3+4 und cT1c und cT2a, Tumor in weniger als <= 2 Stenzen, <= 50% Tumor pro Stanze	Radikale Prostatektomie, kurative Radiatio, kurative Brachytherapie	Active Surveillance, Watchful Waiting	Morbidität, PCA-Mortalität, PSA-Progress, kurative Intervention	Aggregierte Evidenz (Systematischer Review, Leitlinienadaptation) + RCT, prospektive Kohortenstudien

12.4.6.2. Recherchestrategien

Anmerkung: Nach bereits erfolgter Recherche wurde der Suchzeitraum weiter eingegrenzt: Zeitraum nach der Recherche (17.01.2011) für die Aktualisierung 2011 bis 03.04.2013.

Ausschlusskriterien für Relevanzsichtung:

A1: andere Erkrankung (nicht PCa)

A2: Methodik (Letter, Editorial, News, Comment)

A3: Dubletten durch Suche in verschiedenen Datenbanken

A4: Publikationen vor 2011 und nicht deutsch oder englisch (Cochrane Library)

PubMed (03. April 2013)

Nr.	Suchfrage	Anzahl
#4	#1 AND #2 Limits: English, German, Publication date from 2008/01/01	1194
#3	#1 AND #2	2659
#2	("watchful waiting"[MeSH Terms] OR ("watchful"[All Fields] AND "waiting"[All Fields]) OR "watchful waiting"[All Fields] OR ("active"[All Fields] AND "surveillance"[All Fields]) OR "active surveillance"[All Fields]) OR "expectant management"[All Fields] OR "deferred treatment"[All Fields] OR "delayed intervention"[All Fields] OR "defensive strategies"[All Fields] OR "PSA kinetics"[All Fields] OR "PSA velocity"[All Fields] OR "PSA doubling time"[All Fields] OR "PSA density"[All Fields])	13146

Nr.	Suchfrage	Anzahl
#1	"prostatic neoplasms"[MeSH Terms] OR ("prostatic"[All Fields] AND "neoplasms"[All Fields]) OR "prostatic neoplasms"[All Fields] OR ("prostate"[All Fields] AND "cancer"[All Fields]) OR "prostate cancer"[All Fields]	107786

Anzahl der Treffer: 1194

Davon relevant: 1078

Davon nach 2011: 584

Cochrane (03. April 2013)

Suchstrategie:

Nr.	Suchfrage	Anzahl
#4	#1 AND #2 from 2008 to 2013, in Cochrane Reviews (Reviews only), Other Reviews, Trials, Methods Studies, Technology Assessment and Economic Evaluations	53
#3	#1 AND #2	137
#2	(watchful AND waiting) OR (active AND surveillance) OR "expectant management" OR "deferred treatment" OR "delayed intervention" OR "defensive strategies" OR "PSA kinetics" OR "PSA velocity" OR "PSA doubling time" OR "PSA density":ti,ab,kw	875
#1	(prostatic OR prostate) AND (neoplasm OR neoplasms OR cancer):ti,ab,kw	4111

- Cochrane Database of Systematic Reviews (4)
- Database of Abstracts of Reviews of Effects (1)
- Cochrane Central Register of Controlled Trials (45)
- Cochrane Methodology Register (0)
- Health Technology Assessment Database (2)
- NHS Economic Evaluation Database (1)

Anzahl der Treffer: 53

Davon neu: 7

Davon relevant: 4

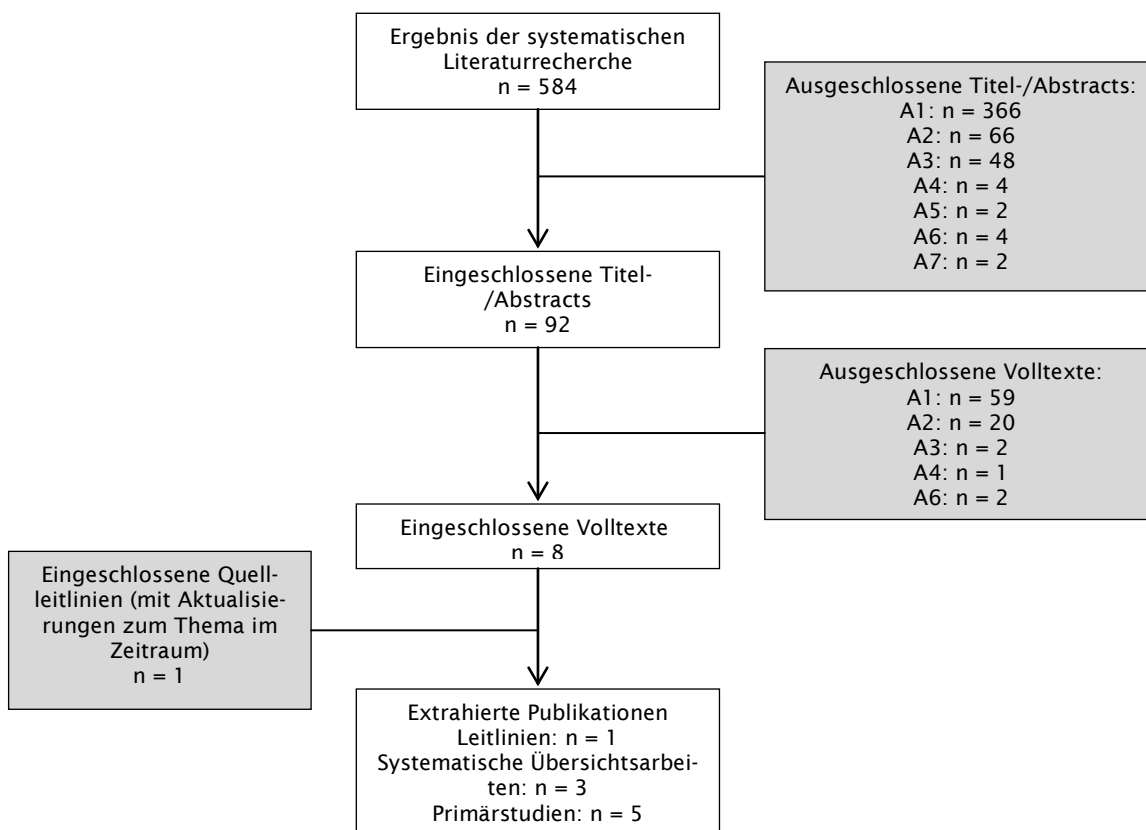
Davon nach 2011: 0

12.4.6.3. Ein- und Ausschlusskriterien

Ausschlusskriterien	
A1:	andere Erkrankung, andere Fragestellung, anderes Thema (analog Festlegung in PICO-Tabelle – Auszug s.u.)
A2:	anderer Publikationstyp (z.B. Fallberichte, Fall-Kontroll-Studien, Editorial u.ä.) als a priori für die Fragestellung definiert (hier: Systematischer Review, RCT)

Ausschlusskriterien	
A3:	unsystematischer Review oder Review <u>ohne</u> Einschluss von RCT und/ oder prospektiven Kohortenstudien
A4:	retrospektive Kohortenstudie
A5:	n < 25
A6:	Doppelpublikation oder nicht erhältlich
A7:	Sonstiges (z.B. Sprache, Publikation außerhalb des Suchzeitraums etc.)
Einschlusskriterien	
E1:	Systematischer Review (aus RCTs und/oder prospektiven Kohortenstudien) (wahrscheinlich) passend zu Fragestellungen 7.1 und/oder 7.3 analog PICO-Tabelle
E2:	RCT (wahrscheinlich) passend zu Fragestellungen 7.1 und/oder 7.3 analog PICO-Tabelle

12.4.6.4. Ergebnisse der Recherche



12.4.6.4.1. Extrahierte Publikationen

Eingeschlossene Volltexte

1. 152. Dall'era MA, Albertsen PC, Bangma C, Carroll PR, Carter HB, Cooperberg MR, Freedland SJ, Klotz LH, Parker C, Soloway MS. Active surveillance for prostate cancer: a systematic review of the literature. *Eur Urol* 2012;62(6):976-83 PM:22698574, DOI: S0302-2838(12)00691-4 [pii];10.1016/j.eururo.2012.05.072.
2. 372. Wilt TJ. The Prostate Cancer Intervention Versus Observation Trial: VA/NCI/AHRQ Cooperative Studies Program #407 (PIVOT): design and baseline results of a randomized controlled trial comparing radical prostatectomy with watchful waiting for men with clinically localized prostate cancer. *J Natl Cancer Inst Monogr* 2012;2012(45):184-90 PM:23271771, DOI: lgs041 [pii];10.1093/jncimonographs/lgs041.
3. 373. Wilt TJ, Brawer MK, Jones KM, Barry MJ, Fox S, Gingrich JR, Wei JT, Gilhooly P, Grob BM, Nsouli I, Iyer P, Cartagena R, Snider G, Roehrborn C, Sharifi R, Blank W, Pandya P, Andriole GL, Culkin D, Wheeler T. Radical prostatectomy versus observation for localized prostate cancer. *N Engl J Med* 2012;367(3):203-13 PM:22808955, DOI: 10.1056/NEJMoa1113162.
4. 359. van den Bergh RC, Korfage IJ, Roobol MJ, Bangma CH, de Koning HJ, Steyerberg EW, Essink-Bot ML. Sexual function with localized prostate cancer: active surveillance vs radical therapy. *BJU Int* 2012;110(7):1032-9 PM:22260273, DOI: 10.1111/j.1464-410X.2011.10846.x.
5. 406. Bill-Axelsson A, Holmberg L, Ruutu M, Garmo H, Stark JR, Busch C, Nordling S, Haggman M, Andersson SO, Bratell S, Spangberg A, Palmgren J, Steineck G, Adami HO, Johansson JE. Radical prostatectomy versus watchful waiting in early prostate cancer. *N Engl J Med* 2011;364(18):1708-17 PM:21542742, DOI: 10.1056/NEJMoa1011967.
6. 448. Ganz PA, Barry JM, Burke W, Col NF, Corso PS, Dodson E, Hammond ME, Kogan BA, Lynch CF, Newcomer L, Seifter EJ, Tooze JA, Viswanath KV, Wessells H. NIH State-of-the-Science Conference Statement: Role of active surveillance in the management of men with localized prostate cancer. *NIH Consens State Sci Statements* 2011;28(1):1-27 PM:23392076, DOI: 2011-00035-STMT [pii].
7. 467. Ip S, Dahabreh IJ, Chung M, Yu WW, Balk EM, Iovin RC, Mathew P, Luongo T, Dvorak T, Lau J. An evidence review of active surveillance in men with localized prostate cancer. *Evid Rep Technol Assess (Full Rep)* 2011;(204):1-341 PM:23126653.
8. 470. Johansson E, Steineck G, Holmberg L, Johansson JE, Nyberg T, Ruutu M, Bill-Axelsson A. Long-term quality-of-life outcomes after radical prostatectomy or watchful waiting: the Scandinavian Prostate Cancer Group-4 randomised trial. *Lancet Oncol* 2011;12(9):891-9 PM:21821474, DOI: S1470-2045(11)70162-0 [pii];10.1016/S1470-2045(11)70162-0.

Extrahierte Quelleitlinie

1. Heidenreich A, Bolla M, Joniau S, Mason MD, Matveev V, Mottet N, Schmid HP, van der Kwast TH, Wiegel T, Zattoni F. EAU guidelines on prostate cancer. 2013

12.4.6.4.2. Ausgeschlossene Volltexte (nach Volltextsichtung)

A1: Andere Erkrankung, andere Fragestellung, anderes Thema (analog Festlegung in PICO-Tabelle siehe oben)

1. 9. Bangma CH, Bul M, Van Der Kwast TH, Pickles T, Korfage IJ, Hoeks CM, Steyerberg EW, Jenster G, Kattan MW, Bellardita L, Carroll PR, Denis LJ, Parker C, Roobol MJ, Emberton M, Klotz LH, Rannikko A, Kakehi Y, Lane JA, Schroder FH, Semjonow A, Trock BJ, Valdagni R. Active surveillance for low-risk prostate cancer. *Crit Rev Oncol Hematol* 2013;85(3):295-302 PM:22878262, DOI: S1040-8428(12)00154-0 [pii];10.1016/j.critrevonc.2012.07.005.
2. 10. Bellardita L, Rancati T, Alvisi MF, Villani D, Magnani T, Marengi C, Nicolai N, Procopio G, Villa S, Salvioni R, Valdagni R. Predictors of Health-related Quality of Life and Adjustment to Prostate Cancer During Active Surveillance. *Eur Urol* 2013; PM:23357351, DOI: S0302-2838(13)00012-2 [pii];10.1016/j.eururo.2013.01.009.

3. 11. Berg KD, Toft BG, Roder MA, Brasso K, Vainer B, Iversen P. Is it possible to predict low-volume and insignificant prostate cancer by core needle biopsies? *APMIS* 2013;121(4):257-65 PM:23030402, DOI: 10.1111/j.1600-0463.2012.02965.x.
4. 16. Bul M, Zhu X, Valdagni R, Pickles T, Kakehi Y, Rannikko A, Bjartell A, van der Schoot DK, Cornel EB, Conti GN, Boeve ER, Staerman F, Vis-Maters JJ, Vergunst H, Jaspars JJ, Strolin P, van ME, Schroder FH, Bangma CH, Roobol MJ. Active Surveillance for Low-Risk Prostate Cancer Worldwide: The PRIAS Study. *Eur Urol* 2013;63(4):597-603 PM:23159452, DOI: S0302-2838(12)01336-X [pii];10.1016/j.eururo.2012.11.005.
5. 33. Godtman RA, Holmberg E, Khatami A, Stranne J, Hugosson J. Outcome following active surveillance of men with screen-detected prostate cancer. Results from the Goteborg randomised population-based prostate cancer screening trial. *Eur Urol* 2013;63(1):101-7 PM:22980443, DOI: S0302-2838(12)01019-6 [pii];10.1016/j.eururo.2012.08.066.
6. 50. Lin DW, Newcomb LF, Brown EC, Brooks JD, Carroll PR, Feng Z, Gleave M, Lance RD, Sanda MG, Thompson IM, Jr., Wei JT, Nelson PS. Urinary TMPRSS2:ERG and PCA3 in an active surveillance cohort: results from a baseline analysis in the Canary Prostate Active Surveillance Study. *Clin Cancer Res* 2013; PM:23515404, DOI: 1078-0432.CCR-12-3283 [pii];10.1158/1078-0432.CCR-12-3283.
7. 73. Selvadurai ED, Singhera M, Thomas K, Mohammed K, Woode-Amisah R, Horwich A, Huddart RA, Dearnaley DP, Parker CC. Medium-term Outcomes of Active Surveillance for Localised Prostate Cancer. *Eur Urol* 2013; PM:23473579, DOI: S0302-2838(13)00132-2 [pii];10.1016/j.eururo.2013.02.020.
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13. 158. Donovan JL. Presenting treatment options to men with clinically localized prostate cancer: the acceptability of active surveillance/monitoring. *J Natl Cancer Inst Monogr* 2012;2012(45):191-6 PM:23271772, DOI: lgs030 [pii];10.1093/jncimonographs/lgs030.
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 19. 330. Shapiro RH, Johnstone PA. Risk of Gleason grade inaccuracies in prostate cancer patients eligible for active surveillance. *Urology* 2012;80(3):661-6 PM:22925240, DOI: S0090-4295(12)00674-7 [pii];10.1016/j.urology.2012.06.022.
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 23. 484. Klotz L. Active surveillance for favorable risk prostate cancer: rationale, results, and vis a vis focal therapy role. *Minerva Urol Nefrol* 2011;63(2):145-53 PM:21623332, DOI: R19111922 [pii].
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12.4.6.4.3. Ausgeschlossene Titel/Abstracts (nach Titel-/Abstractscreening durchgeführt von Weißbach)

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- Watchful Waiting in Prostate Cancer: A Longitudinal Study from the Scandinavian Prostate Cancer Group-4 Randomized Clinical Trial. *Eur Urol* 2013; PM:23465517, DOI: S0302-2838(13)00137-1 [pii];10.1016/j.eururo.2013.02.025.
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A3: unsystematischer Review oder Review ohne Einschluss von RCT und/ oder prospektiven Kohortenstudien)

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1. 379. Xu J, Neale AV, Dailey RK, Eggly S, Schwartz KL. Patient perspective on watchful waiting/active surveillance for localized prostate cancer. *J Am Board Fam Med* 2012;25(6):763-70 PM:23136314, DOI: 25/6/763 [pii];10.3122/jabfm.2012.06.120128.
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1. 172. Garcia-Cruz E, Huguet J, Piqueras M, Marquez MP, Peri L, Izquierdo L, Franco A, Alvarez-Vijande R, Ribal MJ, Alcaraz A. Low testosterone bioavailability is related to prostate cancer diagnose in patients submitted to prostate biopsy. *World J Urol* 2012;30(3):361-5 PM:21833558, DOI: 10.1007/s00345-011-0741-9.
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A7: Sonstiges (z.B. Sprache, Publikation außerhalb des Suchzeitraums etc.)

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12.4.7. Recherche zum Thema Systemtherapie beim metastasierten kastrationsresistenten Prostatakarzinom (Kapitel 6.4 und 6.5 der Leitlinie)

12.4.7.1. Fragestellung

Fragestellung/ Themenbereich	Population	Intervention	Kontrolle	Outcome	Evidenzgrundlage
Systemtherapie beim metastasierten Prostatakarzinom: Welche Substanzen sind beim kastrationsresistenten Prostatakarzinom wirksam?	Patienten mit metastasiertem PCA und Progress der Erkrankung unter Hormontherapie (kastrationsresistentes PCa)	Docetaxel, Cabazitaxel, Abirateron, Enzalutamid	symptomorientiert, Gabe von Glukokortikoiden	PSA-Ansprechrate, Toxizität, PSA-Progression, Mortalität, PCa-Mortalität, Gesamtmortalität, Morbidität, Lebensqualität	Aggregierte Evidenz (Systematischer Review) + RCT
Systemtherapie beim metastasierten Prostatakarzinom: Sind Kombinationstherapien beim kastrationsresistenten Prostatakarzinom wirksam? <u>Wörmann, Zastrow, Heidenreich, Wirth, Miller</u>	Kastrationsresistentes PCa	Standard-Kombination: -LH-RH Antagonist oder Agonist + Abirateron; Bei Knochenmetastasen zusätzlich Bisphosphonat oder Denosumab. Abirateron kombiniert mit Cabazitaxel oder Docetaxel	Keine Kombinationstherapien, sondern Monotherapie mit LH-RH Agonist ODER LH-RH Antagonist	PSA-Ansprechrate, Toxizität, PSA-Progression, Mortalität, Morbidität, Lebensqualität	Aggregierte Evidenz (Systematischer Review, Leitlinienadaptation) + RCT

12.4.7.2. Recherchestrategien

Ausschlusskriterien für Relevanzsichtung festlegen:

A1: andere Erkrankung (nicht PCa)

A2: Methodik (Letter, Editorial, News, Comment)

A3: Dubletten durch Suche in verschiedenen Datenbanken

A4: Publikationen vor 2008 und nicht deutsch oder englisch (Cochrane Library)

PubMed (10. April 2013)

Nr.	Suchfrage	Anzahl
#10	#5 AND #8 Limits: English, German, Publication date from 2008/01/01	451
#9	#5 AND #8	746
#8	#6 OR #7	2566395
#7	(randomized controlled trial [pt] OR controlled clinical trial [pt] OR randomized [tiab] OR placebo [tiab] OR drug therapy [sh] OR randomly [tiab] OR trial [tiab] OR groups [tiab]) AND humans [mh]	2434194
#6	systematic[sb]	199523
#5	#3 AND #4	965
#4	#1 AND #2	4165
#3	("docetaxel"[Supplementary Concept] OR "docetaxel"[All Fields]) OR ("cabazitaxel"[Supplementary Concept] OR "cabazitaxel"[All Fields]) OR ("abiraterone"[Supplementary Concept] OR "abiraterone"[All Fields]) OR ("MDV 3100"[Supplementary Concept] OR "MDV 3100"[All Fields]) OR "enzalutamide"[All Fields]	9090
#2	((("orchietomy"[MeSH Terms] OR "orchietomy"[All Fields] OR "castration"[All Fields] OR "castration"[MeSH Terms]) AND resistant[All Fields]) OR (("hormones"[MeSH Terms] OR "hormones"[All Fields] OR "hormone"[All Fields] OR "hormones"[Pharmacological Action]) AND refractory[All Fields])	10870
#1	"prostatic neoplasms"[MeSH Terms] OR ("prostatic"[All Fields] AND "neoplasms"[All Fields]) OR "prostatic neoplasms"[All Fields] OR ("prostate"[All Fields] AND "cancer"[All Fields]) OR "prostate cancer"[All Fields]	107976

Anzahl der Treffer: 451

Davon relevant: 432

Cochrane (10. April 2013)

Suchstrategie:

Nr.	Suchfrage	Anzahl
#4	#1 AND #2 from 2008 to 2013, in Cochrane Reviews (Reviews only), Other Reviews, Trials, Methods Studies, Technology Assessment and Economic Evaluations	64
#3	#1 AND #2	81
#2	((orchietomy OR castration) AND resistant) OR (hormone? AND refractory):ti,ab,kw	122

Nr.	Suchfrage	Anzahl
#1	(prostatic OR prostate) AND (neoplasm OR neoplasms OR cancer):ti,ab,kw	4111

- Cochrane Database of Systematic Reviews (2)
- Database of Abstracts of Reviews of Effects (1)
- Cochrane Central Register of Controlled Trials (54)
- Cochrane Methodology Register (0)
- Health Technology Assessment Database (6)
- NHS Economic Evaluation Database (1)

Anzahl der Treffer: 64

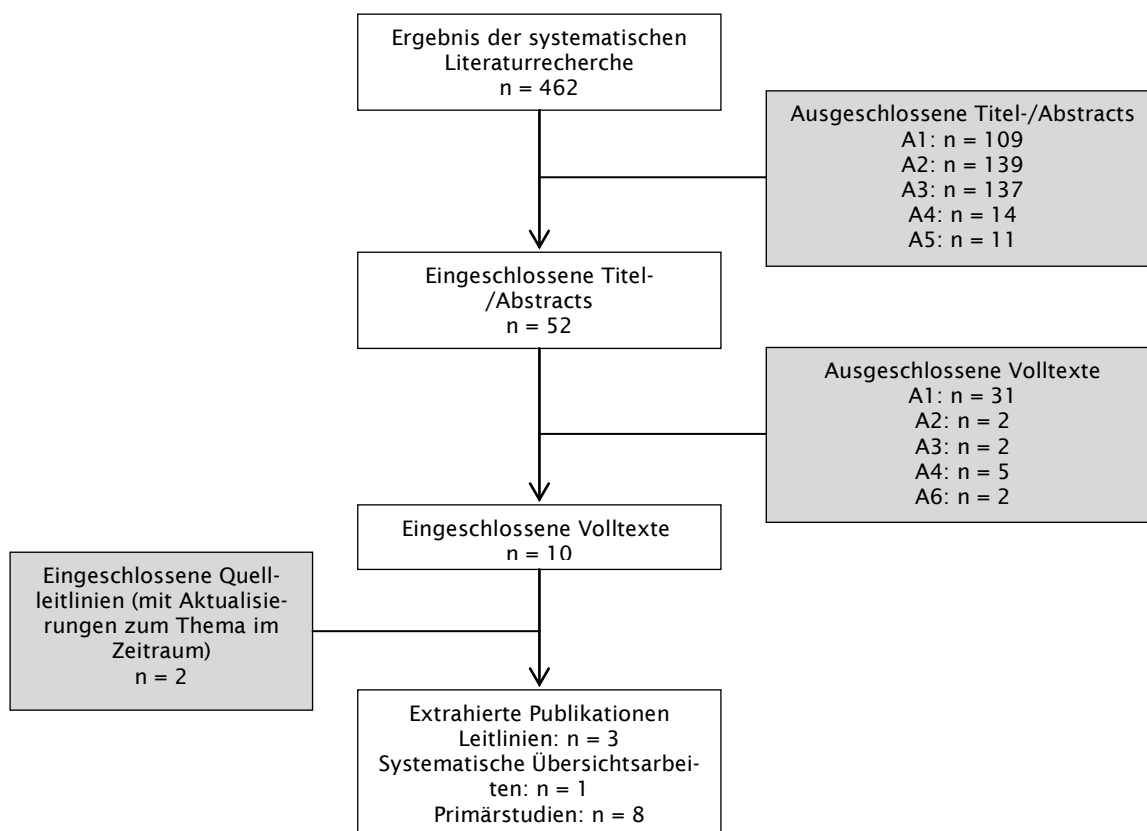
Davon neu: 32

Davon relevant: 30

12.4.7.3. Ein- und Ausschlusskriterien

Ausschlusskriterien	
A1:	andere Erkrankung, andere Fragestellung, anderes Thema (analog Festlegung in PICO-Tabelle – Auszug s.u.)
A2:	anderer Publikationstyp (z.B. Fallberichte, Fall-Kontroll-Studien, Editorial u.ä.) als a priori für die Fragestellung definiert (hier: Systematischer Review, RCT)
A3:	unsystematischer Review oder Review <u>ohne</u> Einschluss von RCT und/ oder prospektiven Kohortenstudien
A4:	retrospektive Kohortenstudie
A5:	n < 25
A6:	Doppelpublikation oder nicht erhältlich
A7:	Sonstiges (z.B. Sprache, Publikation außerhalb des Suchzeitraums etc.)
Einschlusskriterien	
E1:	Systematischer Review (aus RCTs und/oder prospektiven Kohortenstudien) (wahrscheinlich) passend zu Fragestellungen 7.1 und/oder 7.3 analog PICO-Tabelle
E2:	RCT (wahrscheinlich) passend zu Fragestellungen 7.1 und/oder 7.3 analog PICO-Tabelle

12.4.7.4. Ergebnisse der Recherche



12.4.7.4.1. Extrahierte Publikationen

Eingeschlossene Volltexte (nach Volltexttsichtung)

110. Scher HI, Fizazi K, Saad F, Taplin ME, Sternberg CN, Miller K, de WR, Mulders P, Chi KN, Shore ND, Armstrong AJ, Flaig TW, Flechon A, Mainwaring P, Fleming M, Hainsworth JD, Hirmand M, Selby B, Seely L, de Bono JS. Increased survival with enzalutamide in prostate cancer after chemotherapy. *N Engl J Med* 2012;367(13):1187-97 PM:22894553, DOI: 10.1056/NEJMoa1207506.
157. de Bono JS, Logothetis CJ, Molina A, Fizazi K, North S, Chu L, Chi KN, Jones RJ, Goodman OB, Jr., Saad F, Staffurth JN, Mainwaring P, Harland S, Flaig TW, Hutson TE, Cheng T, Patterson H, Hainsworth JD, Ryan CJ, Sternberg CN, Ellard SL, Flechon A, Saleh M, Scholz M, Efstathiou E, Zivi A, Bianchini D, Loriot Y, Chieffo N, Kheoh T, Haqq CM, Scher HI. Abiraterone and increased survival in metastatic prostate cancer. *N Engl J Med* 2011;364(21):1995-2005 PM:21612468, DOI: 10.1056/NEJMoa1014618.
261. de Bono JS, Oudard S, Ozguroglu M, Hansen S, Machiels JP, Kocak I, Gravis G, Bodrogi I, Mackenzie MJ, Shen L, Roessner M, Gupta S, Sartor AO. Prednisone plus cabazitaxel or mitoxantrone for metastatic castration-resistant prostate cancer progressing after docetaxel treatment: a randomised open-label trial. *Lancet* 2010;376(9747):1147-54 PM:20888992, DOI: S0140-6736(10)61389-X [pii];10.1016/S0140-6736(10)61389-X.
28. Climent MA, Piulats JM, Sanchez-Hernandez A, Arranz JA, Cassinello J, Garcia-Donas J, Gonzalez del AA, Leon-Mateos L, Mellado B, Mendez-Vidal MJ, Perez-Valderrama B. Recommendations from the Spanish Oncology Genitourinary Group for the treatment of patients with metastatic castration-resistant prostate cancer. *Crit Rev Oncol Hematol* 2012;83(3):341-52 PM:22285697, DOI: S1040-8428(12)00003-0 [pii];10.1016/j.critrevonc.2012.01.002.
4. Kellokumpu-Lehtinen PL, Harmenberg U, Joensuu T, McDermott R, Hervonen P, Ginman C, Luukka M, Nyandoto P, Hemminki A, Nilsson S, McCaffrey J, Asola R,

- Turpeenniemi-Hujanen T, Laestadius F, Tasmuth T, Sandberg K, Keane M, Lehtinen I, Luukkaala T, Joensuu H. 2-Weekly versus 3-weekly docetaxel to treat castration-resistant advanced prostate cancer: a randomised, phase 3 trial. *Lancet Oncol* 2013;14(2):117-24 PM:23294853, DOI: S1470-2045(12)70537-5 [pii];10.1016/S1470-2045(12)70537-5.
6. 405. Berthold DR, Pond GR, Roessner M, de WR, Eisenberger M, Tannock AI. Treatment of hormone-refractory prostate cancer with docetaxel or mitoxantrone: relationships between prostate-specific antigen, pain, and quality of life response and survival in the TAX-327 study. *Clin Cancer Res* 2008;14(9):2763-7 PM:18451243, DOI: 14/9/2763 [pii];10.1158/1078-0432.CCR-07-0944.
 7. 41. Fizazi K, Scher HI, Molina A, Logothetis CJ, Chi KN, Jones RJ, Staffurth JN, North S, Vogelzang NJ, Saad F, Mainwaring P, Harland S, Goodman OB, Jr., Sternberg CN, Li JH, Kheoh T, Haqq CM, de Bono JS. Abiraterone acetate for treatment of metastatic castration-resistant prostate cancer: final overall survival analysis of the COU-AA-301 randomised, double-blind, placebo-controlled phase 3 study. *Lancet Oncol* 2012;13(10):983-92 PM:22995653, DOI: S1470-2045(12)70379-0 [pii];10.1016/S1470-2045(12)70379-0.
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A1: Andere Erkrankung, andere Fragestellung, anderes Thema (analog Festlegung in PICO-Tabelle siehe oben)

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A2: anderer Publikationstyp (z.B. Fallberichte, Fall-Kontroll-Studien, Editorial u.ä.) als a priori für die Fragestellung definiert (hier: Systematischer Review, RCT, prospektive Kohortenstudien)

1. 11. MDV-3100 for castration-resistant prostate cancer (Structured abstract). *Health Technology Assessment Database* 2012;1 <http://onlinelibrary.wiley.com/o/cochrane/clhta/articles/HTA-32012000079/frame.html>.
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A3: unsystematischer Review oder Review ohne Einschluss von RCT und/ oder prospektiven Kohortenstudien)

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12.4.7.4.3. Ausgeschlossene Titel-/Abstracts (nach Titel-/Abstractscreening durchgeführt von Wörmann/Miller/Zastrow)

A1: Andere Erkrankung, andere Fragestellung, anderes Thema (analog Festlegung in PICO-Tabelle siehe oben)

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A2: anderer Publikationstyp (z.B. Fallberichte, Fall-Kontroll-Studien, Editorial u.ä.) als a priori für die Fragestellung definiert (hier: Systematischer Review, RCT, prospektive Kohortenstudien)

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A3: unsystematischer Review oder Review ohne Einschluss von RCT und/ oder prospektiven Kohortenstudien)

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9. 416. Di LG, Figg WD, Fossa SD, Mirone V, Autorino R, Longo N, Imbimbo C, Perdon S, Giordano A, Giuliano M, Labianca R, De PS. Combination of bevacizumab and docetaxel in docetaxel-pretreated hormone-refractory prostate cancer: a phase 2 study. *Eur Urol* 2008;54(5):1089-94 PM:18276061, DOI: S0302-2838(08)00136-X [pii];10.1016/j.eururo.2008.01.082.
10. 454. Suttman H, Grgic A, Lehmann J, Zwergel U, Kamradt J, Gouverneur E, Pinkert J, Stockle M, Kirsch CM, Nestle U. Combining 153Sm-lexidronam and docetaxel for the treatment of patients with hormone-refractory prostate cancer: first experience. *Cancer Biother Radiopharm* 2008;23(5):609-18 PM:18999933, DOI: 10.1089/cbr.2008.0487.

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11. 455. Takenaka A, Yamada Y, Kurahashi T, Soga H, Miyake H, Fujisawa M. Combination chemotherapy with weekly docetaxel and estramustine for hormone refractory prostate cancer in Japanese patients. *Int J Urol* 2008;15(1):106-9
PM:18184188, DOI: IJU1929 [pii];10.1111/j.1442-2042.2007.01929.x.

12.4.8. Recherche zum Thema Knochenmetastasen (Kapitel 6.5 der Leitlinie)

12.4.8.1. Fragestellung

Fragestellung/T hemenbereich	Populati on	Inter- vention	Compari son	Outcome	Evidenzgrund- lage/ Zusatz- information
Systemtherapie beim metastasier- ten Prostatakarzi- nomWelche Sub- stanzen sind beim ossär metastasier- ten Prostatakarzi- nom wirksam? <u>Wörmann, Zastrow,</u> <u>Heidenreich, Wirth,</u> <u>Miller, Palmedo</u>	Patienten mit ossär metasta- siertem PCa	Denosumab, Bis- phosphonat (Zoledronsäure) Radium (Alpharidin)	Symptom- orientiert, Gabe von Glukokor- tikoiden	PSA-Ansprech- rate, Toxizi- tät, PSA- Progression, Mortalität, PCa-Morta- lität, Gesamt- mortalität Morbidity, Lebens- qualität	Aggregierte Evi- denz (Systemati- scher Review) + RCT AKdÄ-Seiten

12.4.8.2. Recherchestrategien

12.4.8.2.1. 1. Recherche

Ausschlusskriterien für Relevanzsichtung festlegen:

A1: Dubletten durch Suche in verschiedenen Datenbanken

A2: Publikationen vor 2008 und nicht deutsch oder englisch (Cochrane Library)

PubMed (10. April 2013)

Nr.	Suchfrage	Anzahl
#10	#5 AND #8 Limits: English, German, Publication date from 2008/01/01	111
#9	#5 AND #8	344
#8	#6 OR #7	2566395
#7	(randomized controlled trial [pt] OR controlled clinical trial [pt] OR randomized [tiab] OR placebo [tiab] OR drug therapy [sh] OR randomly [tiab] OR trial [tiab] OR groups [tiab]) AND humans [mh]	2434194
#6	systematic[sb]	199523
#5	#3 AND #4	829
#4	#1 AND #2	3264

Nr.	Suchfrage	Anzahl
#3	("denosumab"[Supplementary Concept] OR "denosumab"[All Fields]) OR ("diphosphonates"[MeSH Terms] OR "diphosphonates"[All Fields] OR "bisphosphonate"[All Fields]) OR ("zoledronic acid"[Supplementary Concept] OR "zoledronic acid"[All Fields]) OR (("radium"[MeSH Terms] OR "radium"[All Fields]) AND 233[All Fields]) OR ("Radioisotopes"[Mesh] OR radionuclide*[tiab] OR "Radiotherapy"[Mesh] OR radiation OR radiotherapy)	969244
#2	("bone and bones"[MeSH Terms] OR ("bone"[All Fields] AND "bones"[All Fields]) OR "bone and bones"[All Fields] OR "bone"[All Fields]) AND ("neoplasm metastasis"[MeSH Terms] OR ("neoplasm"[All Fields] AND "metastasis"[All Fields]) OR "neoplasm metastasis"[All Fields] OR "metastasis"[All Fields])	23756
#1	"prostatic neoplasms"[MeSH Terms] OR ("prostatic"[All Fields] AND "neoplasms"[All Fields]) OR "prostatic neoplasms"[All Fields] OR ("prostate"[All Fields] AND "cancer"[All Fields]) OR "prostate cancer"[All Fields]	107976

Anzahl der Treffer: 111

Davon relevant: 111

Cochrane (10. April 2013)

Suchstrategie:

Nr.	Suchfrage	Anzahl
#4	#1 AND #2 from 2008 to 2013, in Cochrane Reviews (Reviews only), Other Reviews, Trials, Methods Studies, Technology Assessment and Economic Evaluations	51
#3	#1 AND #2	260
#2	bone metastasis:ti,ab,kw	1128
#1	(prostatic OR prostate) AND (neoplasm OR neoplasms OR cancer):ti,ab,kw	4111

- Cochrane Database of Systematic Reviews (4)
- Database of Abstracts of Reviews of Effects (0)
- Cochrane Central Register of Controlled Trials (44)
- Cochrane Methodology Register (0)
- Health Technology Assessment Database (1)
- NHS Economic Evaluation Database (2)

Anzahl der Treffer: 51

Davon neu: 45

Davon relevant: 40

12.4.8.2.2. Zusätzliche Recherche in den Rote-Hand-Briefen der AkdÄ (2008-2013)

unter <http://www.akdae.de/Arzneimittelsicherheit/RHB/Archiv/index.html>

Anzahl der Treffer: 3

12.4.8.2.3. Ergänzende Recherche

Ausschlusskriterien für Relevanzsichtung:

A1: Dubletten durch Suche in verschiedenen Datenbanken

A2: Publikationen vor 2008 und nicht deutsch oder englisch (Cochrane Library)

PubMed (12. Juni 2013)

Nr.	Suchfrage	Anzahl
#10	#5 AND #8 Limits: Publication date from 2008/01/01 to 2013/04/10	283
#9	#5 AND #8	824
#8	#6 OR #7	2592357
#7	(randomized controlled trial [pt] OR controlled clinical trial [pt] OR randomized [tiab] OR placebo [tiab] OR drug therapy [sh] OR randomly [tiab] OR trial [tiab] OR groups [tiab]) AND humans [mh]	2456960
#6	systematic[sb]	204074
#5	#3 AND #4	1842
#4	#1 AND #2	5315
#3	("denosumab"[Supplementary Concept] OR "denosumab"[All Fields]) OR ("diphosphonates"[MeSH Terms] OR "diphosphonates"[All Fields] OR "bisphosphonate"[All Fields]) OR ("zoledronic acid"[Supplementary Concept] OR "zoledronic acid"[All Fields]) OR (("radium"[MeSH Terms] OR "radium"[All Fields]) AND 233[All Fields]) OR ("Radioisotopes"[Mesh] OR radionuclide*[tiab] OR "Radiotherapy"[Mesh] OR radiation OR radiotherapy)	976143
#2	("bone and bones"[MeSH Terms] OR ("bone"[All Fields] AND "bones"[All Fields]) OR "bone and bones"[All Fields] OR "bone"[All Fields]) AND (("neoplasm metastasis"[MeSH Terms] OR ("neoplasm"[All Fields] AND "metastasis"[All Fields]) OR "neoplasm metastasis"[All Fields] OR "metastasis"[All Fields]) OR ("neoplasm metastasis"[MeSH Terms] OR ("neoplasm"[All Fields] AND "metastasis"[All Fields]) OR "neoplasm metastasis"[All Fields] OR "metastases"[All Fields]))	35096
#1	"prostatic neoplasms"[MeSH Terms] OR ("prostatic"[All Fields] AND "neoplasms"[All Fields]) OR "prostatic neoplasms"[All Fields] OR ("prostate"[All Fields] AND "cancer"[All Fields]) OR "prostate cancer"[All Fields]	110051

Anzahl der Treffer: 283

Davon noch nicht in der Suche vom 10. April 2013 enthalten: 122

Cochrane (12. Juni 2013)

Suchstrategie:

Nr.	Suchfrage	Anzahl
#4	#1 AND #2 from 2008 to 2013, in Cochrane Reviews (Reviews only), Other Reviews, Trials, Methods Studies, Technology Assessment and Economic Evaluations	53
#3	#1 AND #2	262
#2	bone AND (metastasis OR metastases):ti,ab,kw	1137
#1	(prostatic OR prostate) AND (neoplasm OR neoplasms OR cancer):ti,ab,kw	4182

- Cochrane Database of Systematic Reviews (4)
- Database of Abstracts of Reviews of Effects (1)
- Cochrane Central Register of Controlled Trials (45)
- Cochrane Methodology Register (0)
- Health Technology Assessment Database (1)
- NHS Economic Evaluation Database (2)

Anzahl der Treffer: 53

Davon noch nicht in Suche vom 10. April 2013 enthalten: 2

Davon noch nicht in PubMed gefunden: 1

12.4.8.2.4. Handsuche nach Publikationen zu Radium-223

Zusätzlich erfolgte eine Handsuche in PubMed und im Internet zu Publikationen, Abstracts und Kongressberichten zu Radium-223.

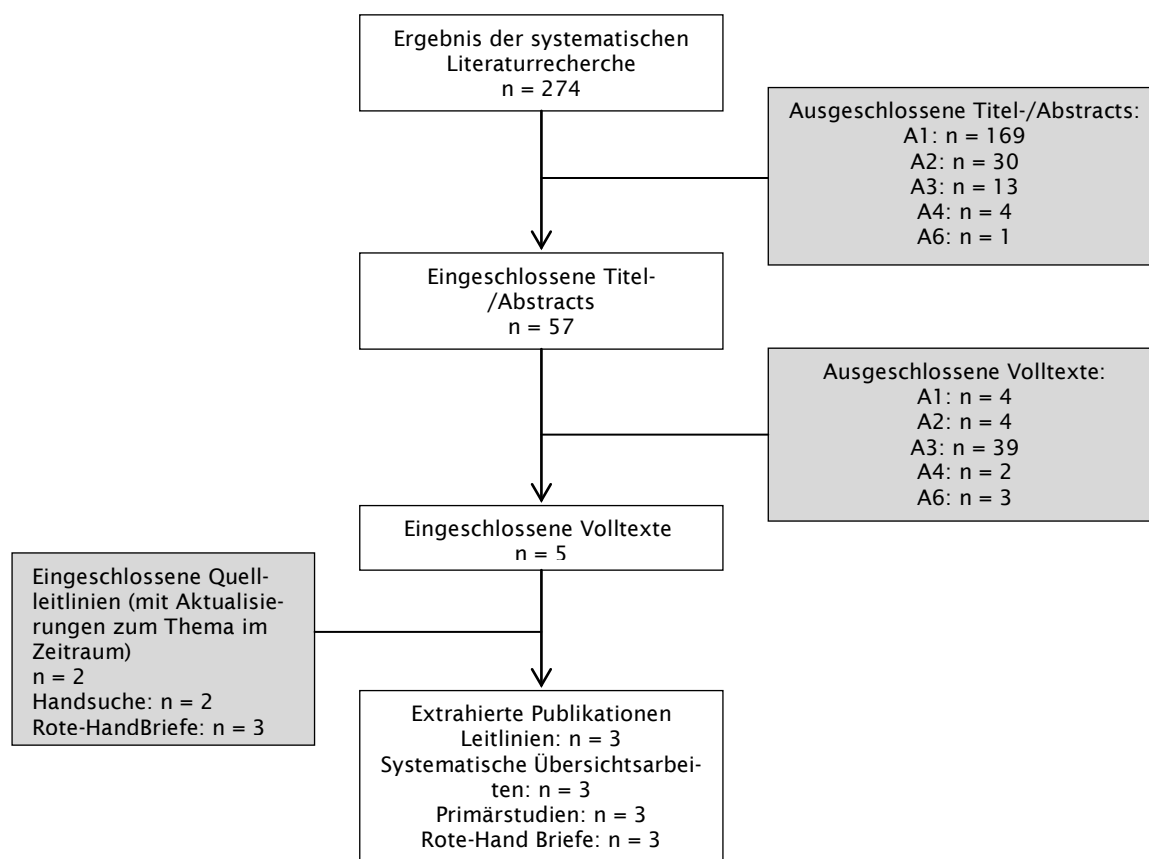
12.4.8.3. Ein- und Ausschlusskriterien

Ausschlusskriterien:

A1:	andere Erkrankung, andere Fragestellung, anderes Thema (analog Festlegung in PICO-Tabelle – Auszug s.u.)
A2:	anderer Publikationstyp (z.B. Fallberichte, Fall-Kontroll-Studien, Editorial u.ä.) als a priori für die Fragestellung definiert (hier: Systematischer Review, RCT)
A3:	unsystematischer Review oder Review <u>ohne</u> Einschluss von RCT und/ oder prospektiven Kohortenstudien)
A4:	retrospektive Kohortenstudie
A5:	n < 25

Ausschlusskriterien:	
A6:	Doppelpublikation oder nicht erhältlich
A7:	Sonstiges (z.B. Sprache, Publikation außerhalb des Suchzeitraums etc.)
Einschlusskriterien:	
E1:	Systematischer Review (aus RCTs und / oder prospektiven Kohortenstudien) (wahrscheinlich) passend zur Fragestellung analog PICO-Tabelle
E2:	RCT (wahrscheinlich) passend zur Fragestellung analog PICO-Tabelle

12.4.8.4. Ergebnisse der Recherche



12.4.8.4.1. Extrahierte Publikationen

Eingeschlossene Volltexte (nach Volltextsichtung)

3. Agarwal N, Sonpavde G, Sternberg CN. Novel molecular targets for the therapy of castration-resistant prostate cancer. Eur Urol 2012;61(5):950-60 PM:22209376, DOI: S0302-2838(11)01412-6 [pii];10.1016/j.eururo.2011.12.028.
12. Climent MA, Piulats JM, Sanchez-Hernandez A, Arranz JA, Cassinello J, Garcia-Donas J, Gonzalez del AA, Leon-Mateos L, Mellado B, Mendez-Vidal MJ, Perez-Valderrama B. Recommendations from the Spanish Oncology Genitourinary Group

- for the treatment of patients with metastatic castration-resistant prostate cancer. *Crit Rev Oncol Hematol* 2012;83(3):341-52 PM:22285697, DOI: S1040-8428(12)00003-0 [pii];10.1016/j.critrevonc.2012.01.002.
3. 98. Saad F, Eastham J. Zoledronic Acid improves clinical outcomes when administered before onset of bone pain in patients with prostate cancer. *Urology* 2010;5 http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/725/CN-00770725/frame.html.
 4. 1. Ford JA, Jones R, Elders A, Mulatero C, Royle P, Sharma P, Stewart F, Todd R, Mowatt G. Denosumab for treatment of bone metastases secondary to solid tumours: systematic review and network meta-analysis. *Eur J Cancer* 2013;49(2):416-30 PM:22906748, DOI: S0959-8049(12)00577-1 [pii];10.1016/j.ejca.2012.07.016.
 5. 110. Dhillon S, Lyseng-Williamson KA. Zoledronic acid : a review of its use in the management of bone metastases of malignancy. *Drugs* 2008;68(4):507-34 PM:18318568, DOI: 68410 [pii].

Extrahierte Quelleitlinien

1. Cookson MS, Roth BJ, Dahm P, Engstrom C, Freedland SJ, Hussain M, Lin DW, Lowrance WT, Murad MH, Oh WK, Penson DF, Kibel AS. Castration-Resistant Prostate Cancer: AUA Guideline. *Journal of Urology* 2013
2. Heidenreich A, Bolla M, Joniau S, Mason MD, Matveev V, Mottet N, Schmid HP, van der Kwast TH, Wiegel T, Zattoni F. EAU guidelines on prostate cancer. 2013

Eingeschlossene Volltexte (Handsuche)

1. Parker C, Nilsson S, Heinrich D, Helle SI, O'Sullivan JM, Fossa SD, Chodacki A, Wiechno P, Logue J, Seke M, Widmark A, Johannessen DC, Hoskin P, Bottomley D, James ND, Solberg A, Syndikus I, Kliment J, Wedel S, Boehmer S, Dall'oglio M, Franzen L, Coleman R, Vogelzang NJ, O'Bryan-Tear CG, Staudacher K, Garcia-Vargas J, Shan M, Bruland OS, Sartor O. Alpha emitter radium-223 and survival in metastatic prostate cancer. *The New England journal of medicine* 2013;369(3):213-23
2. Nilsson S, Franzen L, Parker C, Tyrrell C, Blom R, Tennvall J, Lennernas B, Petersson U, Johannessen DC, Sokal M, Pigott K, O'Bryan-Tear CG, Thuresson M, Bolstad B, Bruland OS. Two-year survival follow-up of the randomized, double-blind, placebo-controlled phase II study of radium-223 chloride in patients with castration-resistant prostate cancer and bone metastases. *Clin Genitourin Cancer* 2013;11(1):20-6

Extrahierte Rote-Hand-Briefe

1. AMGEN. XGEVA (Denosumab). Rote Hand Brief. 2012
2. AMGEN. Prolia (Denosumab). Rote Hand Brief. 2013
3. Novartis. Ergänzende Sicherheitsinformationen zu Berichten über Nierenfunktionsstörung und Nierenversagen unter Aclasta (Zoledronsäure, 5 mg Infusionslösung). Rote Hand Brief. 2010

12.4.8.4.2. Ausgeschlossene Volltexte (nach Volltextsichtung)

A1: Andere Erkrankung, andere Fragestellung, anderes Thema (analog Festlegung in PICO-Tabelle siehe oben)

1. 8. Berruti A, Cook R, Saad F, Buttigliero C, Lipton A, Tampellini M, Lee KA, Coleman RE, Smith MR. Prognostic role of serum parathyroid hormone levels in advanced prostate cancer patients undergoing zoledronic acid administration. *Oncologist* 2012;17(5):645-52 PM:22523198, DOI: theoncologist.2011-0448 [pii];10.1634/theoncologist.2011-0448.
2. 27. Nilsson S, Strang P, Aksnes AK, Franzen L, Olivier P, Pecking A, Staffurth J, Vasanthan S, Andersson C, Bruland OS. A randomized, dose-response, multicenter phase II study of radium-223 chloride for the palliation of painful bone metastases in patients with castration-resistant prostate cancer. *Eur J Cancer* 2012;48(5):678-86 PM:22341993, DOI: S0959-8049(11)01072-0 [pii];10.1016/j.ejca.2011.12.023.

3. 35. Semenas J, Allegrucci C, Boorjian SA, Mongan NP, Persson JL. Overcoming drug resistance and treating advanced prostate cancer. *Curr Drug Targets* 2012;13(10):1308-23 PM:22746994, DOI: CDT-EPUB-20120629-1 [pii].
4. 108. Fizazi K, Lipton A, Mariette X, Body JJ, Rahim Y, Gralow JR, Gao G, Wu L, Sohn W, Jun S. Randomized phase II trial of denosumab in patients with bone metastases from prostate cancer, breast cancer, or other neoplasms after intravenous bisphosphonates. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology* 2009;10
<http://onlinelibrary.wiley.com/doi/cochrane/clcentral/articles/470/CN-00684470/frame.html>.

A2: anderer Publikationstyp (z.B. Fallberichte, Fall-Kontroll-Studien, Editorial u.ä.) als a priori für die Fragestellung definiert (hier: Systematischer Review, RCT, prospektive Kohortenstudien)

1. 52. Coleman R. Prostate cancer: targeted therapy for prostate cancer metastases to bone. *Nat Rev Urol* 2011;8(6):296-8 PM:21587226, DOI: nrur.2011.63 [pii];10.1038/nrur.2011.63.
2. 71. Weintraub B. Trials define anti-tumor effects of anti-resorptive agents: denosumab ahead of zoledronate 2 to 1. *BioDrugs* 2011;25(2):135-8 PM:21443276, DOI: 6 [pii];10.2165/11590730-000000000-00000.
3. 81. Chedgy EC, Niematallah I, Hawary A. Osteosclerotic prostatic metastasis. *ScientificWorldJournal* 2010;10:1330-1 PM:20623091, DOI: 10.1100/tsw.2010.105.
4. 127. Benowitz S. As metastasis yields its biological secrets, researchers hope to apply findings. *J Natl Cancer Inst* 2008;100(15):1054-7 PM:18664646, DOI: djn283 [pii];10.1093/jnci/djn283.

A3: unsystematischer Review oder Review ohne Einschluss von RCT und/ oder prospektiven Kohortenstudien)

1. 35. So A, Chin J, Fleshner N, Saad F. Management of skeletal-related events in patients with advanced prostate cancer and bone metastases: Incorporating new agents into clinical practice. *Can Urol Assoc J* 2012;6(6):465-70 PM:23282666, DOI: cuaj.12149 [pii];10.5489/cuaj.12149.
2. 36. Spencer S, Marini BL, Figg WD. Novel approaches in the pharmacotherapy of skeletal-related events in metastatic castrate-resistant prostate cancer. *Anticancer Res* 2012;32(7):2391-8 PM:22753695, DOI: 32/7/2391 [pii].
3. 48. Bishr M, Lattouf JB, Gannon PO, Saad F. Updates on therapeutic targets and agents in castration-resistant prostate cancer. *Minerva Urol Nefrol* 2011;63(2):131-43 PM:21623331, DOI: R19111920 [pii].
4. 56. Lee RJ, Saylor PJ, Smith MR. Treatment and prevention of bone complications from prostate cancer. *Bone* 2011;48(1):88-95 PM:20621630, DOI: S8756-3282(10)01289-5 [pii];10.1016/j.bone.2010.05.038.
5. 72. Lee RJ, Saylor PJ, Smith MR. Contemporary therapeutic approaches targeting bone complications in prostate cancer. *Clin Genitourin Cancer* 2010;8(1):29-36 PM:21208853, DOI: S1558-7673(11)70005-2 [pii];10.3816/CGC.2010.n.005.
6. 81. Saad F, Eastham J. Maintaining bone health in prostate cancer throughout the disease continuum. *Semin Oncol* 2010;37 Suppl 1:S30-S37 PM:20682370, DOI: S0093-7754(10)00086-2 [pii];10.1053/j.seminoncol.2010.06.007.
7. 90. Doggrell SA. Clinical efficacy and safety of zoledronic acid in prostate and breast cancer. *Expert Rev Anticancer Ther* 2009;9(9):1211-8 PM:19761424, DOI: 10.1586/era.09.95.
8. 100. Morgan C, Wagstaff J. Is there a role for ibandronate in the treatment of prostate cancer patients with bony metastases? *Acta Oncol* 2009;48(6):882-9 PM:19925378, DOI: 10.1080/02841860902874748.
9. 103. Santini D, Fratto ME, Galluzzo S, Vincenzi B, Tonini G. Are bisphosphonates the suitable anticancer drugs for the elderly? *Crit Rev Oncol Hematol* 2009;69(1):83-94 PM:18692400, DOI: S1040-8428(08)00148-0 [pii];10.1016/j.critrevonc.2008.07.008.
10. 107. Aapro M, Abrahamsson PA, Body JJ, Coleman RE, Colomer R, Costa L, Crino L, Dirix L, Gnant M, Gralow J, Hadji P, Hortobagyi GN, Jonat W, Lipton A, Monnier A, Paterson AH, Rizzoli R, Saad F, Thurlimann B. Guidance on the use of bisphosphonates in solid tumours: recommendations of an international expert panel.

- Ann Oncol 2008;19(3):420-32 PM:17906299, DOI: mdm442 [pii];10.1093/annonc/mdm442.
11. 122. Saad F. New research findings on zoledronic acid: survival, pain, and anti-tumour effects. *Cancer Treat Rev* 2008;34(2):183-92 PM:18061356, DOI: S0305-7372(07)00156-9 [pii];10.1016/j.ctrv.2007.10.002.
 12. 6. Brown JE, Coleman RE. Denosumab in patients with cancer—a surgical strike against the osteoclast. *Nat Rev Clin Oncol* 2012;9(2):110-8 PM:22231759, DOI: nrclinonc.2011.197 [pii];10.1038/nrclinonc.2011.197.
 13. 8. Cassinello EJ, Gonzalez Del Alba BA, Rivera HF, Holgado ME. SEOM guidelines for the treatment of bone metastases from solid tumours. *Clin Transl Oncol* 2012;14(7):505-11 PM:22721794, DOI: 1383 [pii];10.1007/s12094-012-0832-0.
 14. 13. Coleman RE. Adjuvant bone-targeted therapy to prevent metastasis: lessons from the AZURE study. *Curr Opin Support Palliat Care* 2012;6(3):322-9 PM:22801464, DOI: 10.1097/SPC.0b013e32835689cd.
 15. 18. Helo S, Manger JP, Krupski TL. Role of denosumab in prostate cancer. *Prostate Cancer Prostatic Dis* 2012;15(3):231-6 PM:22370723, DOI: pcan20122 [pii];10.1038/pcan.2012.2.
 16. 19. Iranikhah M, Wilborn TW, Wensel TM, Ferrell JB. Denosumab for the prevention of skeletal-related events in patients with bone metastasis from solid tumor. *Pharmacotherapy* 2012;32(3):274-84 PM:22392458, DOI: 10.1002/j.1875-9114.2011.01092.x.
 17. 26. Mackiewicz-Wysocka M, Pankowska M, Wysocki PJ. Progress in the treatment of bone metastases in cancer patients. *Expert Opin Investig Drugs* 2012;21(6):785-95 PM:22500564, DOI: 10.1517/13543784.2012.679928.
 18. 29. Moltzahn F, Thalmann GN. [Bone metastasis in prostate cancer]. *Urologe A* 2012;51(1):20-6 PM:22258372, DOI: 10.1007/s00120-011-2741-1.
 19. 30. Paller CJ, Carducci MA, Philips GK. Management of bone metastases in refractory prostate cancer—role of denosumab. *Clin Interv Aging* 2012;7:363-72 PM:23049248, DOI: 10.2147/CIA.S27930 [doi];cia-7-363 [pii].
 20. 33. Richardson ED, Price DK, Figg WD. Significant addition to treatment options for bone metastasis in prostate cancer. *Cancer Biol Ther* 2012;13(2):69-70 PM:22336908, DOI: 18441 [pii];10.4161/cbt.13.2.18441.
 21. 41. Yuasa T, Yamamoto S, Urakami S, Fukui I, Yonese J. Denosumab: a new option in the treatment of bone metastases from urological cancers. *Onco Targets Ther* 2012;5:221-9 PM:23055747, DOI: 10.2147/OTT.S30578 [doi];ott-5-221 [pii].
 22. 47. Castellano D, Sepulveda JM, Garcia-Escobar I, Rodriguez-Antolin A, Sundlov A, Cortes-Funes H. The role of RANK-ligand inhibition in cancer: the story of denosumab. *Oncologist* 2011;16(2):136-45 PM:21285392, DOI: theoncologist.2010-0154 [pii];10.1634/theoncologist.2010-0154.
 23. 50. Coleman R, Cook R, Hirsh V, Major P, Lipton A. Zoledronic acid use in cancer patients: more than just supportive care? *Cancer* 2011;117(1):11-23 PM:21235033.
 24. 51. Coleman R. The use of bisphosphonates in cancer treatment. *Ann N Y Acad Sci* 2011;1218:3-14 PM:20946581, DOI: 10.1111/j.1749-6632.2010.05766.x.
 25. 52. Coleman RE, McCloskey EV. Bisphosphonates in oncology. *Bone* 2011;49(1):71-6 PM:21320652, DOI: S8756-3282(11)00055-X [pii];10.1016/j.bone.2011.02.003.
 26. 68. Sonpavde G, Sternberg CN. Contemporary management of metastatic castration-resistant prostate cancer. *Curr Opin Urol* 2011;21(3):241-7 PM:21455038, DOI: 10.1097/MOU.0b013e3283449e19 [doi];00042307-201105000-00013 [pii].
 27. 69. Todenhofer T, Schwentner C, Schilling D, Gakis G, Stenzl A. [Treatment of metastatic bone disease and treatment-induced osteoporosis in prostate cancer. Evolution of osteoprotective strategies]. *Urologe A* 2011;50(9):1055-63 PM:21744161, DOI: 10.1007/s00120-011-2623-6.
 28. 79. Buijs JT, Kuijpers CC, van der Pluijm G. Targeted therapy options for treatment of bone metastases; beyond bisphosphonates. *Curr Pharm Des* 2010;16(27):3015-27 PM:20722621, DOI: BSP/CPD/E-Pub/000205 [pii].
 29. 92. Lipton A. Implications of bone metastases and the benefits of bone-targeted therapy. *Semin Oncol* 2010;37 Suppl 2:S15-S29 PM:21111244, DOI: S0093-7754(10)00172-7 [pii];10.1053/j.seminoncol.2010.10.002.
 30. 93. Morgan G, Lipton A. Antitumor effects and anticancer applications of bisphosphonates. *Semin Oncol* 2010;37 Suppl 2:S30-S40 PM:21111246, DOI: S0093-7754(10)00175-2 [pii];10.1053/j.seminoncol.2010.10.005.

31. 100. Tu SM, Lin SH, Podoloff DA, Logothetis CJ. Multimodality therapy: bone-targeted radioisotope therapy of prostate cancer. *Clin Adv Hematol Oncol* 2010;8(5):341-51 PM:20551894.
32. 102. Woodward EJ, Coleman RE. Prevention and treatment of bone metastases. *Curr Pharm Des* 2010;16(27):2998-3006 PM:20722624, DOI: BSP/CPD/E-Pub/000202 [pii].
33. 105. Coleman R, Gnant M. New results from the use of bisphosphonates in cancer patients. *Curr Opin Support Palliat Care* 2009;3(3):213-8 PM:19561507, DOI: 10.1097/SPC.0b013e32832f4149.
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12.4.8.4.3. Ausgeschlossene Titel-/Abstracts (nach Titel-/Abstractscreening)

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3. 70. Hanamura M, Iwamoto T, Soga N, Sugimura Y, Okuda M. Risk factors contributing to the development of hypocalcemia after zoledronic acid administration in patients with bone metastases of solid tumor. *Biol Pharm Bull* 2010;33(4):721-4 PM:20410614, DOI: JST.JSTAGE/bpb/33.721 [pii].
4. 89. Christodoulou C, Pervena A, Klouvas G, Galani E, Falagas ME, Tsakalos G, Viskvikis A, Nikolakopoulou A, Acholos V, Karapanagiotidis G, Batziou E, Skarlos DV. Combination of bisphosphonates and antiangiogenic factors induces osteonecrosis of the jaw more frequently than bisphosphonates alone. *Oncology* 2009;76(3):209-11 PM:19212145, DOI: 000201931 [pii];10.1159/000201931.

A6: Doppelpublikation oder nicht erhältlich

1. 58. Mottet N, Bellmunt J, Bolla M, Joniau S, Mason M, Matveev V, Schmid HP, Van der Kwast T, Wiegel T, Zattoni F, Heidenreich A. EAU guidelines on prostate cancer. Part II: Treatment of advanced, relapsing, and castration-resistant prostate cancer. *Eur Urol* 2011;59(4):572-83 PM:21315502, DOI: S0302-2838(11)00046-7 [pii];10.1016/j.eururo.2011.01.025.

12.4.9. Recherche zum Thema Geriatrisches Assessment (de novo Recherche)

12.4.9.1. Fragestellung

Fragestellung /Themenbereich	Population	Intervention	Comparison	Outcome	Evidenzgrundlage/Zusatzinformation
Geriatrisches Assessment <u>Weißbach, Wedding</u>	Patienten vor Chemotherapie	Bewertung der Behandlungsfähigkeit mit ChT durch Comprehensive Geriatric Assessment (CGA)	Kein Assessment	Abbruchrate, UAW, Dosismodifikation	Leitlinienadaptation, RCT, prospektive Kohortenstudien

12.4.9.2. Recherchestrategien

PubMed (15. April 2013)

Nr.	Suchfrage	Anzahl
#4	#1 AND #2 Limits: English, German, Publication date from 2003/01/01	137
#3	#1 AND #2	202
#2	("geriatric assessment"[MeSH Terms] OR ("geriatric"[All Fields] AND "assessment"[All Fields]) OR "geriatric assessment"[All Fields]) OR CGA[All Fields]	24723
#1	"prostatic neoplasms"[MeSH Terms] OR ("prostatic"[All Fields] AND "neoplasms"[All Fields]) OR "prostatic neoplasms"[All Fields] OR ("prostate"[All Fields] AND "cancer"[All Fields]) OR "prostate cancer"[All Fields]	108062

Anzahl der Treffer: 137

Cochrane (15. April 2013)

Suchstrategie:

Nr.	Suchfrage	Anzahl
#4	#1 AND #2 from 2003 to 2013, in Cochrane Reviews (Reviews only), Other Reviews, Trials, Methods Studies, Technology Assessment and Economic Evaluations	2
#3	#1 AND #2	2
#2	geriatric assessment:ti,ab,kw	1428
#1	(prostatic OR prostate) AND (neoplasm OR neoplasms OR cancer):ti,ab,kw	4111

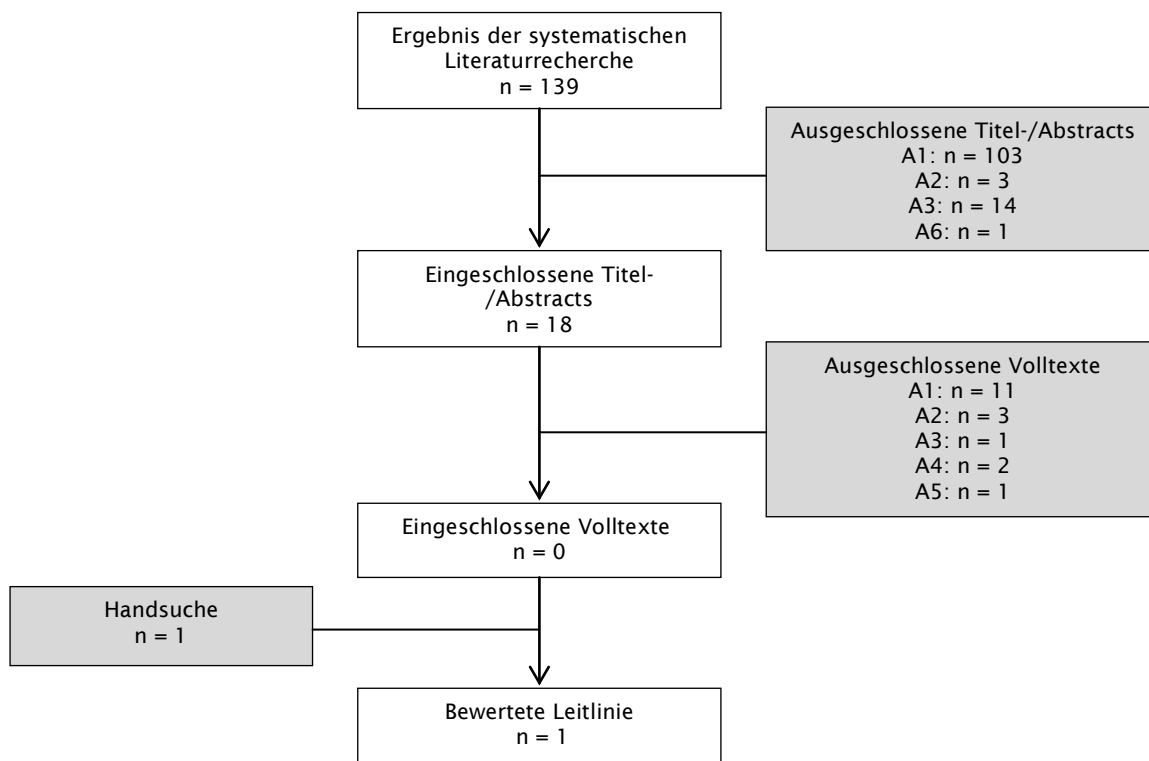
- Cochrane Database of Systematic Reviews (0)
- Database of Abstracts of Reviews of Effects (0)
- Cochrane Central Register of Controlled Trials (2)
- Cochrane Methodology Register (0)
- Health Technology Assessment Database (0)
- NHS Economic Evaluation Database (0)

Anzahl der Treffer: 2

12.4.9.3. Ein- und Ausschlusskriterien

Ausschlussgründe (Mehrfachnennungen möglich)	
A1	andere Erkrankung, andere Fragestellung, anderes Thema (analog Festlegung in PICO-Tabelle – Auszug s.u.)
A2	anderer Publikationstyp (z.B. Fallberichte, Fall-Kontroll-Studien, Editorial u.ä.) als a priori für die Fragestellung definiert (hier: Systematischer Review, RCT, prospektive Kohortenstudien)
A3	unsystematischer Review oder Review <u>ohne</u> Einschluss von RCT und/ oder prospektiven Kohortenstudien)
A4	retrospektive Kohortenstudie
A5	n < 25
A6	Doppelpublikation oder nicht erhältlich
A7	Sonstiges (z.B. Sprache, Publikation außerhalb des Suchzeitraums etc.)
Einschlussgründe	
E1	Systematischer Review (aus RCTs und / oder prospektiven Kohortenstudien) (wahrscheinlich) passend zur Fragestellung analog PICO-Tabelle
E2	RCT, prospektive Kohortenstudien (wahrscheinlich) passend zur Fragestellung analog PICO-Tabelle

12.4.9.4. Ergebnisse der Recherche



12.4.9.4.1. Bewertete Leitlinie

Die gefundene Leitlinie wurde mit DELBI bewertet (dabei ist 0 der niedrigste und 1 der höchste zu erreichende Wert).

Droz JP, Balducci L, Bolla M, Emberton M, Fitzpatrick JM, Joniau S, Kattan MW, Monfardini S, Moul JW, Naeim A, Van PH, Saad F, Sternberg CN. Management of prostate cancer in older men: recommendations of a working group of the International Society of Geriatric Oncology. *BJU Int* 2010;106(4):462-9

Domäne 1: Geltungsbereich und Zweck	Domäne 2: Beteiligung von Interessengruppen	Domäne 3: Methodische Exaktheit der Leitlinienentwicklung	Domäne 4: Klarheit und Gestaltung	Domäne 5: Generelle Anwendbarkeit	Domäne 6: Redaktionelle Unabhängigkeit	Domäne 7: Anwendbarkeit im deutschen Gesundheitssystem
0,44	0,08	0,24	0,17	0,00	0,17	0,00

12.4.9.4.2. Ausgeschlossene Volltexte (nach Volltextsichtung)

A1: Andere Erkrankung, andere Fragestellung, anderes Thema (analog Festlegung in PICO-Tabelle siehe oben)

16. Flechon A, Pouessel D, Ferlay C, Perol D, Beuzeboc P, Gravis G, Joly F, Oudard S, Deplanque G, Zanetta S, Fargeot P, Priou F, Droz JP, Culine S. Phase II study of carboplatin and etoposide in patients with anaplastic progressive metastatic cas-

- tration-resistant prostate cancer (mCRPC) with or without neuroendocrine differentiation: results of the French Genito-Urinary Tumor Group (GETUG) P01 trial. *Ann Oncol* 2011;22(11):2476-81 PM:21436186, DOI: mdr004 [pii];10.1093/annonc/mdr004.
2. 29. Sciarra A, Cattarino S, Gentilucci A, Alfaroni A, Innocenzi M, Gentile V, Salciccia S. Predictors for response to intermittent androgen deprivation (IAD) in prostate cancer cases with biochemical progression after surgery. *Urol Oncol* 2011; PM:21665494, DOI: S1078-1439(11)00144-X [pii];10.1016/j.urolonc.2011.05.005.
 3. 51. Loriot Y, Massard C, Gross-Goupil M, Di PM, Escudier B, Bossi A, Fizazi K. Combining carboplatin and etoposide in docetaxel-pretreated patients with castration-resistant prostate cancer: a prospective study evaluating also neuroendocrine features. *Ann Oncol* 2009;20(4):703-8 PM:19179557, DOI: mdn694 [pii];10.1093/annonc/mdn694.
 4. 63. Greenspan SL, Nelson JB, Trump DL, Wagner JM, Miller ME, Perera S, Resnick NM. Skeletal health after continuation, withdrawal, or delay of alendronate in men with prostate cancer undergoing androgen-deprivation therapy. *J Clin Oncol* 2008;26(27):4426-34 PM:18802155, DOI: 26/27/4426 [pii];10.1200/JCO.2007.15.1233.
 5. 90. Dyche DJ, Ness J, West M, Allareddy V, Konety BR. Prevalence of prostate specific antigen testing for prostate cancer in elderly men. *J Urol* 2006;175(6):2078-82 PM:16697807, DOI: S0022-5347(06)00266-7 [pii];10.1016/S0022-5347(06)00266-7.
 6. 106. Kurtz ME, Kurtz JC, Given CW, Given BA. Utilization of services among elderly cancer patients--relationship to age, symptoms, physical functioning, comorbidity, and survival status. *Ethn Dis* 2005;15(2 Suppl 2):S17-S22 PM:15822832.
 7. 124. Stommel M, Kurtz ME, Kurtz JC, Given CW, Given BA. A longitudinal analysis of the course of depressive symptomatology in geriatric patients with cancer of the breast, colon, lung, or prostate. *Health Psychol* 2004;23(6):564-73 PM:15546224, DOI: 2004-20316-002 [pii];10.1037/0278-6133.23.6.564.
 8. 125. Terret C, Albrand G, Droz JP. Geriatric assessment in elderly patients with prostate cancer. *Clin Prostate Cancer* 2004;2(4):236-40 PM:15072607.
 9. 126. Toliusiene J, Lesauskaite V. The nutritional status of older men with advanced prostate cancer and factors affecting it. *Support Care Cancer* 2004;12(10):716-9 PM:15322967, DOI: 10.1007/s00520-004-0635-0.
 10. 127. Weber BA, Roberts BL, Resnick M, Deimling G, Zauszniewski JA, Musil C, Yarandi HN. The effect of dyadic intervention on self-efficacy, social support, and depression for men with prostate cancer. *Psychooncology* 2004;13(1):47-60 PM:14745745, DOI: 10.1002/pon.718.
 11. 131. Di SF, Sciarra A. Combination therapy of ethinylestradiol and somatostatin analogue reintroduces objective clinical responses and decreases chromogranin a in patients with androgen ablation refractory prostate cancer. *J Urol* 2003;170(5):1812-6 PM:14532782, DOI: 10.1097/01.ju.0000092480.71873.26 [doi];S0022-5347(05)62939-4 [pii].

A2: anderer Publikationstyp (z.B. Fallberichte, Fall-Kontroll-Studien, Editorial u.ä.) als a priori für die Fragestellung definiert (hier: Systematischer Review, RCT, prospektive Kohortenstudien)

1. 14. Deckx L, van AD, Nelissen K, Daniels L, Stinissen P, Bulens P, Linsen L, Rummens JL, Robaey G, de Jonge ET, Houben B, Pat K, Walgraeve D, Spaas L, Verheezan J, Verniest T, Goegebuer A, Wildiers H, van den Berkmoortel F, Tjan-Heijnen VC, Buntinx F, van den Akker M. Study protocol of KLIMOP: a cohort study on the wellbeing of older cancer patients in Belgium and the Netherlands. *BMC Public Health* 2011;11:825 PM:22026575, DOI: 1471-2458-11-825 [pii];10.1186/1471-2458-11-825.
2. 71. Assessing care of vulnerable elders-3 quality indicators. *J Am Geriatr Soc* 2007;55 Suppl 2:S464-S487 PM:17910572, DOI: JGS1329 [pii];10.1111/j.1532-5415.2007.01329.x.
3. 80. Mohile SG, Bylow K, Dale W, Dignam J, Martin K, Petrylak DP, Stadler WM, Rodin M. A pilot study of the vulnerable elders survey-13 compared with the comprehensive geriatric assessment for identifying disability in older patients with

prostate cancer who receive androgen ablation. *Cancer* 2007;109(4):802-10
PM:17219443, DOI: 10.1002/cncr.22495.

A3: unsystematischer Review oder Review ohne Einschluss von RCT und/ oder prospektiven Kohortenstudien)

1. 61. Droz JP, Chaladaj A. Management of metastatic prostate cancer: the crucial role of geriatric assessment. *BJU Int* 2008;101 Suppl 2:23-9 PM:18307689, DOI: BJU7486 [pii];10.1111/j.1464-410X.2007.07486.x.

A4: retrospektive Kohortenstudie

1. 27. Mohile SG, Fan L, Reeve E, Jean-Pierre P, Mustian K, Peppone L, Janelins M, Morrow G, Hall W, Dale W. Association of cancer with geriatric syndromes in older Medicare beneficiaries. *J Clin Oncol* 2011;29(11):1458-64 PM:21402608, DOI: JCO.2010.31.6695 [pii];10.1200/JCO.2010.31.6695.
2. 49. Italiano A, Ortholan C, Oudard S, Pouessel D, Gravis G, Beuzebec P, Bompas E, Flechon A, Joly F, Ferrero JM, Fizazi K. Docetaxel-based chemotherapy in elderly patients (age 75 and older) with castration-resistant prostate cancer. *Eur Urol* 2009;55(6):1368-75 PM:18706755, DOI: S0302-2838(08)00934-2 [pii];10.1016/j.eururo.2008.07.078.

A5: Eingeschlossene Patienten n < 25

1. 92. Hurria A, Fleming MT, Baker SD, Kelly WK, Cutchall K, Panageas K, Caravelli J, Yeung H, Kris MG, Gomez J, Miller VA, D'Andrea G, Scher HI, Norton L, Hudis C. Pharmacokinetics and toxicity of weekly docetaxel in older patients. *Clin Cancer Res* 2006;12(20 Pt 1):6100-5 PM:17062686, DOI: 12/20/6100 [pii];10.1158/1078-0432.CCR-06-0200.

12.4.9.4.3. Ausgeschlossene Volltexte (nach Titel-/Abstractscreening durchgeführt von Wedding)

A1: Andere Erkrankung, andere Fragestellung, anderes Thema (analog Festlegung in PICO-Tabelle siehe oben)

1. 1. Kani K, Malihi PD, Jiang Y, Wang H, Wang Y, Ruderman DL, Agus DB, Mallick P, Gross ME. Anterior gradient 2 (AGR2): blood-based biomarker elevated in metastatic prostate cancer associated with the neuroendocrine phenotype. *Prostate* 2013;73(3):306-15 PM:22911164, DOI: 10.1002/pros.22569.
2. 2. Nordin A, Wang W, Welen K, Damber JE. Midkine is associated with neuroendocrine differentiation in castration-resistant prostate cancer. *Prostate* 2013;73(6):657-67 PM:23129424, DOI: 10.1002/pros.22607.
3. 3. Vanella L, Barbagallo I, Acquaviva R, Di GC, Cardile V, Abraham NG, Sorrenti V. Ellagic Acid: cytodifferentiating and antiproliferative effects in human prostatic cancer cell lines. *Curr Pharm Des* 2013;19(15):2728-36 PM:23092326, DOI: CPD-E PUB-20121018-12 [pii].
4. 5. Chang YJ, Liang WM, Wu HC, Lin HC, Wang JY, Li TC, Yeh YC, Chang CH. Psychometric evaluation of the Taiwan Chinese version of the EORTC QLQ-PR25 for HRQOL assessment in prostate cancer patients. *Health Qual Life Outcomes* 2012;10:96 PM:22901052, DOI: 1477-7525-10-96 [pii];10.1186/1477-7525-10-96.
5. 6. De NC, Albisinni S, Presicce F, Lombardo R, Cancrini F, Tubaro A. Serum levels of chromogranin A are not predictive of high-grade, poorly differentiated prostate cancer: Results from an Italian biopsy cohort. *Urol Oncol* 2012; PM:23153859, DOI: S1078-1439(12)00254-2 [pii];10.1016/j.urolonc.2012.07.012.
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7. 13. Matei DV, Renne G, Pimentel M, Sandri MT, Zorzino L, Botteri E, De CC, Musi G, Brescia A, Mazzoleni F, Tringali V, Detti S, de CO. Neuroendocrine differentiation in castration-resistant prostate cancer: a systematic diagnostic attempt. *Clin*

- Genitourin Cancer 2012;10(3):164-73 PM:22401754, DOI: S1558-7673(12)00039-0 [pii];10.1016/j.clgc.2011.12.004.
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 9. 17. Glossmann H. Vitamin D, UV, and skin cancer in the elderly: to expose or not to expose? *Gerontology* 2011;57(4):350-3 PM:21196703, DOI: 000322521 [pii];10.1159/000322521.
 10. 18. Heinrich E, Trojan L, Friedrich D, Voss M, Weiss C, Michel MS, Grobholz R. Neuroendocrine tumor cells in prostate cancer: evaluation of the neurosecretory products serotonin, bombesin, and gastrin - impact on angiogenesis and clinical follow-up. *Prostate* 2011;71(16):1752-8 PM:21480309, DOI: 10.1002/pros.21392.
 11. 19. Heinrich E, Probst K, Michel MS, Trojan L. Gastrin-releasing peptide: predictor of castration-resistant prostate cancer? *Prostate* 2011;71(6):642-8 PM:20945407, DOI: 10.1002/pros.21280.
 12. 20. Janelins MC, Kohli S, Mohile SG, Usuki K, Ahles TA, Morrow GR. An update on cancer- and chemotherapy-related cognitive dysfunction: current status. *Semin Oncol* 2011;38(3):431-8 PM:21600374, DOI: S0093-7754(11)00084-4 [pii];10.1053/j.seminoncol.2011.03.014.
 13. 22. Joung JY, Lee YS, Park S, Yoon H, Lee SJ, Park WS, Seo HK, Chung J, Kim SY, Hong SH, Kim JS, Lee KH. Haplotype analysis of prostate stem cell antigen and association with prostate cancer risk. *J Urol* 2011;185(6):2112-8 PM:21497359, DOI: S0022-5347(11)00235-7 [pii];10.1016/j.juro.2011.01.083.
 14. 23. Khan MO, Ather MH. Chromogranin A--serum marker for prostate cancer. *J Pak Med Assoc* 2011;61(1):108-11 PM:22368921.
 15. 24. Krauss DJ, Hayek S, Amin M, Ye H, Kestin LL, Zadora S, Vicini FA, Cotant M, Brabbins DS, Ghilezan MI, Gustafson GS, Martinez AA. Prognostic significance of neuroendocrine differentiation in patients with Gleason score 8-10 prostate cancer treated with primary radiotherapy. *Int J Radiat Oncol Biol Phys* 2011;81(3):e119-e125 PM:21596486, DOI: S0360-3016(11)00069-1 [pii];10.1016/j.ijrobp.2010.12.064.
 16. 25. Man YG, Fu SW, Liu AJ, Stojadinovic A, Izadjoo MJ, Chen L, Gardner WA. Aberrant expression of chromogranin A, miR-146a, and miR-146b-5p in prostate structures with focally disrupted basal cell layers: an early sign of invasion and hormone-refractory cancer? *Cancer Genomics Proteomics* 2011;8(5):235-44 PM:21980038, DOI: 8/5/235 [pii].
 17. 26. Mearini L, Zucchi A, Scarponi E, Nunzi E, Aglietti MC, Bini V, Porena M. Correlation between age and Chromogranin A determination in prostate diseases. *Cancer Biomark* 2011;10(3-4):117-23 PM:22674297, DOI: BJ314N1U18T12815 [pii];10.3233/CBM-2012-0237.
 18. 30. Sidana A, Wang M, Chowdhury WH, Toubaji A, Shabbeer S, Netto G, Carducci M, Lupold SE, Rodriguez R. Does valproic acid induce neuroendocrine differentiation in prostate cancer? *J Biomed Biotechnol* 2011;2011:607480 PM:20981253, DOI: 10.1155/2011/607480.
 19. 31. Wu JM, Lin MH, Peng LN, Chen LK, Hwang SJ. Evaluating diagnostic strategy of older patients with unexplained unintentional body weight loss: a hospital-based study. *Arch Gerontol Geriatr* 2011;53(1):e51-e54 PM:21071102, DOI: S0167-4943(10)00265-7 [pii];10.1016/j.archger.2010.10.016.
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 21. 33. Berruti A, Bollito E, Cracco CM, Volante M, Ciccone G, Porpiglia F, Papotti M, Scarpa RM, Dogliotti L. The prognostic role of immunohistochemical chromogranin a expression in prostate cancer patients is significantly modified by androgen-deprivation therapy. *Prostate* 2010;70(7):718-26 PM:20087896, DOI: 10.1002/pros.21104.
 22. 35. Glinicki P, Jeske W. Chromogranin A (CgA)--the influence of various factors in vivo and in vitro, and existing disorders on it's concentration in blood. *Endokrynol Pol* 2010;61(4):384-7 PM:20806183.
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24. 37. Reis LO, Vieira LF, Zani EL, Denardi F, de Oliveira LC, Ferreira U. Assessment of serum chromogranin-A as prognostic factor in high-risk prostate cancer. *J Investig Med* 2010;58(8):957-60 PM:20818262, DOI: 10.231/JIM.0b013e3181f5d610.
25. 38. Sarkar D, Singh SK, Mandal AK, Agarwal MM, Mete UK, Kumar S, Mavuduru RS, Prasad R. Plasma chromogranin A: clinical implications in patients with castrate resistant prostate cancer receiving docetaxel chemotherapy. *Cancer Biomark* 2010;8(2):81-7 PM:21896995, DOI: F652161WV7715083 [pii];10.3233/CBM-2011-0198.
26. 39. Tarjan M. Prognostic significance of focal neuroendocrine differentiation in prostate cancer: cases with autopsy-verified cause of death. *Indian J Urol* 2010;26(1):41-5 PM:20535283, DOI: 10.4103/0970-1591.60442.
27. 40. Trosko JE. Commentary on "Toxicity testing in the 21st century: a vision and a strategy": stem cells and cell-cell communication as fundamental targets in assessing the potential toxicity of chemicals. *Hum Exp Toxicol* 2010;29(1):21-9 PM:20061464, DOI: 29/1/21 [pii];10.1177/0960327109354663.
28. 41. Van Londen GJ, Lembersky BC. Metabolic effects of hormone deprivation therapy: weighing the evidence. *Oncology (Williston Park)* 2010;24(9):846-7 PM:20923042.
29. 43. Bowman MA, Neale AV. In this issue: mini-theme on geriatric care and cancer screening. *J Am Board Fam Med* 2009;22(3):231-3 PM:19429726, DOI: 22/3/231 [pii];10.3122/jabfm.2009.03.090054.
30. 44. Deimling GT, Arendt JA, Kyriotakis G, Bowman KF. Functioning of older, long-term cancer survivors: the role of cancer and comorbidities. *J Am Geriatr Soc* 2009;57 Suppl 2:S289-S292 PM:20122020, DOI: JGS2515 [pii];10.1111/j.1532-5415.2009.02515.x.
31. 47. Hudson SV, Ohman-Strickland P, Ferrante JM, Lu-Yao G, Orzano AJ, Crabtree BF. Prostate-specific antigen testing among the elderly in community-based family medicine practices. *J Am Board Fam Med* 2009;22(3):257-65 PM:19429731, DOI: 22/3/257 [pii];10.3122/jabfm.2009.03.080136.
32. 50. Komiya A, Suzuki H, Imamoto T, Kamiya N, Nihei N, Naya Y, Ichikawa T, Fuse H. Neuroendocrine differentiation in the progression of prostate cancer. *Int J Urol* 2009;16(1):37-44 PM:19120524, DOI: IJU2175 [pii];10.1111/j.1442-2042.2008.02175.x.
33. 53. Sandhu A, Mundt AJ. Radiation therapy for urologic malignancies in the elderly. *Urol Oncol* 2009;27(6):643-52 PM:19879475, DOI: S1078-1439(09)00219-1 [pii];10.1016/j.urolonc.2009.07.019.
34. 54. Sciarra A, Di SF, Autran AM, Salciccia S, Gentilucci A, Alfarone A, Gentile V. Distribution of high chromogranin A serum levels in patients with nonmetastatic and metastatic prostate adenocarcinoma. *Urol Int* 2009;82(2):147-51 PM:19321999, DOI: 000200789 [pii];10.1159/000200789.
35. 55. Tarle M, Spajic B, Kraljic I, Kusic Z. Continuous finasteride therapy for benign prostate hypertrophy upgrades both neuroendocrine differentiation and aggressive prostate cancer. *Anticancer Res* 2009;29(5):1797-801 PM:19443407, DOI: 29/5/1797 [pii].
36. 56. Tucci M, Mosca A, Lamanna G, Porpiglia F, Terzolo M, Vana F, Cracco C, Russo L, Gorzegno G, Tampellini M, Torta M, Reimondo G, Poggio M, Scarpa RM, Angeli A, Dogliotti L, Berruti A. Prognostic significance of disordered calcium metabolism in hormone-refractory prostate cancer patients with metastatic bone disease. *Prostate Cancer Prostatic Dis* 2009;12(1):94-9 PM:18332901, DOI: pcan200810 [pii];10.1038/pcan.2008.10.
37. 57. Warshaw G. Providing quality primary care to older adults. *J Am Board Fam Med* 2009;22(3):239-41 PM:19429728, DOI: 22/3/239 [pii];10.3122/jabfm.2009.03.090049.
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39. 59. Ather MH, Abbas F, Faruqui N, Israr M, Pervez S. Correlation of three immunohistochemically detected markers of neuroendocrine differentiation with clinical predictors of disease progression in prostate cancer. *BMC Urol* 2008;8:21 PM:19115997, DOI: 1471-2490-8-21 [pii];10.1186/1471-2490-8-21.

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A2: anderer Publikationstyp (z.B. Fallberichte, Fall-Kontroll-Studien, Editorial u.ä.) als a priori für die Fragestellung definiert (hier: Systematischer Review, RCT, prospektive Kohortenstudien)

1. 7. Fitzpatrick JM, Graefen M, Payne HA, Scotte F, Aapro MS. A comment on the International Society of Geriatric Oncology guidelines: evidence-based advice for the clinical setting. *Oncologist* 2012;17 Suppl 1:31-5 PM:23015683, DOI: 17/suppl_1/31 [pii];10.1634/theoncologist.2012-S1-31.
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3. 11. Lagro J, Studenski SA, Olde Rikkert MG. Predicting chemotherapy toxicity in older adults and the importance of geriatric assessment. *J Clin Oncol* 2012;30(5):560-2 PM:22184377, DOI: JCO.2011.39.4858 [pii];10.1200/JCO.2011.39.4858.

A3: unsystematischer Review oder Review ohne Einschluss von RCT und/ oder prospektiven Kohortenstudien)

1. 4. Bompas E, Dedecker L. Management of advanced prostate cancer in elderly patients. *Bull Cancer* 2012; PM:22511114, DOI: bdc.2012.1561 [pii];10.1684/bdc.2012.1561.
2. 9. Hoffman KE. Management of older men with clinically localized prostate cancer: the significance of advanced age and comorbidity. *Semin Radiat Oncol* 2012;22(4):284-94 PM:22985811, DOI: S1053-4296(12)00048-3 [pii];10.1016/j.semradonc.2012.05.005.
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A6: Doppelpublikation oder nicht erhältlich

1. 128. Weber BA, Roberts BL, Resnick M, Deimling G, Zauszniewski JA, Musil C, Yarandi HN. The effect of dyadic intervention on self-efficacy, social support, and depression for men with prostate cancer. *Psycho oncology* 2004;1
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12.5. Methodik und Ergebnisse zur Recherche nach internationalen QI

12.5.1. Recherchestrategien PubMed (07. Oktober 2013)

Nr.	Suchfrage	Anzahl
#4	#1 AND #2; Filters activated: English, German	51
#3	#1 AND #2	53
#2	"prostatic neoplasms"[MeSH Terms] OR ("prostatic"[All Fields] AND "neoplasms"[All Fields]) OR "prostatic neoplasms"[All Fields] OR ("prostate"[All Fields] AND "cancer"[All Fields]) OR "prostate cancer"[All Fields]	112596
#1	(quality[TI] OR performance[TI] OR health[TI]) AND (indicator[TI] OR indicators[TI] OR measure[TI] OR measures[TI])	11157

Anzahl der Treffer: 51

Davon relevant: 46

Cochrane (07. Oktober 2013)

Suchstrategie:

Nr.	Suchfrage	Anzahl
#3	#1 AND #2	4
#2	(prostate OR prostatic) AND (cancer OR neoplasm):ti,ab,kw	4279
#1	(quality or performance or health) and (indicator or indicators or measure or measures):ti	674

- Cochrane Database of Systematic Reviews (0)
- Database of Abstracts of Reviews of Effects (0)

- Cochrane Central Register of Controlled Trials (2)
- Cochrane Methodology Register (2)
- Health Technology Assessment Database (0)
- NHS Economic Evaluation Database (0)

Anzahl der Treffer: 4

Davon neu: 0

Organisationen/Trefferzahlen

- AQUA-Institut, Sektorenübergreifende Qualitätssicherung → 0 Treffer
- AQUA-Institut, QISA → 16 Treffer
- BQS-Institut, Qualitätsindikatoren datenbank → 0 Treffer
- GKV-Spitzenverband, Qualitätsindikatoren-Thesaurus (QUINTH) → 7 Treffer
- GKV-Spitzenverband, Qualitätssicherung Medizinische Rehabilitation → 0 Treffer
- KBV, AQUIK Ambulante Qualitätsindikatoren und Kennzahlen → 3 Treffer
- AHRQ (Agency for Health Research and Quality) Quality Indicators → 0 Treffer
- AHRQ (Agency for Health Research and Quality) National Quality Measures Clearinghouse → 7 Treffer
- AMA (American Medical Association) Set of Indicators → 4 Treffer
- ASCO (American Society of Clinical Oncology) National Initiative for Cancer Care Quality → 0 Treffer
- ASCO (American Society of Clinical Oncology) Quality Oncology Practice Initiative → 1 Treffer
- ASCO (American Society of Clinical Oncology) + NCCN (National Comprehensive Cancer Network) Set of quality indicators → 0 Treffer
- CIHI (Canadian Institute for Health Information) Health Indicators → 0 Treffer
- CQCO (Cancer Quality Council of Ontario) Cancer System Quality Index – set of indicators → 18 Treffer
- ISD Scotland Health Indicators → 1 Treffer
- JCAHO (Joint Commission on Accreditation of Healthcare Organizations) → 0 Treffer
- NHS (National Health Services) Indicators for Quality Improvement → 9 Treffer
- NQF (National Quality Forum) Performance Measures → 6 Treffer
- OECD Health Care Quality Indicators → 0 Treffer
- RAND Corporation Quality of Care Assessment Tools (QA Tools) → 0 Treffer

12.5.2. Ergebnisse der systematischen Recherche

Achtung: unterstrichene Treffer sind Hyperlinks.

Qualitätsindikator	gefunden bei
Prävention/Früherkennung	
Versicherte mit dokumentiertem Status körperlicher Aktivität	AQUA/QiSA
Versicherte mit Beratung zu körperlicher Aktivität	AQUA/QiSA

Qualitätsindikator	gefunden bei
Körperlich aktive Versicherte	AQUA/QiSA
Versicherte mit BMI-Messung	AQUA/QiSA
Übergewichtige mit Beratung	AQUA/QiSA
Versicherte mit dokumentiertem Raucherstatus	AQUA/QiSA
Raucher mit Kurzberatung zur Raucherentwöhnung	AQUA/QiSA
Anteil der Raucher	AQUA/QiSA
Anteil der Patienten, deren Raucherstatus während der letzten zwei Jahre mindestens einmal erhoben wurde	KBV/AQUIK
Anteil der Raucher, denen Maßnahmen zum Beenden des Rauchens empfohlen wurden und in deren Akte dies dokumentiert wurde	KBV/AQUIK
Anteil der übergewichtigen Patienten, die eine Beratung hinsichtlich Maßnahmen zur Gewichtsabnahme erhielten und in deren Akte dies dokumentiert ist	KBV/AQUIK
Adult body mass index (BMI) assessment: percentage of members 18 to 74 years of age who had an outpatient visit and whose BMI was documented during the measurement year or the year prior to the measurement year.	AHRQ/NQMC
Preventive care and screening: percentage of patients aged 18 years and older for whom body mass index (BMI) is documented at least once during the two-year measurement period	AHRQ/NQMC
Prevention Care and Screening Physician Performance Measurement Set	AMA
Modifiable Risk Faktors	CQCO
Histologische Untersuchung nach Prostataresektion	GKV/QUINTH
Diagnose/Behandlung	
Indikation zur Protonentherapie des Prostatakarzinoms	GKV/QUINTH
Anforderungen an ambulante Verlaufskontrollen der Protonentherapie des Prostatakarzinoms	GKV/QUINTH
Qualifikation des Personals bei Protonentherapie des Prostatakarzinoms	GKV/QUINTH
Anforderungen an das Krankenhaus bei Protonentherapie des Prostatakarzinoms	GKV/QUINTH

Qualitätsindikator	gefunden bei
Anforderungen an die Dokumentation bei Protonentherapie des Prostatakarzinoms	GKV/QUINTH
Anforderungen an die Dokumentation der Verlaufskontrollen bei Protonentherapie des Prostatakarzinoms	GKV/QUINTH
Prostate cancer: percentage of patients, regardless of age, with a diagnosis of prostate cancer, at low risk of recurrence, receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	AHRQ/NQMC
Prostate cancer: percentage of patients, regardless of age, with a new diagnosis of prostate cancer with documented evaluation of prostate-specific antigen (PSA), AND primary tumor (T) stage, AND Gleason score	AHRQ/NQMC
Prostate cancer: percentage of patients, regardless of age, with a diagnosis of prostate cancer at high risk of recurrence, receiving external beam radiotherapy to the prostate who were prescribed adjuvant hormonal therapy (GnRH agonist or antagonist).	AHRQ/NQMC
Prostate cancer: percentage of patients, regardless of age, with a diagnosis of prostate cancer receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy with documented evaluation of prostate-specific antigen (PSA), AND primary tumor (T) stage, AND Gleason score prior to initiation of treatment.	AHRQ/NQMC
Prostate cancer: percentage of patients, regardless of age, with a diagnosis of clinically localized prostate cancer receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who received counseling on, at a minimum, the following treatment options for clinically localized disease prior to initiation of treatment: active surveillance, AND interstitial prostate brachytherapy, AND external beam radiotherapy, AND radical prostatectomy	AHRQ/NQMC
Prostate Cancer Physician Performance Measurement Set	AMA
Oncology Physician Performance Measurement Set	AMA
QOPI Quality Measures Summary	ASCO/QOPI
Percent of cancer pathology reports submitted in a discrete synoptic format	CQCO
Reporting of Cancer Stage at Diagnosis	CQCO
PET/CT Scan Utilization	CQCO

Qualitätsindikator	gefunden bei
Patient Experience with Diagnosis Assessment Programs (DAPs)	CQCO
Team Oriented Care for the Patient – Multidisciplinary Case Conferences (MCCs)	CQCO
Margin Status in Prostate Cancer Surgery	CQCO
Consultation with a Medical Oncologist	CQCO
Systemic Treatment Safety Best Practice Drug Ordering	CQCO
Patient Experience with Outpatient Cancer Care	CQCO
Symptom Assessment and Management	CQCO
Wait time for Cancer Surgery	CQCO
Wait time for Systemic Treatment “Referral to Consult”	CQCO
Wait times for Radiation Treatment “Referral to Consult”	CQCO
Radiation Equipment Utilization - Adjusted	CQCO
Intensity Modulated Radiation Therapy (MRT) Utilization	CQCO
Radiation Treatment Utilization	CQCO
Clinical Indicators – Prostate Cancer	ISD
Cancer 31-Day Subsequent Treatments Target (Drug Treatments)	NHS
Cancer 31-Day Subsequent Treatments Target (Radiotherapy)	NHS
Cancer 31-Day Subsequent Treatments Target (Surgery Treatments)	NHS
Extended 62-Day Cancer Treatment Targets	NHS
Percentage of patients first seen by a specialist within two weeks when urgently referred with suspected cancer	NHS
Percentage of patients waiting no more than 31 days for cancer treatment	NHS
The percentage of patients with cancer, diagnosed within the last 18 months who have a patient review recorded as occurring within 6 months of the practice receiving confirmation of the diagnosis	NHS
The practice can produce a register of all cancer patients defined as a ‘register of patients with a diagnosis of cancer excluding non-melanotic	NHS

Qualitätsindikator	gefunden bei
skin cancers from 1 April 2003	
People who in last 6 months, have had enough support from local services or organisations to help manage long-term health condition(s)	NHS
External Beam Radiotherapy for Bone Metastases	NQF
Adjuvant Hormonal Therapy for High-Risk Patients	NQF
Avoidance of Overuse Measure – Bone Scan for Staging Low-Risk Patients	NQF
Radical Prostatectomy Pathology Reporting	NQF
Palliativversorgung	
Verfügbarkeit eines Registers der Palliativpatienten je Praxis	AQUA/QiSA
Anteil der Palliativpatienten, für die ein Ansprechpartner dokumentiert ist	AQUA/QiSA
Anteil der Palliativpatienten, die zu Hause oder im Hospiz versterben	AQUA/QiSA
Anteil der Palliativpatienten, die an anhaltender opioidbedingter Verstopfung leiden und mit Laxantien behandelt werden	AQUA/QiSA
Anteil der Palliativpatienten mit dokumentierten Symptomen: Wundstatus bei Dekubitus, Schwindel, Übelkeit und Erbrechen oder Obstipation	AQUA/QiSA
Anteil der Palliativpatienten mit einem Behandlungsplan bei Atemnot (Dyspnoe)	AQUA/QiSA
Anteil der Palliativpatienten mit einem Behandlungsplan für den Fall der Schmerzzunahme	AQUA/QiSA
Anteil der Palliativpatienten mit nicht sinnvollen Kombinationen von Opioiden	AQUA/QiSA
Palliative and End of Life Care Physician Performance Measurement Set	AMA
End-of-Life Care Measures	CQCO
Comfortable Dying: Pain brought to a Comfortable Level Within 48 Hours of Initial Assessment	NQF
Family Evaluation of Hospice Care	NQF

12.5.3. Sonstige gefundene Qualitätsindikatoren (Handsuche nach der systematischen Recherche)

12.5.3.1. International Consortium for Health Outcomes Measurement (ICHOM, <http://www.ichom.org/>)



1. Major Acute Complications of Surgery

Definition: Indicate whether patient experienced a Clavien grade III-V complication within first 6 months following treatment

Response Options: Yes/No; record maximal grade

Inclusion/Exclusion Criteria: Include: patients who undergo surgical interventions

Data Collection Options: Clinical data or patient-reported

2. Major Acute Complications of Radiation

Definition: Indicate whether patient experienced a CTCAE grade III-V complication within first 6 months following treatment

Response Options: Yes/No; record maximal grade

Inclusion/Exclusion Criteria: Include: patients who undergo radiation therapy

Data Collection Options: Clinical data or patient-reported

3. Overall survival

Definition: Indicate whether patient has died

Response Options: Yes/No; If yes, provide date of death (DD/MM/YYYY)

Inclusion/Exclusion Criteria: N/A

Data Collection Options: Administrative data

4. Cause-specific survival

Definition: If applicable, indicate if death is attributable to prostate cancer

Response Options: Yes/No

Inclusion/Exclusion Criteria: N/A

Data Collection Options: Administrative data. Additional data based on physician review according to local custom can be tracked/reported *in addition* to death certificate cause of death, but should be done so as a separate data point

5. Metastasis

Definition: Indicate whether patient was diagnosed with metastatic disease

Response Options: Yes/No; If yes, record date of diagnosis (DD/MM/YYYY)

Inclusion/Exclusion Criteria: N/A

Data Collection Options: Clinical data or patient-reported

6. Biochemical recurrence

Definition: Indicate whether patient has biochemical recurrence, which is defined as: - Controlled PSA > 0.2 ng/ml after surgery - Phoenix criteria after radiation

Recommended that PSA is measured annually and providers record all PSA values and dates to accommodate future changes to definitions

Response Options: Yes/No

Inclusion/Exclusion Criteria: N/A

Data Collection Options: Clinical data or patient-reported

12.5.3.2. Scottish Cancer Taskforce (Stand May 2012)

3. Quality Performance Indicators for Prostate Cancer***QPI 1: Biopsy Procedure***

QPI Title:	Procedure for performing prostate biopsy should be optimised.
Description:	Proportion of patients with prostate cancer who undergo trans-rectal ultrasound guided (TRUS) prostate biopsy for histological diagnosis where a minimum of 10 cores are received by pathology.
Rationale and Evidence:	<p>Where biopsy is being undertaken to diagnose prostate cancer a minimum of ten cores of tissue should be taken to ensure adequate sampling^{3 4 5}</p> <p>In line with recommended best practice local anaesthetic should be given to patients undergoing TRUS prostate biopsy⁶.</p>
Specifications:	<p>Numerator: Number of patients with prostate cancer who undergo TRUS biopsy where a minimum of 10 cores are received by pathology.</p> <p>Denominator: All patients with prostate cancer who undergo TRUS biopsy of the prostate.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • Patients enrolled in clinical trials • Patients with advanced (T4NanyMany) or metastatic disease (TanyNanyM1)
Target:	<p>90%</p> <p>The tolerance within this target is designed to account for situations where, due to clinical suspicion, a smaller number of cores will suffice if the biopsy operator is satisfied they have taken sufficient tissue to make a histological diagnosis.</p> <p>In addition, some patients may become unwell during the procedure, meaning that the procedure may have to be abandoned.</p>

QPI 2: Radiological Staging

QPI Title:	Patients with intermediate or high risk prostate cancer, who are suitable for radical treatment, should be evaluated for locally advanced, nodal or bony metastatic disease.
Description:	Proportion of patients with intermediate or high risk prostate cancer undergoing radical treatment who have had Magnetic Resonance Imaging (MRI) and bone scan staging.
Rationale and Evidence:	<p>Local staging is of importance in helping guide both patient and clinician towards a treatment decision. Whilst digital rectal examination, Prostate Specific Androgen (PSA) level and needle biopsy histology together help predict the likelihood of organ-confined disease, this is on a population rather than individual patient basis. In addition, needle biopsies are prone to sampling error. Therefore the management of a patient predicted to have organ confined disease by the above parameters who unexpectedly on MRI has definite capsular, seminal vesicle, nodal or bony involvement (or a predominant anterior tumour not palpable or reached by biopsy) may be radically changed by that MRI result. Similarly, patients predicted to have significant risk of locally advanced disease may be considered suitable for radical treatment if the MRI shows organ-confined disease. Clearly patients found to have bone metastases are by definition not suitable for radical treatment^{7 8 9}.</p> <p>Patients with high-risk prostate cancer should have MRI to assess the extent of disease ahead of radical treatment⁴.</p>
Specifications:	<p>Numerator: Number of patients with intermediate or high risk prostate cancer undergoing radical treatment who have an MRI of the prostate and an isotope bone scan* (or alternative whole body MRI evaluation).</p> <p>Denominator: All patients with intermediate or high risk prostate cancer undergoing radical treatment.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • Patients unable to undergo an MRI scan: <ul style="list-style-type: none"> ○ Pacemaker or other MRI incompatible implanted device. ○ Cerebral aneurysm clip. ○ Metal in eye. ○ Claustrophobia. ○ Unable to fit bore of scanner. ○ Too heavy for MRI table. • Patients who refuse MRI. <p>* For patients with intermediate risk prostate cancer with PSA <10 at diagnosis a bone scan is not routinely recommended⁴.</p>
Target:	100%

QPI 3: Pathology Reporting

QPI Title:	All surgical pathology reports for prostate needle biopsies should contain full pathology information to inform treatment decision making.
Description:	Proportion of patients who undergo needle biopsy where the pathology report contains a full set of data items (as defined by the Scottish Urological Pathologists dataset – see appendix 4).
Rationale and Evidence:	To help plan treatment for men diagnosed with prostate cancer, prognostic information from the needle biopsy is necessary. The use of datasets improves the completeness of data in pathology reports and a minimum prostate cancer dataset has been agreed for Scotland based on the Royal College of Pathologists most recent Standard and Guideline for Prostate Cancer ^{10,11} .
Specifications:	<p>Numerator: Number of patients with prostate adenocarcinoma who undergo prostate needle biopsy where needle biopsy pathology report contains all data items (as defined in the Scottish Urological Pathologists dataset – see appendix 4).</p> <p>Denominator: All patients with prostate adenocarcinoma who undergo prostate needle biopsy.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • No exclusions.
Target:	90% The tolerance within this target is designed to account for situations where it is not possible to report all components of the dataset due to specimen size.

QPI 4: Surgical Margins

QPI Title:	Organ confined prostate cancers which are surgically treated with radical prostatectomy should be completely excised.
Description:	Proportion of patients with pathologically confirmed, organ confined (stage pT2) prostate cancer who undergo radical prostatectomy in which tumour is present at the margin, i.e. positive surgical margin.
Rationale and Evidence:	Positive surgical margin is an independent prognostic factor in adversely impacting biochemical recurrence free (PSA failure) period and progression free survival ¹² .
Specifications:	<p>Numerator: Number of patients with stage pT2 prostate cancer who underwent radical prostatectomy in which tumour is present at the margin.</p> <p>Denominator: All patients with stage pT2 prostate cancer who underwent radical prostatectomy.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • None
Target:	<25% Please Note: Varying evidence exists regarding the most appropriate target level therefore this may need redefined in the future, to take account of new evidence.

QPI 5: Volume of Cases per Surgeon

QPI Title:	Surgery should be performed by surgeons who perform the procedure routinely.
Description:	Number of radical prostatectomy procedures performed by a surgeon over a 1 year period.
Rationale and Evidence:	<p>Radical prostatectomy should be performed by surgeons who work in high-volume hospitals, with outcomes audited regularly ^{3 6}.</p> <p>The European and North American literature supports the view that there is a relationship between increasing surgeon volume and improved patient outcomes, for example, rates of post-operative and late urinary complications and positive surgical margin rates ⁶.</p>
Specifications:	<p>Number of radical prostatectomies performed by each surgeon in a given year.</p> <p>Exclusions: • None</p>
Target:	<p>Minimum 12 procedures per surgeon in a 1 year period.</p> <p>This is a minimum target level and is designed to ensure that all surgeons performing radical prostatectomy perform a minimum of 12 procedures per year.</p> <p>Please Note: Varying evidence exists regarding the most appropriate target level for surgical case volume. In order to ensure that the target level takes account of level 1 evidence and will drive continuous quality improvement as intended this performance indicator will be kept under regular review.</p> <p>It is recognised that multiple factors affect overall performance and that the end point focus must be clinical outcomes in what is a team delivered goal. It is recommended that where two consultants operate together on the same patient each should count the case in his/her numbers as this best reflects the partnership accountability of such shared procedures.</p>

QPI 6: Hormone Therapy

QPI Title:	Patients with metastatic prostate cancer should undergo immediate hormone therapy ¹ .
Description:	<p>Proportion of patients with metastatic prostate cancer (TanyNanyM1) who undergo immediate management with hormone therapy, who are managed with any hormone therapy licensed and approved for use by Scottish Medicines Consortium (SMC)² in this indication, as monotherapy or in combination with an anti-androgen for maximum androgen blockade, or bilateral orchiectomy.</p> <p>Note: Developing new LHRH agonists³ may be included when SMC licensing for appropriate use approved.</p>
Rationale and Evidence:	<p>There is evidence for symptom palliation and possible survival benefit in symptomatic metastatic patients, and for prolonged progression-free survival in asymptomatic patients with metastatic prostate cancer^{4,5}.</p> <p>LHRH agonist monotherapy or Maximum Androgen Blockade (LHRH agonist plus anti-androgen combined therapy) or bilateral orchiectomy should be offered as immediate therapy to all patients with metastatic prostate cancer^{6,7,8}.</p>
Specifications:	<p>Numerator: Number of patients presenting with metastatic prostate cancer (TanyNanyM1) treated with immediate hormone therapy (LHRH agonist monotherapy, maximum androgen blockade or bilateral orchiectomy).</p> <p>Denominator: All patients presenting with metastatic prostate cancer (TanyNanyM1).</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • Patients documented to have refused immediate hormone therapy. • Patients enrolled in clinical trials.
Target:	100%

4. Post Radical Treatment QPIs for Prostate Cancer

Some of the issues of high importance identified by the Prostate Cancer QPI Development Group and patient focus groups involve the collection and analysis of follow up data, these include:

1. Post surgical incontinence
2. Post radiotherapy toxicity
3. PSA relapse rate

This information is not currently collected across NHSScotland and the feasibility of consistent and comparable data capture has not, as yet, been tested in practice.

An initial assessment of the feasibility of data collection and measurability of these issues has been undertaken as part of the prostate cancer QPI development process. While there is general agreement that data collection is feasible, it is envisaged that this will be more resource intensive due to the complexity of the QPIs, volume of patients for whom data will require to be collected and would require development and implementation of new data collection methodology with a higher level of direct clinical input.

Taking account of the complexity of these QPIs, and to better understand and test the feasibility of consistent and comparable data capture using existing resources, the Prostate Cancer QPI Development Group has agreed the following approach to implementation:

Year 1 Implementation Strategy for Post Radical Treatment QPIs for Prostate Cancer

QPI 7 – Post Surgical Incontinence	This QPI will be fully implemented and data collection tested across all NHS Boards. The QPI will be reviewed after Year 1 to determine reliability and validity of data collection.
QPI 8 – Post Radiotherapy Toxicity	This QPI will be piloted in year 1 across selected NHS Boards to assess future feasibility of data collection and reporting.
QPI 9 – PSA Relapse Rate	This QPI will not be introduced in year 1; however work to determine the feasibility of establishing a robust and sustainable data collection methodology will be progressed by the National Cancer Quality Steering Group.

This approach will allow for fuller assessment of the data collection methodology and data quality to be undertaken ahead of proposing system wide implementation.

QPI 7: Post Surgical Incontinence

QPI Title:	Post surgical incontinence for patients with prostate cancer should be minimised.
Description:	Proportion of prostate cancer patients who undergo radical prostatectomy with post surgical incontinence approximately 1 year (between 10 and 14 months) after surgery.
Rationale and Evidence:	Urinary incontinence, especially over the long-term, is significant and is associated with poor quality of life, this therefore requires to be minimised in men undergoing surgery for prostate cancer ^{4 6} .
Specification 1:	<p>Numerator: Number of patients with prostate cancer undergoing radical prostatectomy with post surgical incontinence (>0 pads per day) at 1 year (10-14 months) post radical prostatectomy.</p> <p>Denominator: All patients with prostate cancer undergoing radical prostatectomy.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • Patients who undergo salvage prostatectomy. • Patients who receive adjuvant radiotherapy within 6 months of surgery.
Target	<20%
Specification 2:	<p>Numerator: Number of patients with prostate cancer undergoing radical prostatectomy with post surgical incontinence (greater than 1 pad per day) at 1 year (10-14 months) post radical prostatectomy.</p> <p>Denominator: All patients with prostate cancer undergoing radical prostatectomy.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> • Patients who undergo salvage prostatectomy. • Patients who receive adjuvant radiotherapy within 6 months of surgery.
Target:	<10%

Please Note:

Due to the difficulty in reaching an appropriate definition of incontinence and a lack of clear evidence to determine this, two distinct targets based on the use of incontinence pads are detailed.

These two distinct target levels have been chosen as they account for differences in patient perceptions of the severity of symptoms following surgery. Evidence suggests that the degree to which these symptoms bother individuals is very variable⁴.

This QPI will be fully implemented in Year 1, for data collection and reporting across all NHS Boards. The QPI will be reviewed after Year 1 to determine reliability and validity of data collection.

QPI 8: Post Radiotherapy Toxicity

QPI Title:	Complications following radical radiotherapy should be minimised for patients with prostate cancer.	
Description:	Proportion of patients who undergo radical radiotherapy who have a recorded assessment of Radiation Therapy Oncology Group (RTOG) grade 3 or above bowel or bladder toxicity between 6 and 12 months post treatment.	
Rationale and Evidence:	<p>It is important to measure the impact on subsequent quality of life of treatment delivered.</p> <p>For patients with prostate cancer undergoing radiotherapy acute and longer term bowel and bladder toxicities are significant, treatment related, complications⁴.</p> <p>RTOG toxicity scales are established tools within oncology for assessing the rate of radiation induced post treatment damage. It is important to know the rate of toxicity that requires further intervention such as laser coagulation, hospital admission, steroid enemas sigmoidoscopy or cystoscopy⁶. A higher than expected rate may indicate poor radiotherapy delivery.</p>	
Specifications:	Numerator:	Number of patients undergoing radical external beam radiotherapy (EBRT) with RTOG grade 3 or above urinary or bowel toxicity between 6 and 12 months post completion of EBRT.
	Denominator:	All patients undergoing radical external beam radiotherapy (EBRT).
	Exclusions:	No exclusions.
Target:	<10%	

This QPI will be piloted in Year 1 across NHS Greater Glasgow and Clyde, NHS Lothian and NHS Tayside to assess future feasibility of robust, comparable data collection and reporting.

QPI 9: PSA Relapse Rate

QPI Title:	Post radical treatment relapse rate for patients with prostate cancer should be minimised.	
Description:	Proportion of patients with intermediate risk prostate cancer who undergo radical treatment with curative intent for prostate cancer (radical prostatectomy, external beam radiotherapy or brachytherapy) with PSA relapse (defined as over 0.2 ug/l post prostatectomy) at 1 year (following radical prostatectomy) or at 5 years (following external beam radiotherapy or brachytherapy).	
Rationale and Evidence:	<p>PSA relapse is usually associated with decreased biochemical recurrence free period and reduced progression free survival⁴.</p> <p>Following external beam radiotherapy (EBRT) and prostate brachytherapy 5 year and 10 year PSA relapse free and overall cause specific survival data should be known. The Houston definition of PSA relapse of 2.0ug/l above the nadir level post treatment is adopted world wide and provides a unified standard. Prostate brachytherapy patients may experience a phenomenon of PSA bounce in year 2. Patients who fail to fall below the 2.0ug/l threshold above nadir by the end of year 2 will have failed and the date of failure backdated to the first 2.0ug/l rise above nadir^{3 4 6}.</p>	
Specifications:	Numerator:	Number of intermediate risk prostate cancer patients with PSA relapse at 1 year (10-14 months) post radical prostatectomy OR at 5 years (54-66 months) post completion of brachytherapy or EBRT.
	Denominator:	All patients with intermediate risk prostate cancer undergoing radical treatment (radical prostatectomy, EBRT or brachytherapy).
	Exclusions:	<ul style="list-style-type: none"> • Patients who receive adjuvant treatment.
Target:	<20%	

This QPI will not be introduced in year 1.

Work to determine the feasibility of establishing a robust and sustainable data collection methodology will be progressed by the National Cancer Quality Steering Group.

12.6. Ergebnisse der Konsultationsphase zur 1. Auflage der Leitlinie 2009

12.6.1. Kapitel Epidemiologie, Risikofaktoren, Ernährung und Prävention

Inhalt des Kommentars	Änderung der Leitlinie, ggf. Begründung
Hintergrundtext Empfehlung 2.1 : keine Angaben zur Prävalenz genannt.	Angaben zur Prävalenz des Prostatakarzinoms unter Verwendung der vom Kommentator zitierten Quelle aufgenommen.
Empfehlung 2.2 und Hintergrundtext: erhöhtes Risiko für PCa bei familiärer Belastung durch Mammakarzinom soll thematisiert werden.	Keine Änderung, da bisher kein eindeutiger Nachweis der klinischen Relevanz bei familiärer Belastung durch Mammakarzinom erbracht wurde.
Empfehlung 2.2 und Hintergrundtext: Diabetes mellitus als Risikofaktor für das Entstehen eines Prostatakarzinoms in der schwarzen Bevölkerung soll thematisiert werden.	Keine Änderung, da die Kausalität von Diabetes mellitus als Risikofaktor schwer nachzuweisen ist und sich die Leitlinie trotz bekannter Migrationsphänomene v. a. auf die kaukasische Bevölkerung bezieht.
Hintergrundtext Empfehlung 2.7 : „five a day“, d. h. die Empfehlung, fünfmal Obst und Gemüse pro Tag zu sich zu nehmen, ist nicht wissenschaftlich nachgewiesen.	Der Ausdruck „five a day“ wurde im Leitlinientext gestrichen.
Hintergrundtext Empfehlung 2.7 : die gezielte Supplementierung (Selen, Vit. E) ist erfolgreich, das negative Ergebnis der SELECT-Studie zum Nutzen von Selen-Substitution zur Prävention soll hinterfragt werden.	Keine Änderung, die aktuellen Studienergebnisse werden weiterhin berücksichtigt, es liegen keine spezifischen anderslautenden Ergebnisse für Deutschland vor.

12.6.2. Kapitel Früherkennung und Biopsie

Inhalt des Kommentars	Änderung der Leitlinie ggf. Begründung
Hintergrundtext Empfehlung 3.3 : Aufklärungsinhalte zur Früherkennung sollen spezifiziert werden, es sollen korrekte Angaben für die Studie von Schröder et al. 2009 angeführt werden – insbesondere, dass es sich um 48 Übertherapien pro gerettetem Leben handelt. Es sollen auch unabhängige Aufklärungs-Stellen empfohlen werden.	Der Hintergrundtext in der Leitlinie in Bezug auf die Zahlen der Studie von Schröder et al, 2009 wurde geändert und als unabhängige mögliche zusätzliche Aufklärungsstelle wird das Deutsches Krebsforschungszentrum (DKFZ) genannt.

Inhalt des Kommentars	Änderung der Leitlinie ggf. Begründung
Empfehlung 3.5 und Hintergrundtext: Antrag auf Nennung des 3-dimensionalen Farbduplex-Transrektalsonographie- Systems (3D-FCDESTRUS) als für die Früherkennung geeignetes bildgebendes Verfahren.	Keine Änderung. Die vom Kommentator genannte Studie weist einen interessanten Ansatz auf, beinhaltet aber keinen randomisierten Vergleich mit der Standardmethode. Die Testgüteparameter sind deshalb - bei fraglicher Reproduzierbarkeit - nicht realistisch einzuordnen. Die Technik ist kaum verfügbar.
Empfehlung 3.11: Antrag auf Aufnahme des Prostatavolumens als Indikation zur Biopsie , nicht nur starres Festhalten an Grenzwert von 4 ng/ml. Kapitel 3.2: Antrag auf Empfehlung auch der Feinnadelbiopsie als diagnosesicherndes minimal-invasives Verfahren.	Keine Änderung, da die Indikationsstellung zur Biopsie anhand des Prostatavolumens als nicht ausreichend wissenschaftlich gesichert eingeschätzt wurde. Keine Änderung, da die Feinnadelbiopsie nicht als ausreichende wissenschaftlich gesichert eingeschätzt wurde.
Empfehlung 3.15 und Hintergrundtext: es erfolgt keine explizite Thematisierung des Zugangswegs zur Biopsie, insbesondere der perinealen Biopsie, bei der kein Antibiotikumschutz erforderlich ist.	Keine Änderung der Leitlinie, die perineale Biopsie wurde als Rarität eingestuft und der Zugangsweg wurde deshalb nicht thematisiert.
Empfehlung 3.17: Antrag auf Änderung der Empfehlung, da laut neuerer Literatur eine Rebiopsie bei hochgradige prostaticher intraepitheliale Neoplasie (HIGH-Grade PIN) nicht grundsätzlich erforderlich sei, die Literatur in der Leitlinie wird als nicht aktuell eingeschätzt.	Die Empfehlung zur hochgradigen prostaticher intraepitheliale Neoplasie (High-Grade-PIN) wurde neu abgestimmt, eine Rebiopsie wird nun nur bei ausgedehnter High-Grade-PIN empfohlen (Nachweis in mind. vier Gewebeproben). Es erfolgte eine Aufnahme der vom Kommentator genannten Literaturzitate.

12.6.3. Kapitel Diagnostik und Stadieneinteilung

Inhalt des Kommentars	Änderung der Leitlinie ggf. Begründung
Kapitel 4.1: Primärdiagnose: Antrag auf Aufnahme einer kann-Empfehlung zur MRT nach erfolgloser Biopsie mit Verweis auf die besseren Testgüteparameter im Vergleich zum TRUS.	Es erfolgte eine Aufnahme der folgenden Empfehlung nach Neuabstimmung: Die endorektale MRT kann als ergänzende bildgebende Diagnostik nach negativer Biopsie eingesetzt werden.
Kapitel 4.2: Staging: Antrag auf Berücksichtigung der MRT-Untersuchung zum Staging entsprechend der niederländischen Leitlinie von 2007.	Keine Neuabstimmung. Die Empfehlungen zum Staging wurden belassen, die MRT erschien adäquat gewürdigt – gestrichen wurde lediglich der Zusatz „ein CT“ in Empfehlung 4.5 und im Hintergrundtext wird darauf verwiesen, dass bei Verfügbarkeit die MRT die vorzuziehende Untersuchung ist.

Inhalt des Kommentars	Änderung der Leitlinie ggf. Begründung
<p>Kapitel 4.3.1: Antrag auf Aufnahme der DNA-Zytometrie als prognostischer Faktor. Es wurde kritisiert, dass offensichtlich keine systematische Recherche zu dem Thema prognostische Faktoren für das Prostatakarzinom erfolgt ist.</p>	<p>Keine Änderung von Empfehlungen. Die Empfehlung 4.10 des Kapitels 4.3.1 zu prognostischen Faktoren beruht auf einem Consensusstatement des College of American Pathologists von 2000, aufgenommen wurden Prognosefaktoren der Kategorie 1. Für das Kapitel pathomorphologische Diagnostik erfolgten bislang keine systematischen Recherchen nach Primärstudien, sondern es handelt sich um ein auf Leitlinien gestütztes Kapitel.</p>
<p>Empfehlung 4.15: Antrag auf Aufnahme des modifizierten Gleason-Grading mit Literatur (Helpap 2008) in den Hintergrundtext. Begründung: bei Einsatz dieses Gradings wird eine bessere Korrelation zwischen Biopsie- und Operationspräparat erreicht. Allerdings verändert (erhöht) sich der Gleason-Score der Biopsie.</p>	<p>Das modifizierte Gleason-Grading wurde in den Hintergrundtext aufgenommen.</p>
<p>Kapitel 4.3: Antrag auf Überprüfung des Gebrauchs der Bezeichnungen „T-Stadium“ und „R-Status“.</p>	<p>Die Hintergrundtexte wurden modifiziert: T-Stadium wurde an den entsprechenden Stellen korrigiert in T-Kategorie, R-Status wurde erläutert als Residualtumor nicht als Status bezüglich des Randsaums des Operationspräparats.</p>
<p>Empfehlung 4.12 Antrag auf Überprüfung der Notwendigkeit dreier Kriterien zur Karzinomdiagnose.</p>	<p>Es wurde redaktionell bezüglich der Erfordernis der drei Kriterien eingefügt „in der Regel“.</p>
<p>Empfehlung 4.17: Antrag auf Streichen des Empfehlungsteils: Prostatastanziopsien sollten in Histologiekapseln auf Schaumstoffplättchen gelegt und in 4 % gepuffertem Formalin fixiert werden, da zum Beispiel der Transport auf Filterpapier im Ergebnis gleichwertig ist.</p>	<p>Die Empfehlung wurde neu abgestimmt. Die genannte Passage wurde gestrichen. Im Hintergrundtext heißt es nun: Prostatastanziopsien können zur gestreckten Fixierung (in 4 % Formalin) zum Beispiel auf Schaumstoffplättchen (oder Filterpapier) gelegt werden.</p>
<p>Empfehlung 4.20: die Notwendigkeit der ventralen und dorsalen Farbmarkierung wird in ihrer Relevanz in Frage gestellt.</p>	<p>Keine Änderung. Die Angabe trägt zur standardisierten Aufarbeitung des Operationspräparats bei.</p>
<p>Empfehlung 4.20: die Bezeichnung „Kapseldurchbruch“ bei Kategorie pT3a ist nicht korrekt – Vorschlag der Bezeichnung: extraprostatiche Tumorausdehnung.</p>	<p>Der Begriff extraprostatiche Tumorausdehnung wurde ergänzt.</p>
<p>Empfehlung 4.20: die Angabe des minimalen Randsaums ist überflüssig und führt ggf. zur Übertherapie.</p>	<p>Keine Änderung. Die Angabe trägt zur standardisierten Aufarbeitung bei und wurde nicht als eine Übertherapie fördernd eingeschätzt. Eine Strahlentherapie wird nur bei nicht tumorfreiem Randsaum empfohlen.</p>

Inhalt des Kommentars	Änderung der Leitlinie ggf. Begründung
Empfehlung 4.21/4.22: die Leitlinie empfiehlt generell die Einbettung einer sehr großen Menge von TUR-Material ohne Abgleich mit der klinischen Situation.	Redaktionell wurde bei Empfehlung 4.22 ergänzt: „wenn der Nachweis eines Karzinoms therapeutische Konsequenzen hat“.
Empfehlung 4.23: Antrag auf Streichen der Empfehlung zur Angabe der Zahl makroskopisch erkennbarer Lymphknoten, da diese in Praxis schlecht abgrenzbar sind.	Keine Änderung, die Angabe der makroskopisch erkennbaren Lymphknoten wurde als machbar eingeschätzt und ist auch bei anderen Tumoren Usus.

12.6.4. Therapie des nichtmetastasierten Prostatakarzinoms

Inhalt des Kommentars	Änderung der Leitlinie ggf. Begründung
Hintergrundtext zu Empfehlung 5.5: das Risiko für eine Entwicklung von Zweitmalignomen für die LDR-Brachytherapie ist nicht korrekt dargestellt.	Der Hintergrundtext wurde spezifiziert und Ergebnisse einer vom Kommentator genannten Studie aufgenommen.
Empfehlung 5.1 und 5.3: Antrag auf Änderung der Empfehlung zur Aufklärung über Active Surveillance (AS). Hier sollte eine vorsichtiger Formulierung gewählt werden, da es sich um eine „experimentelle Therapie“ handelt und die Kriterien für AS nicht klar sind.	Keine Änderung der Empfehlung. Es erfolgte eine Ergänzung des Hintergrundtextes um erforderliche Informationsinhalte zu AS. Eine Tabelle mit Ergebnissen neuerer Studien zu Active Surveillance wurde ergänzt.
Hintergrundtext zum den Empfehlungen 5.11 und 5.12: Antrag auf folgende Änderungen: bei dem RCT (Bill-Axelsson et al, 2005+2008) handelt es sich in der Kontrollgruppe um eine palliative, nicht eine abwartende Therapiestrategie. Es erfolgte für die Studiengruppe keine Stratifizierung nach Risikogruppen. Weiterhin erfolgte ein Antrag auf Ergänzung von Aufklärungsinhalten in Bezug auf die Patienten die nach den Ergebnissen der Publikation des RCT von Bill-Axelsson et al. 2008 (im Vergleich zu 2005) von der RPE profitieren.	In den Hintergrundtexten wurde abwartende Strategie durch palliative Strategie ersetzt. Es wird nun dargelegt, dass keine Stratifizierung der Ergebnisse nach Risikogruppen möglich ist. Weiterhin wurden die Angaben zum altersstratifizierten relativen und absoluten Vorteil der Operation in Bezug auf die prostata-spezifische Mortalität ergänzt.
Antrag auf Aufnahme einer Fallserie zur RPE, da diese aktuelle deutsche Ergebnisse der operativen Therapie aufweist.	Studie wurde nicht aufgenommen, da nicht gut nach Tumorstadien auswertbar.
Kapitel 5.3.3.1: 3 Antrag, die LDR-Brachytherapie entsprechend der EAU-Leitlinie auch für Tumoren des mittleren Risikoprofils zu empfehlen. Antrag, die LDR-Brachytherapie als Monotherapie oder mit perkutaner Strahlentherapie kom-	Keine Änderung von Empfehlungen. Es erfolgte eine Änderung Hintergrundtextes: bisher wurde eine systematische Literaturrecherche für LDR-Monotherapie durchgeführt. Für die Überarbeitung der Leitlinie ist eine systematische Recherche und eine Neubewertung der LDR-

Inhalt des Kommentars	Änderung der Leitlinie ggf. Begründung
<p>binierte Therapie auch für Tumoren des mittleren und des hohen Risikoprofils zu empfehlen.</p> <p>Antrag, Literatur zu LDR bzw. LDR+perkutane Strahlentherapie für Tumoren des mittleren oder hohen Risikoprofils zu ergänzen.</p>	<p>Monotherapie und der LDR-Therapie kombiniert mit perkutaner Strahlentherapie geplant.</p>
<p>Empfehlung 5.36: Antrag auf Neubewertung der HIFU-Therapie unter Berücksichtigung von Literatur aus 2008.</p>	<p>Es erfolgte eine redaktionelle Änderung der Empfehlung zur HIFU-Therapie. Sie lautet nun: Es liegen keine Studiendaten vor, die derzeit eine Bewertung der HIFU-Therapie in der Behandlung des lokal begrenzten Prostatakarzinoms ermöglichen. Daher ist ein routinemäßiger Einsatz der HIFU für diese Indikation nicht gerechtfertigt.</p> <p>Der Hintergrundtext wurde unter Berücksichtigung der vom Kommentator genannten Literatur aus 2008 aktualisiert.</p>

12.6.5. Diagnostik und Therapie des rezidierten und metastasierten Prostatakarzinoms

Inhalt des Kommentars	Änderung der Leitlinie ggf. Begründung
<p>Empfehlung 6.4: Antrag auf Änderung der Empfehlung zur Biopsie bei V. a. Rezidiv nach RPE.</p> <p>Begründung: Die Biopsie hat zwar schlechte Testgüteparameter, der Karzinomnachweis erlaubt aber eine gesicherte und ggf. anders dosierte Strahlentherapie.</p>	<p>Die Empfehlung wurde neu abgestimmt und lautet nun: Eine bioptische Sicherung eines biochemischen Rezidivs nach RPE ist nicht erforderlich.</p>
<p>Empfehlung 6.2 und 6.3: Antrag auf Präzisierung des Zeitabstands der zweiten Messung bei V. a. ein Rezidiv nach RPE/nach Strahlentherapie.</p>	<p>Die Angabe zum Mindestabstand zur zweiten Messung wurde im Hintergrundtext ergänzt: „mindestens zwei Wochen“ nach RPE, „nach ca. drei Monaten“ nach Strahlentherapie.</p>
<p>Empfehlungen 6.39 und 6.40: Antrag zu Erhöhung des Empfehlungsgrads für die beiden Empfehlungen zum Einsatz von Bisphosphonaten bei Knochenmetastasen und Antrag auf eine neue Empfehlung in Bezug auf symptomatische Knochenmetastasen.</p> <p>Änderung des Hintergrundtextes zur Schmerzreduktion durch Bisphosphonate und zum Therapieansprechen osteoblastischer Knochenmetastasen.</p> <p>Aufnahme der Einzelstudie zur Wirksamkeit der Zoledronsäure (2002/2004).</p>	<p>Die Empfehlungsgrade wurden jeweils belassen.</p> <p>Die Empfehlung 6.40 zum Einsatz von Zoledronsäure bei Knochenmetastasen wurde neu abgestimmt – der Zusatz symptomfrei ist nun gestrichen. Redaktionell wurde in den Empfehlungen ergänzt: „im hormonrefraktären Stadium“.</p> <p>Die Hintergrundtexte zu den Empfehlungen wurden geändert und die Literatur ergänzt.</p>

12.7. Ergebnisse der Konsultationsphase zur 1. Aktualisierung 2011

12.7.1. Allgemeine Kommentare

Inhalt des Kommentars	Änderung der Leitlinie, ggf. Begründung
Es wird darauf hingewiesen, dass die neuen Substanzen Denosumab, Cabazitaxel und Abirateron nicht berücksichtigt wurden.	Keine Änderungen, da die Substanzen berücksichtigt wurden (z. B. Empfehlungen 6.41, 6.35, 6.34)
Es wird darauf aufmerksam gemacht, dass im Kapitel Nachsorge nicht spezifisch darauf eingegangen, welche Diagnostik bei Verdacht auf Rezidiv durchgeführt werden muss. Es wird eine klare Empfehlung gewünscht, damit bestimmte Verfahren dem gesetzlich versicherten Patienten nicht vorenthalten werden.	Keine Änderung, da die Überarbeitung zum jetzigen Zeitpunkt zu aufwendig ist. Thema wird aber für die nächste Aktualisierung priorisiert.

12.7.2. Kommentare zum Thema Früherkennung und Biopsie

Inhalt des Kommentars	Änderung der Leitlinie, ggf. Begründung
Unter Verweis auf aktuelle Daten (Lilja et al. 2011) wird vorgeschlagen, bzgl. der Kontrollintervalle für die Früherkennung mit PSA-Test, eine gesonderte Empfehlung für Männer zwischen 40 und 50 Jahren abzugeben. Es wird argumentiert, dass die Daten abhängig vom PSA-Wert wesentlich längere Intervalle rechtfertigen und durch risikoabhängige Intervalle die bestehende Überversorgung für diese Altersgruppe reduziert werden kann.	Es wurde eine Ergänzung der Empfehlung 3.7 vorgenommen. Für die Altersgruppe 40-50 wurde eine Empfehlung zur risikoabhängigen Wahl der Kontrollintervalle ergänzt und durch eine schriftliche Abstimmung konsentiert.
Es wird vorgeschlagen aufgrund der Zunahme von Fluorchinolon-resistenter Enterobakterien in der Darmflora und der daraus resultierenden Zunahme von febrilen Harnwegsinfektionen und Urosepsis, Patienten vor einer Prostatastanzbiopsie auf Fluorchinolon-resistente Erreger zu screenen und bei positivem Befund eine Antibiotikaprophylaxe mit Cephalosporin durchzuführen.	Keine Änderung, da die Überarbeitung zum jetzigen Zeitpunkt zu aufwendig ist. Thema wird aber für die nächste Aktualisierung priorisiert.
Es wird angemerkt im Hintergrundtext zur Empfehlung 3.15 die Optionen nach wiederholter negativer Biopsie zu nennen.	Der Hintergrundtext wurde entsprechend geändert.

12.7.3. Kommentare zum Thema Diagnostik und Stadieneinteilung

Inhalt des Kommentars	Änderung der Leitlinie, ggf. Begründung
<p>Es wird gefordert, für die transrektale Ultraschalluntersuchung der Prostata (TRUS) Qualitätskriterien bzgl. technischer Anforderungen zu benennen.</p>	<p>Die Empfehlung 4.2 wurde geändert und im schriftlichen Umlaufverfahren konsentiert (Änderungen unterstrichen):</p> <p>Die transrektale Ultraschalluntersuchung kann als ergänzende bildgebende Diagnostik eingesetzt werden, <u>wenn sie den geltenden Qualitätsanforderungen genügt.</u></p> <p>Im Rahmen der Biopsie können gezielte Biopsien auffälliger Areale im Ultraschall nach definierten Malignitätskriterien zusätzlich zur systematischen Biopsieentnahme durchgeführt werden.</p> <p>Im Hintergrundtext wurden Qualitätskriterien ergänzt.</p>
<p>Es wird darauf hingewiesen, dass im Hintergrundtext zur Empfehlung 4.3 die Formulierung „eher nicht empfohlen“ unverständlich ist. Weiterhin wird vorgeschlagen den Satz zu streichen, dass der kontrastverstärkte Ultraschall nur angewendet werden soll, wenn prospektive belegt wurde, dass damit statistisch und klinisch signifikant verbesserte Testgüteparameter erreicht wurden.</p>	<p>Der Hintergrundtext wurde geringfügig für eine bessere Verständlichkeit geändert (statt eher nicht empfohlen nun „nicht routinemäßig empfohlen“).</p>
<p>In mehreren Kommentaren wurden Änderungen im Abschnitt 4.3 Pathomorphologische Untersuchungen gefordert. Zu 4.24 wurde gefordert, die Anzahl der Stenzen mit HGPIN anzugeben. Zu 4.28 wurde vorgeschlagen, den Prozentsatz des Karzinoms pro Stanze sowie den Gleason Score pro Stanze anzugeben. Zu Empfehlung 4.31 wurde angemerkt, hier eine ‚standardisierte Aufarbeitung‘ statt einer kompletten Einbettung zu empfehlen und die angegebene Literatur für das empfohlene Lamellieren in 3-5 mm dicke Scheiben nicht geeignet ist. Hinsichtlich der Empfehlung 4.33 wird gefordert, den Empfehlungsgrad auf Option (0, kann) zu reduzieren oder gänzlich zu streichen, da die Literatur die Empfehlung nicht stützt. Für Empfehlung 4.34 wurde angemerkt, dass es eine Kategorie pT1a oder pT1b nach der UICC Klassifikation nicht definiert ist (es existiert lediglich die cT1-Kategorie).</p>	<p>Da eine umfangreiche Überarbeitung des Kapitels im aktuellen Aktualisierungsverfahren nicht mehr möglich ist, werden keine Änderungen vorgenommen und das Kapitel für die nächste Aktualisierung priorisiert.</p>

12.7.4. Kommentare zum Thema Therapie des nichtmetastasierten Prostatakarzinoms

Inhalt des Kommentars	Änderung der Leitlinie, ggf. Begründung
Es wird darauf hingewiesen, dass bei der Active Surveillance (AS) Strategie (Empfehlung 5.8) die PSA-Verdopplungszeit (PSADT) zwar als Abbruchkriterium aufgeführt wird, aber nicht als Voraussetzung für AS.	Die Empfehlung wird nicht geändert, da die PSA-Verdopplungszeit zu diesem Zeitpunkt oft nicht vorliegt. Der Hintergrundtext wurde entsprechend ergänzt.
Es wird angemerkt, dass in der Empfehlung 5.8 im Unterschied zur EAU-Leitlinie die Stadien T1a und T1b nicht als Indikationen für AS aufgeführt werden.	Die Empfehlung wurde nicht geändert, da es dafür keine ausreichenden Daten gibt. Der Hintergrundtext wurde um entsprechende Erläuterungen ergänzt.
Es wird vorgeschlagen, DNA-zytometrische Untersuchungen im Einzelfall als Zusatzuntersuchung bei bestimmten Fragestellungen zu empfehlen.	Es werden keine Änderungen an der Leitlinie vorgenommen. Das Thema soll bei der nächsten Aktualisierung bearbeitet werden.
Unter Hinweis auf methodische Diskussionen und die Entscheidung eines Landessozialgerichtes, die Mindestmenge für Knieendoprothesen für unwirksam zu erklären, wird gefordert, die Empfehlung 5.18 zu streichen.	Es werden keine Änderungen an der Leitlinie vorgenommen. An der Datenlage hat sich seit Verabschiedung der Empfehlung nichts Wesentliches geändert. Die methodischen Limitationen der verfügbaren Daten sind bekannt und wurden bei der Verabschiedung der Empfehlung berücksichtigt. Der Hintergrundtext wurde um aktuellere Studien ergänzt.
In mehreren Kommentaren wurde gefordert, die Formulierung in Empfehlung 5.39 „Die HIFU-Therapie ist ein experimentelles Verfahren...“ zu streichen bzw. zu ändern.	Es werden keine Änderungen an der Leitlinie vorgenommen. Die Formulierung der Empfehlung wurde im formalen Konsensusverfahren abgestimmt. Im Rahmen der Konsultation wurden keine aktuelleren Studien mit relevanten Ergebnissen eingebracht, die eine Änderung der Empfehlung rechtfertigen würden. Es wird außerdem darauf hingewiesen, dass auch in der EAU-Leitlinie HIFU im Kapitel „EXPERIMENTAL LOCAL TREATMENT OF PROSTATE CANCER“ behandelt wird. HIFU soll bei Vorliegen neuer relevanter Daten prioritär bei Aktualisierungen berücksichtigt werden.
Es wird darauf hingewiesen, dass zum Thema ‚Bestrahlung der pelvinen Lymphabflusswege‘ mehrere Hintergrundtexte mit teilweise unterschiedlichen Studien existieren.	Es wurde ein einheitlicher Hintergrundtext erstellt, auf den in den jeweiligen Abschnitten verwiesen wird.

12.7.5. Kommentare zum Thema Diagnostik und Therapie des rezidierten oder metastasierten Prostatakarzinoms

Inhalt des Kommentars	Änderung der Leitlinie, ggf. Begründung
Bei der Empfehlung 6.5 wird nachgefragt, ob tatsächlich wie im Hintergrundtext formuliert, die transperineal durchgeführte Stanzbiopsie ausgeschlossen werden soll.	Die transperineale Stanzbiopsie soll nicht grundsätzlich ausgeschlossen werden und wurde deshalb im Hintergrundtext ergänzt.
Bei Empfehlung 6.20 wird angezweifelt, angesichts von zwei gleichwertigen Alternativen eine starke Empfehlung abzugeben	Die Leitlinienautoren erachteten eine Änderung der Empfehlung nicht als notwendig. Medikamentöse und operative Androgendeprivation sollen gleichermaßen empfohlen werden
Es wurde vorgeschlagen, in Empfehlung 6.31 den folgenden Satz zu ergänzen: „Zytostatika sollten nur durch Ärzte verabreicht werden, die auf die Gabe von zytotoxischen Substanzen spezialisiert sind. Eine adäquate Patientenselektion und ein sorgfältiges Monitoring potentieller Nebenwirkungen sind unerlässlich.“	Die Empfehlung wurde nicht geändert. Es wurde nicht als Aufgabe der Leitlinie gesehen, die Fachinformationen zu Arzneimitteln zu zitieren.
Für den Hintergrundtext der Empfehlung 6.34 wurde vorgeschlagen, Informationen aus der Fachinformation zum Monitoring und Hinweise auf das bisher untersuchte, eingeschränkte Patientenkollektiv aufzunehmen. Es wurde außerdem darauf hingewiesen, dass die Zulassung für Abirateron mittlerweile erfolgt ist.	Im Hintergrundtext wurden die Angaben zum Zulassungsstatus von Abirateron aktualisiert.
Es wurde vorgeschlagen, in der Empfehlung 6.35 zu Cabazitaxel, die adressierte Population von ECOG Status 0-1 auf 0-2 zu ändern. Außerdem wurde gefordert, den letzten Satz zu den Nebenwirkungen entweder im Hintergrundtext aufzuführen oder die Nebenwirkungsprofile von Docetaxel und Mitoxantron in ähnlicher Weise zu adressieren.	Die Empfehlung wurde nicht geändert, da die Leitliniengruppe sich bewusst dazu entschieden hat, Cabazitaxel nur bei ECOG 0-1 zu empfehlen, da ECOG 2 nur 8 % der Studienteilnehmer in der relevanten Studie von de Bono et al. 2010 hatten. Die Leitliniengruppe hatte sich außerdem bewusst dafür entschieden, bei Cabazitaxel auf die erhöhte Rate der Nebenwirkungen hinzuweisen.
Es wurde vorgeschlagen, den Satz zum fehlenden Vergleich mit Docetaxel-Zweitlinientherapie im Hintergrundtext zur Empfehlung 6.35 zu streichen oder auch bei den anderen Therapieoptionen (Mitoxantron, Abirateron, Docetaxel in wöchentlicher und dreiwöchentlicher Dosis) aufzuführen. Dies wurde (mit Verweis auf de Bono et al. 2010) damit begründet, dass eine Studie mit Abirateron oder Cabazitaxel bei docetaxelrefraktären Patienten nicht durchführbar ist.	Der Hintergrundtext wurde nicht geändert, da eine Docetaxel-Zweitlinientherapie nach einer Ersttherapie nach einem Intervall von 6 Mo. grundsätzlich wieder möglich ist.

Inhalt des Kommentars	Änderung der Leitlinie, ggf. Begründung
Unter Verweis auf die Fachinformation wurde vorgeschlagen, zur Empfehlung 5.35 den Hinweis auf ein Neutropenie-Management zu ergänzen.	Die Empfehlung wurde nicht geändert. Es wurde nicht als Aufgabe einer Leitlinie gesehen, die Fachinformationen zu Arzneimitteln zu zitieren.
Zur Empfehlung 6.36 wurde angemerkt, dass der Evidenzlevel von 1+ nicht für Estramustin gilt, da zu dieser Substanz keine RCTs mit relevanten Endpunkten vorliegen.	Der Evidenzlevel wurde nicht geändert. Estramustin wird von den Autoren zwar als „Auslaufmodell“ angesehen, es liegen aber RCTs vor, die einen LoE von 1+ rechtfertigen
Zum Statement 6.42 (in der Konsultationsfassung) wurde gefordert, zu Denosumab eine ähnlich starke Handlungsempfehlung anzugeben wie zu Zoledronsäure.	Es wurde eine gemeinsame Empfehlung zu den Substanzen entwickelt und im schriftlichen Umlaufverfahren konsentiert (siehe 6.41).
Es wurde darauf hingewiesen, in der Tabelle zu ‚Typischen und häufigen Nebenwirkungen einer hormonablativen Therapie und Möglichkeiten der Prophylaxe und Behandlung ‚Denosumab als Therapie bei ‚Reduktion der Knochendichte‘ aufzuführen.	Die Tabelle wurde entsprechend ergänzt

12.8. Ergebnisse der Konsultationsphase zur 2. Aktualisierung 2014

Kommentar	Antwort
<p>Zu Empfehlung 2.6</p> <p>Die empfohlenen Intervalle nach 6 Monaten entsprechen nicht mehr den aktuellen endokrinologischen Leitlinien (<i>Leitlinie Männlicher Hypogonadismus J Reproduktionsmed Endokrinol 2013; 10 (5-6)</i>):</p> <ul style="list-style-type: none"> - Der Hämatokrit sollte nach 3,6 und 12 Monaten überwacht werden, danach jährlich. Die Testosterondosis sollte verringert oder die Therapie gestoppt werden, falls der Hämatokrit sich über normale Spiegel hinaus erhöht. - Die Prostatagesundheit sollte durch digitale Rektaluntersuchung (DRU) und PSA-Bestimmung vor TRT-Beginn beurteilt werden. Ein PSA-Follow-up sollte nach 3,6 und 12 Monaten und danach jährlich erfolgen 	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung, die Anmerkung ist prinzipiell richtig, wird bei der nächsten Aktualisierung berücksichtigt.</p>
<p>Zu Hintergrundtext zu Empfehlung 2.4</p> <p>Besser: Randomisierte Langzeitdaten fehlen. Für die mediane Behandlungsdauer und Nachbeobachtung von sechs Monaten der Patienten des Reviews liegen somit keine ausreichenden Daten vor, um einer Empfehlung zur Substitution wegen eines drohenden Carcinoms zu widersprechen. Weitere Aspekte der Substituti-</p>	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung, die Anmerkung ist prinzipiell richtig, wird bei der nächsten Aktualisierung berücksichtigt.</p>

Kommentar	Antwort
<p>on werden von dieser Leitlinie nicht erörtert.</p> <p>Nebenwirkungen der Testosteronsubstitutionstherapie: Suppression der LH und FSH-Produktion mit Unfruchtbarkeit, Brustspannen oder Brustvergrößerung, Erythrozytose, Erhöhung des LDL-Cholesterin und Senkung des HDL-Cholesterin, kardiovaskuläre Komplikationen denkbar (Thrombose, Dekompensation einer Herzinsuffizienz), Exazerbation eines okkulten Prostatakarzinoms.</p> <p><i>Literatur: Köhn, F.-M. (2004). Urologe A.</i></p> <p>Sehen Sie die Literatur heute anders, bleibt mir unverständlich, warum Sie bei Hypogonadismus (der noch dazu oft fälschlich bei älteren Männern mit niedrigen Testosteron-Spiegeln unterstellt wird) die Testosterongabe explizit empfehlen! Selbst wenn in 6 Monaten keine Malignome entstehen, steigt das kardiovaskuläre Risiko. Bei den bekannten nicht unabhängigen Variablen, (Vorhandensein eines Diabetes mellitus und niedrigem Testosteron-Spiegel) ist die von Ihnen gemachte Aussage sogar gefährlich. Pittelloud et al Diabetes Care 2005; Vigen R et al JAMA 2013;</p>	
<p>Zu Hintergrundtext zu Empfehlung 2.7</p> <p>Zu c: Achten Sie auf eine gesunde Ernährung mit Schwerpunkt auf pflanzliche Produkte</p> <ul style="list-style-type: none"> · Essen Sie jeden Tag verschiedene Obst- und Gemüsesorten. · Essen Sie lieber Vollkorn- als Weißmehlprodukte. · Begrenzen Sie die Zufuhr von Fleischprodukten und rotem Fleisch. · Begrenzen Sie die Zufuhr von Milch und Milchprodukten sowie von hohen Mengen an Calcium. <ol style="list-style-type: none"> 1. Ein hoher Verzehr von Milchprotein steigert das Prostatakrebsrisiko um 22%, Calcium aus Milchprodukten um 18% (<i>EPIC-Studie; Allen et al., 2008</i>). 2. Bei 12 von 23 Studien bestand eine positive Assoziation zwischen dem Konsum von Milchprodukten und dem Prostatakrebsrisiko (<i>Chan und Giovannucci et al., 2001</i>). 3. Eine calciumreiche Ernährung erhöht wahrscheinlich (zweit-höchste Evidenzstufe) das Prostatakrebsrisiko (<i>WCRF, 2007</i>). 4. Milchkonsum erhöht die Inzidenz für Prostatakrebs um 12%. Vollmilchkonsum nach Diagnosestellung erhöht das Risiko für tödlichen Prostatakrebs um 117% (<i>Song et al., 2013</i>). 5. Eine hohe Calciumaufnahme erhöht das Risiko für fortgeschrittenen und tödlichen Prostatakrebs (<i>Giovannucci et al., 1998 und 2006</i>). 6. Milchkonsum korreliert am stärksten mit der Inzidenz von und der Mortalität durch Prostatakrebs (<i>Ganmaa et al., 2002</i>). 	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung, die Anmerkung ist prinzipiell richtig, wird bei der nächsten Aktualisierung berücksichtigt.</p>

Kommentar	Antwort
<p>Zu Empfehlung 3.2</p> <p>Männer, die den Wunsch nach einer Früherkennungsuntersuchung mittels PSA in der Hausarztpraxis nicht von sich aus äußern, sollen darauf nicht aktiv angesprochen werden.</p> <p>Diejenigen Männer, die von sich aus nach einer Früherkennung fragen, sollen ergebnisoffen über die Vor- und Nachteile aufgeklärt werden. Dabei sollen der mögliche Nutzen wie auch die Risiken (Überdiagnose und Übertherapie) in natürlichen Zahlen und auch grafisch dargestellt werden. Ebenso soll die Aussagekraft von positiven und negativen Testergebnissen dargestellt werden.</p> <p>SONDERVOTUM DEGAM</p> <p>Hintergrund: Die beste verfügbare Evidenz zur Früherkennung des Prostatakrebs mittels PSA-Bestimmung ist eine systematischen Übersichtsarbeit aus der Cochrane Collaboration (Ilic et al., Cochrane Database Syst Rev 2013). Die Autoren dieser Arbeit schlussfolgern aus den Ergebnissen ihrer Metaanalyse, einer Auswertung aller vorhandenen Daten aus randomisierten kontrollierten Studien, dass weder die Sterblichkeit an Prostatakrebs noch die Gesamtsterblichkeit von einem Screening beeinflusst wird. Dahingegen erhöht nach den Ergebnissen der Arbeit die Teilnahme an einem Früherkennungsprogramm das Risiko für Überdiagnose (richtig erkannte Prostatakrebskrankungen, die jedoch nie auffällig geworden wären) und Übertherapie (unnötige Behandlungen aufgrund einer Überdiagnose) deutlich (LoE 1). Ilic et al. sprechen sich übereinstimmend mit der U.S. Preventive Services Task Force (Moyer et al., Ann Intern Med 2012) und dem American College of Physicians (ACP; Qaseem et al., Ann Intern Med 2013) gegen ein PSA-Screening zur Früherkennung von Prostatakrebs aus.</p> <p>Anders als in der urologischen Praxis, die von vielen Männern möglicherweise bewusst mit dem Interesse, eine Krebsfrüherkennungs-Untersuchung durchführen zu lassen, aufgesucht wird, eignet sich der Kontext einer Hausarztpraxis wenig für systematische Bemühungen, die Patienten grundsätzlich auf eine Früherkennung anzusprechen – zu heterogen sind die Gründe, eine Hausarztpraxis aufzusuchen.</p> <p>Nach Auffassung der Deutschen Gesellschaft für Allgemeinmedizin und Familienmedizin (DEGAM) ist die Datenlage zu Vor- und Nachteilen einer Früherkennung des Prostata-Karzinoms insgesamt so ungenügend, dass die in Frage kommenden Männer nicht proaktiv auf die Möglichkeit der PSA-Bestimmung angesprochen, sondern eher im Rahmen der Gesundheitsuntersuchung gefragt werden sollten, ob sie allgemein Fragen zur Krebsfrüherkennung haben.</p>	<p>Das Sondervotum der DEGAM wurde unterhalb der Empfehlung 3.2 eingefügt.</p>

Kommentar	Antwort
<p>Zu Empfehlung 3.2</p> <p>Über die DEGAM wurde ein entsprechendes Sondervotum eingegeben. Da dieses ja ein Sondervotum bleibt, müsste der Hintergrund-Text für den urologischen Part erläuternd erweitert werden.</p> <p>Ich verstehe trotz der folgenden Erklärungen nicht, warum Männer über eine Maßnahme, die nachgewiesenermaßen schaden aber nicht nachweisbar nutzen kann, informiert werden sollen. Selbstredend sollen sie aufgeklärt werden, wenn sie selbst den Wunsch nach Aufklärung äußern Ich bitte um eine Erläuterung, die auch an Patienten weitergegeben werden kann, die berechtigterweise fragen werden, warum es zwei Interpretation der selben Literatur gibt.</p> <p>Dubben: Bundesgesundheitsbl 2014</p>	<p>Dieser Sachverhalt ist durch das Sondervotum der DEGAM abgedeckt. Zusätzlich lässt sich eine statistische Signifikanz bzgl. eines Benefits des Overall-Survivals nur durch Screening rein methodisch (Fallzahlen, Nachbeobachtungszeitraum) nur sehr schwer erreichen.</p> <p>Die berücksichtigten Studien bilden nicht den in der Praxis gelebten Umgang mit dem PSA adäquat wieder (keine Berücksichtigung von PSA-Kinetik, individuellen PSA-Ausgangswerten, individuelle Risikostratifizierung). Eine frühe PSA-Bestimmung kann dazu beitragen, das Problem der Überdiagnose zu verringern.</p>
<p>Zu Statement 3.1</p> <p>Die „statements“ sind gewichtet formuliert, unvollständig und suggerieren eine „unethische“ Übertherapie der Patienten. Sie basieren nicht auf dem aktuellen Stand der Literatur (s. ERSPC Daten unten) und stellen die ERSPC Ergebnisse nicht mit dem bereits 2012 im NEJM publizierten 11 Jahres follow-up dar.</p> <p>a. Die Aussage „Die prostatakarzinomspezifische Mortalität wird durch das Screening entweder gesenkt oder nicht signifikant beeinflusst“ basiert auf einer inkorrekten Literaturbewertung. Selbst in der Cochrane Analyse aus 2013 wurden in 4 von 5 auswertbaren RCTs starke methodische Mängel festgestellt, so dass die Aussagen zur CSS ausschließlich aus der ERSPC Studie und ihren Teilstudie abgeleitet werden sollten. Diese Studien sind aber für diese Aussage nicht aktuell zitiert (lediglich Hugosson et al. Lancet Oncol 2010 und Schröder et al NEJM 2009). Es fehlen folgende Publikationen:</p> <p>Schröder FH et al. NEJM 2012 (11 yrs follow up ERSPC), Roobol M et al., Eur Urol 2013 (Rotterdam Cohort, relative Mortalitätsreduktion 32%); Ilic D et al., Cochrane Database Syst Rev 2013; Zappa M et al., Eur Urol 2014; Bokhorst LP et al., Eur Urol 2014</p> <p>Mit diesen Publikationen wird eine wesentlich höhere relative Reduktion der CSS gezeigt (bis zu 32%). Damit ist die Mortalitätsreduktion durch Screening dann bewiesen, wenn der Nachuntersuchungszeitraum für eine Screening Population entsprechend lang ist.</p>	<p>Durch das Statement wird weder die Durchführung noch das Auslassen einer Therapie suggeriert. In der Tat zeigen die berücksichtigten Studien eine Reduktion der prostatakarzinomspezifischen Mortalität (CSS, Cause specific survival) ohne einen statistisch signifikanten Benefit hinsichtlich der Gesamtmortalität erreichen zu können. Dass die Studien methodische Mängel aufweisen, wird in der Diskussion berücksichtigt. Auch wenn die Cochrane Analyse methodische Schwächen aufweist, kommt sie dennoch zum Schluss, dass ein Vorteil für das Screening nicht bewiesen ist.</p> <p>Arbeiten, die nach Literaturabschluss publiziert wurden, werden nur in Ausnahmen aufgenommen. Die aktuellen Studien von Schröder et al</p>

Kommentar	Antwort
<p>Zu Statement 3.1</p> <p>Die Aussagen in 3.1 übersehen komplett die Verlängerung der metastasen-spezifischen Überlebenszeit. Diese ist jedoch für den einzelnen Patienten entscheidend und hierüber muss aufgeklärt werden.</p> <p>Hierzu fehlt folgende Publikation: Schröder FH et al. Eur Urol 2012 (Decrease of metastasis)</p>	<p>und Ilic et al waren enthalten, aber falsch verknüpft. Das wurde inzwischen korrigiert.</p> <p>Es gibt in der Studie Hinweise auf die Verlängerung der metastasenspezifischen Überlebenszeit, trotzdem bleibt die prostatakarzinomspezifische Mortalität unverändert. Die Evidenz der Studie ist allerdings zu gering, als dass die Leitlinie dadurch direkt beeinflusst werden sollte. Es wurde nur die Hälfte der ERSPC-Gesamtstudie berücksichtigt, ohne zu erklären, nach welchen Kriterien die Auswahl erfolgte. Metastasenspezifisches Überleben ist weder ein primärer noch ein sekundärer Endpunkt der initialen Studie. Die Analyse erfolgte retrospektiv.</p>
<p>Zu Empfehlung 3.3</p> <p>Keine Literaturstelle kann belegen, dass die DRU in der Früherkennung sinnvoll ist. Im Gegenteil, in der in der aktuellen Leitlinienversion zitierten Literatur, z. B. Mistry et al aus 2003 (!) und Candas et al. 2000 (!) wird eindeutig gezeigt, dass die DRU bei insgesamt schlechten Werten für Sens/Spec/Acc für PSA und DRU der PSA Wertbestimmung deutlich unterlegen ist. Daher muss diese Empfehlung, die ja als „sollte“ Empfehlung (Grad B) erwähnt ist, gestrichen werden.</p>	<p>Bisher handelte es sich um eine „soll“ Empfehlung, da die Kombination aus DRU und PSA die höchste Sensitivität und Spezifität besitzt. Neuroendokrine Tumoren entgingen bei Wegfall der DRU vollständig der Möglichkeit einer „Früherkennung“. Da die gesamte Literatur sich nicht mit dem Kernproblem, nämlich der Frage was bedeutet das DRU-Ergebnis für die Planung zur Therapie (Stichwort: Übertherapie), beschäftigt, halte ich eine Streichung für zu weitreichend. Eine gute Lösung wäre eine „kann“ Empfehlung, diese wurde bei der Konsensuskonferenz diskutiert, die Mehrheit hat sich aber für die "sollte" Empfehlung entschieden. Siehe auch Hintergrundtext zu Empfehlung 3.3.</p>

Kommentar**Zu Empfehlung 3.6**

In der Empfehlung sollte das Wort „weiterhin“ gestrichen werden, denn es impliziert einen negativen Bias bezüglich der Früherkennung.

Antwort

Das Wort „weiterhin“ verdeutlicht, dass es sich um die Situation nach Erhebung eines erstmalig erhöhten PSA-Wertes im Unterschied zur Entscheidungssituation vor einem ersten Screening handelt. Es gibt durchaus Männer, die sich in der Folge gegen weitere Tests entscheiden.

Zu Empfehlung 3.6

b. Die angegebenen „cut-off“ Werte für das Intervall der PSA Untersuchung ab 45 Jahren im Rahmen der Früherkennung sind komplett willkürlich. Die wesentliche Arbeit zur Beantwortung dieser Frage von Lilja und Vickers ist nicht die Arbeit in Cancer 2011 sondern im BMJ aus dem Jahr 2013. In dieser Arbeit sind in einer case-control Studie exakt Männer aus der Population der 45-55 - Jährigen analysiert, die eine Intervalluntersuchung von 6 Jahren hatten. Es konnten im Unterschied zur Cancer Arbeit 2011 nicht 1312 Männer sondern 4922 Männer analysiert werden, für die zwei PSA Werte im Abstand von 6 Jahren vorlagen. Aus dieser Arbeit müssen für die Beratung zur Früherkennung die wesentlichen Schlüsse gezogen werden, nämlich:

1. ein PSA Wert von > 1.6 ng/ml im Alter von 45-49 Jahren bedeutet ein 44%-iges Risiko, einen PCA Tod zu erleiden
2. liegt der PSA Wert mit 45-49 und mit 51-55 unterhalb des Median (0.68 ng/ml bzw. 0.85 ng/ml) besteht ein Risiko, nach 15 Jahren PCA Metastasen zu entwickeln von nur 0.09% mit 45-49 bzw. von 0.28% mit 51-55.

Die Zitation dieser Arbeit hätte also zu völlig anderen Empfehlungen geführt. Daher muss diese wichtige Empfehlung zu den Intervallen komplett überarbeitet werden. Dies vor allem vor dem Hintergrund, dass in Deutschland mit völlig anderen Grenzwerten, die sich nämlich an der BMJ Arbeit orientieren, eine randomisierte Screening-Studie zum risiko-adaptierten Screening stattfindet (www.probase.de).

Die Publikation der Studie erfolgte kurz nach Literaturabschluss, sie wird in den Hintergrundtext integriert. Es ist richtig, dass die Intervalle relativ willkürlich gewählt wurden, nur der Kommentator bleibt eine Aussage zu anderen Intervallen schuldig. Die Grenzwerte sind zur besseren Handhabbarkeit in der Praxis angepasst. Eine solche Empfehlung sollte aber als „Richtschnur“ enthalten sein, trotz der wissenschaftlichen Schwäche (z.B. zu häufige PSA Bestimmung wegen IGeL, forensische Aspekte...)

Zu Empfehlung 3.6

c. Der cut-off, mit < 1 ng/ml die Früherkennung bei Männern über 70 Jahren nicht mehr zu empfehlen ist erneut vollkommen willkürlich gewählt und orientiert sich nicht an der eigens zitierten Literatur. Mit dem Hinweis auf eine allgemein längere Lebenserwartung wird der eigentlich bewiesene cut-off von 60 Jahren komplett willkürlich mit Empfehlungsgrad B auf 70 Jahre angehoben. Dies entspricht nicht einer wissenschaftlichen Interpretation der Literatur.

Die angeführte Arbeit ist keine prospektiv randomisierte Arbeit und muss daher mit einiger Vorsicht betrachtet werden. Außerdem ist die Rekrutierung der Männer mehr als 20 Jahre her. Seitdem ist sehr wohl ein nicht unerheblicher Anstieg der Lebenserwartung gerade in dieser Altersgruppe

Kommentar	Antwort
	<p>zu verzeichnen. Von der Evidenz wäre es sinnvoll, die Aussage zu streichen, damit würden wir uns aber zusätzliche Übertherapien einhandeln, da diese Gruppe von Männern im klinischen Alltag zu häufig untersucht würde und damit auch PCAs auffallen würden, die eine Übertherapie nach sich ziehen.</p>
<p>Zu Empfehlung 3.7</p> <p>Die Empfehlungen zur Indikation zur Biopsie sind so wenig konkret, dass sie nicht als Empfehlungen gelten können. Z. B. ist der „auffällige“ PSA Anstieg nicht definiert. Auch die Öffnung der Biopsieindikation nur aufgrund des Alters in einen undefinierten Raum „niedriger“ PSA Werte triggert eine Überdiagnostik durch Biopsie und PSA. Die für all diese Aussagen zitierte Literatur basiert aus dem Jahr 2002. Um eine Überdiagnose zu vermeiden, sollte der cut-off für die Anstiegsgeschwindigkeit nicht zu tief angesetzt werden. Der „alte“ cut-off von 0.75 ng/ml/a erweist sich trotz der geringen Fallzahl zu seiner Begründung in der Praxis als außergewöhnlich hilfreich.</p>	<p>Die Aussagen sind wenig konkret, aber immerhin konkreter als in anderen Leitlinien: Das Problem ist doch, dass wir es nicht besser wissen. Würden wir uns an den großen RCTs orientieren, müssten wir starr weiter einen Grenzwert von 3-4 empfehlen. Das ist sicher nicht der richtige Weg. Der „auffällige“ PSA-Anstieg ist im Hintergrundtext weiter ausgeführt und bewegt sich zwischen 0,3ng/ml und 1,0ng/ml pro Jahr mit einem „Richtwert“ von ca. 0,5ng/ml/Jahr.</p>
<p>Zu Hintergrundtext zu Empfehlung 3.2</p> <p>Die Aussage, dass die Information über Früherkennung „bei Männern mit erhöhtem Risiko für ein Prostatakarzinom (...) um 5 Jahre vorverlegt werden“ (kann), ist weder literaturbasiert noch nachvollziehbar.</p> <p>Die Risikogruppen sind unklar definiert, auch das familiäre Risiko rechtfertigt keine Früherkennung ab 40 Jahren. Dazu gibt es keine Daten.</p> <p>Entsprechend wird zu diesem Passus auch keine Literatur zitiert.</p> <p>Im Licht der unkritischen Anwendung des PSA Werts in Deutschland sollte auf solche nicht literatur-basierten Aussagen verzichtet werden. Selbst ein Evidenzlevel 4 reicht als Begründung für diese Spekulationen nicht aus sondern triggert einen weiterhin unkritischen Umgang mit dem PSA als sog. „IGE“-Leistung.</p>	<p>Bereits durch das Sondervotum der DEGAM abgedeckt. Es ist richtig, dass keine verlässliche Literatur zum Einstiegsalter zur Früherkennung mit oder ohne Risikofaktoren existiert. Das gilt aber auch für 50 oder 60 Jahre und mündet in die Frage, ob Früherkennung überhaupt sinnvoll ist. Im Vergleich zur alten Leitlinie sind wir konservativer geworden, hier forderten wir die Früherkennung ab 40 Jahren, insofern sind wir der Bitte des Kommentierenden nachgekommen.</p>

Kommentar	Antwort
<p>Zu Hintergrundtext zu Empfehlung 3.3 und Statement 3.4</p> <p>Ich halte die Aussage im Begleittext für das Statement 3.4, es gäbe nicht genügend Evidenz für den Nutzen einer digital-rektalen Untersuchung zur frühen Erkennung eines Prostatakarzinoms, für falsch. Beim Prostatakarzinom gibt es bekanntermassen Karzinome, auch signifikante, die bei Patienten mit „normalem“ PSA auftreten. Diese werden ausschliesslich aufgrund einer auffälligen DRU entdeckt. In einer aktuellen Arbeit wird der Anteil von PCAs mit normalem PSA auf 14-30% beziffert (Palmero et al, 2012), in einer anderen der Anteil mit Gleason Score 8-10 bei normalem PSA auf 0,5% (Hattangadi et al, 2012), in einer dritten Arbeit aus der Catalona-Gruppe wird beschrieben, dass 2/3 der radikal operierten Patienten mit PCa und PSA < 2,5 ng/ml über eine auffällige DRU entdeckt wurden (Meeks et al, 2009). Dazu – zur Häufigkeit des konventionellen PCa im Bereich von PSA < 4 ng/ml - gibt es auch durchaus umfangreiche Literatur. Auch gibt es auch Varianten des Prostatakarzinoms – z.B. neuroendokrine – bei denen der PSA-Wert rein gar nichts zur Diagnose beiträgt und die alle ausschliesslich nur über die DRU überhaupt entdeckt werden können.</p> <p>Bezüglich der fehlenden Evidenz für die DRU widerspricht sich der Begleittext selbst, wenn gleichzeitig angeführt wird, dass die Kombination von DRU+PSA eine höhere Detektionssensitivität habe, als jede dieser Maßnahmen alleine. Auch ist die DRU die einfachste und am wenigsten invasive Methode der Früherkennung für das PCa ist, verglichen mit venöser Blutentnahme, TRUS-Biopsie, MRT-Biopsie. Die DRU nur noch als optional einzustufen, halte ich deshalb für unangemessen. Allerdings gibt es zahlreiche Untersuchungen, die belegen, dass Expertise bei der DRU unverzichtbar ist; diese gehört nicht in die Hand des Ungeübten oder desjenigen, der sie nur gelegentlich durchführt.</p> <p>Grundsätzlich möchte ich anmerken, dass es „gute ärztliche Praxis“ (GCP) ist und bleibt, ein Organ, welches dafür zugänglich ist, abzutasten, wenn man Aussagen zu einer möglichen Erkrankung dieses Organes machen soll. Es ist nicht notwendig, für jede einfache – banale – klinische Untersuchungshandlung Evidenz zu erheben, dass diese das Outcome beeinflusst. So gibt es bei der Allgemeinmedizin keinerlei Evidenz, dass die Auskultation der Lunge die Diagnoserate bei Pneumonien beeinflusst und nicht stattdessen bei Fieber + Husten gleich das Thoraxröntgen erfolgen sollte. Auch wird es keine Studien dazu geben, ob der Einsatz des Stethoskops die Mortalität an der Aortenstenose senken kann. Ich schlage vor, diese Erklärung zur Evidenz für die DRU im Begleittext wegen Unsinnigkeit komplett zu streichen, nach meinen Dafürhalten sollte das Statement auch schlicht ein „soll“ enthalten.</p>	<p>Es wird zwar zu Recht darauf verwiesen, dass durch die DRU PSA-negative Karzinome entdeckt werden können. Allein ein Vorteil hinsichtlich Überlebenswahrscheinlichkeit und Symptomfreiheit durch diese Untersuchung ist nicht belegt – genauso wenig wie ein Überwiegen des Nutzens vor dem möglichen Schaden. Die Ausführungen zeigen wie kontrovers diese Thema gesehen wird und warum wir uns in der Konsensrunde nur auf eine Abstufung von „soll“ auf „sollte“ einigen konnten. Siehe auch Kommentar zu Empfehlung 3.3</p>

Kommentar	Antwort
<p>Zu Empfehlung 3.8 und 3.14</p> <p>Hier fehlen Empfehlungen 3.15 und 3.16 insbesondere für den hausärztlichen Bereich!</p> <p>3.15 (Kontrollen und Umgang mit Patienten, die keine weitere Diagnostik/Therapie wünschen) und</p> <p>3.16 (Patienten, die keine spezifische Therapie wünschen, dann aber manifest erkranken).</p> <p>Was passiert mit den Patienten, die den Hausarzt für eine Zweitberatung aufsuchen nach erfolgter PSA-Bestimmung mit erhöhtem Wert.</p> <p>Da sind hinsichtlich der primären Befundbestätigungen Erklärungen in der aktuellen S3 - die sind zwar ok. Es gibt sogar die schöne Empfehlung 3.14: die gesamte Beratung sollte noch mal von vorne beginnen vor jeder Biopsie. Aber wie es weiter geht, für die Situation, „der Patient wendet sich von der urologischen Praxis ab und will gar nicht oder nur beim Hausarzt kontrolliert werden“, sieht die Leitlinie nicht vor. Hier fehlen Empfehlungen für den Hausarzt. Hier ist die Leitlinie lückenhaft und muss um systematische Recherchen ergänzt werden.</p> <p>Alternativ kann hier eine Erweiterung der Leitlinie (dann nur S1-Niveau) von Seite des Kommentators/der DEGAM angeboten werden.</p> <p>Für die spezielle Fragestellung liegt mindestens eine prospektive randomisierte Studie vor (PIVOT-Studie, in der Leitlinie als Literaturstelle 269 aufgeführt und erläutert).</p> <p>Da ohne Therapie sogar mehr Männer mit einem symptomatischen Prostata-CA in der (Hausarzt!)-Praxis zu erwarten sind, was bei fehlender krankheitsspezifischer Mortalität zu einer Steigerung der Prävalenz in der Hausarztpraxis führt, handelt es sich hier um eine relevante Fragestellung, die Hausärzten, an die sich diese Leitlinie auch richtet, beantwortet werden muss.</p> <p>Als Mitautor der DEGAM -S1- Leitlinie, die jetzt als Anwenderversion ihren ordentlichen Platz im S3 Prozess gefunden hat, bitte ich um Rückmeldung, ob hier die Hausärzte, ggf. mit einer Arbeitsgruppe aus der S3-Autorenschaft eine weitere Anwenderversion - Handlungsempfehlung erstellen, oder ob hier nachgearbeitet wird und eine entsprechende Literaturrecherche erfolgen wird, um dann Empfehlungen 3.15 (Kontrollen und Umgang mit Patienten, die keine weitere Diagnostik/Therapie wünschen) und 3.16 (Patienten, die keine spezifische Therapie wünschen, dann aber manifest erkranken).</p>	<p>Bei der Konsentierung wurden die Empfehlungen zur Früherkennung gemeinsam mit dem Vertreter der DEGAM verabschiedet und entsprechend den Wünschen dieser Fachgruppe adaptiert (durch Einfügen des Wortes „prinzipiell“ und Erläuterungen im Hintergrundtext). Dennoch besteht weiterhin Klärungsbedarf, was sich durch die konkurrierende S1-Leitlinie und das Sondervotum manifestiert. Ein interdisziplinärer Konsens wäre die beste Lösung, da dieser kurzfristig jedoch nicht herbeigeführt werden kann, ist die bisherige Formulierung plus Sondervotum wahrscheinlich die einzig praktikable Lösung.</p>

Kommentar	Antwort
<p>Zu Empfehlung 4.6</p> <p>In der Literatur erweist sich lediglich die sog. Multiparameter-MRT als Hinweis auf eine Verbesserung der Detektionsrate bei der Sekundärbiopsie. Es sollte erwähnt werden, dass dieses Verfahren noch nicht randomisiert gegen die Standard-Re-TRUS PE getestet wurde und alle Ergebnisse vorläufig sind. Wichtig ist, auf die fehlende Standardisierung dieser Methode hinzuweisen und dass sie bis zum Beweis ihrer Effektivität nur im Rahmen von Studien benutzt und empfohlen werden sollte.</p> <p>Schwierig ist in diesem Zusammenhang erneut, dass bei sehr ausführlicher Datenlage die „Aktualisierungs-Recherche“ nur den Zeitraum 10-2007 bis 12-2010 abdeckt und damit nunmehr fast 3.5 Jahre zurückliegt. Falsch ist insbesondere, dass eine „negative MRT dem Patienten eine erneute Biopsie ersparen“ kann. Dies ist spätestens durch die Publikation von Pokorny et al. Eur Urol 2014 widerlegt, denn bei PIRADS Befunden von 1-2 fanden sich 31% Karzinome. Es muss vermieden werden, dass in der Praxis konventionelle MRT Untersuchungen angeordnet und falsch interpretiert werden und damit dem Patienten eine falsch-genaue Sicherheit vermitteln, kein Karzinom zu haben.</p>	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung und wird bei der nächsten Aktualisierung berücksichtigt.</p>
<p>Zu Empfehlung 4.7/4.8</p> <p>Die „diffusionsgewichtete MRT“ ist ein inkorrekt Begriff. Korrekt muss auf die Kombination von T2 Wichtung, Diffusion und Kontrastmittelverhalten (sog. Multiparameter MRT) in der Definition der ESUR hingewiesen werden. Eine PI-RADS Auswertung ist hier zwingend und erfordert nicht nur ein Diffusions-MRT. Insofern ist die getrennte Auflistung von KM MRT und Diffusions-MRT in den Punkten 4.7 und 4.8 nicht nachvollziehbar. Auch hier fehlt die aktuelle Literatur, denn es werden lediglich Literaturstellen bis 2007 zitiert. Danach setzte aber erst die systematische Evaluation dieser Technik ein (s. u. a. Röthke et al., PI-RADS classification: structured reporting for MRI of the prostate).</p>	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung und wird bei der nächsten Aktualisierung berücksichtigt.</p>
<p>Zu Empfehlung 4.7/4.8</p> <p>Wenn MRT, dann bitte erwähnt als multiparametrisches MRT mit PI-RADS Dokumentation. Betreffend MRT wäre eine Aktualisierung erforderlich. Die Angaben beziehen sich in der Leitlinie auf die Literatur Seite 54 bis 2010. Dies ist überholt!</p> <p><i>PI-RADS -Klassifikation: Strukturiertes Befundungsschema für die MRT der Prostata Fortschr Röntganstr. 2013; 185(3): 253-261</i></p>	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung und wird bei der nächsten Aktualisierung berücksichtigt.</p>

Kommentar	Antwort
<p>Zu Empfehlung 4.13</p> <p>Womit ist die MRT / CT Untersuchung bei Gleason 8 Karzinomen gerechtfertigt? Die „accuracy“ zur Beurteilung des lokalen Tumorstadiums ist so gering, dass darauf kein Therapiewechsel basiert werden kann. Im Gegenteil, eine multimodale Therapiestrategie bei z. B. fraglichen LK Vergrößerungen oder T3 / SV+ Verdacht ist hilfreich und keineswegs sollte eine Operation außer acht gelassen werden, wenn ein solches klinisches Stadium vorliegt. Es ist nicht zielführend, wenn im Erklärungstext angeführt wird, dass aufgrund dieser Problematik nur eine „schwache Empfehlung“ ausgesprochen wird, denn dies führt in dieser Konsequenz zu einer erheblichen Verzerrung in der präoperativen Diagnostik und damit fragwürdigen Therapieentscheidungen.</p>	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung. Die Unsicherheiten sind durch die Formulierung „sollte“ abgebildet, es handelt sich um keinen Standard. Auch die Formulierung „in Abhängigkeit von der Fragestellung“ deckt die in diesem Kommentar aufgeworfenen Fragen ab.</p>
<p>Zu Empfehlung 4.22</p> <p>„vierprozentigen Formaldehyds“ Oder „zehnprozentigen Formalins“</p> <p>„Formalin“ ist eine gesättigte Lösung von Formaldehyd. Sie enthält etwa 40 Anteile Formaldehyd und wird 1:10 verdünnt!</p>	<p>Textvorschlag wurde übernommen und konkretisiert.</p>
<p>Zu Empfehlung 4.22</p> <p>Entspricht nicht mehr der geübten Praxis. Beim Schnellschnittgesteuerten Nervesparing bde. Werden Prostatarandscheiben zum Schnellschnitt eingeschickt und nicht mehr das ganze Präparat (Neurose Verfahren).</p>	<p>Der Hintergrundtext zur Empfehlung wurde dahingehend spezifiziert. Bei der nächsten Aktualisierung wird das aufgenommen.</p>
<p>Zu Empfehlung 4.23</p> <p>Besonders in histopathologischen Paragraphen erwartet man eine exakte Nomenklatur. Das Wort „gewöhnlich“ ist für die pathologische Charakteristik eines PCA unangebracht. Der Autor meint wahrscheinlich Adenokarzinom.</p>	<p>Der Textvorschlag wurde übernommen und konkretisiert. Das azinären Adenokarzinom der Prostata ist in 95 % der Fälle das gewöhnliche Karzinom der Prostata.</p>
<p>Zu Empfehlung 4.29</p> <p>Wie wird das verbalisiert?</p> <p>G1 Hoch differenziertes Adenokarzinom G2 Mittelgradig differenziertes Adenokarzinom G3 Niedrig differenziertes Adenokarzinom</p> <p>Ohne Präzisierung wird in den Diagnosen stehen bleiben „Mäßig differenziertes Adenokarzinom G1“. Was wird aus Gleason 7a / 7b?</p>	<p>Die Autoren teilen den Pessimismus nicht und halten jeden Pathologen für fähig, die Verbalisierung G1=gut/hoch, G2=mäßig, G3=schlecht/wenig differenziert fehlerfrei vorzunehmen. Es ist korrekt, dass Gleason Score 3+4 oder 4+3 beide als G2 betrachtet werden.</p>

Kommentar	Antwort
<p>Zu Empfehlung 4.32</p> <p>Tumurlänge in der Stanze ist einfacher. Was ist gemeint (Beispiel): „1. ...(Gleason 3: 10%, Gleason 4: 5%, Gleason Tertiär 1%), 2. ...(Gleason 3: 15%, Gleason 4: 20%, Gleason Tertiär 10%), etc.“? Gehen diese Angaben rechnerisch in den Gesamtscore ein? Wie geht das? Bezieht sich die Gesamtangabe auf die Gesamtlänge aller Stanzen? Bitte führen Sie ein konkretes Beispiel an!</p> <p>Der Text ist vollständig interpretationsfähig und wird nicht zu einer einheitlichen Formulierung führen.</p>	<p>Der Hintergrundtext zur Empfehlung wurde dahingehend spezifiziert. Bei der nächsten Aktualisierung wird das aufgenommen.</p>
<p>Zu Hintergrundtext zu Empfehlung 4.31</p> <p>(in 4% Formaldehyd)</p> <p>„Formalin“ ist eine gesättigte Lösung von Formaldehyd. Sie enthält etwa 40 Anteile Formaldehyd und wird 1:10 verdünnt!</p>	<p>Textvorschlag wurde übernommen und konkretisiert.</p>
<p>Zu Hintergrundtext zu Empfehlung 4.37 und 4.38</p> <p>Wie geht das am Resektat? Wie soll daran die maximale T-Kategorie bestimmt werden? Bitte Beispiel!</p>	<p>Die Kritik ist berechtigt, da am TUR-Material nie die maximale pT-Kategorie festgelegt werden kann, sondern nur die "T-Kategorie (ohne "p") - da es per definitionem eine pT1-Kategorie nicht gibt. Hier wird der Hintergrundtext korrigiert.</p> <p>Es widerspricht dabei gängiger Praxis, immer die vollständige Einbettung zu fordern. Auf diese kann m.E. verzichtet werden, wenn a) bereits ein großer Anteil des Gewebes eingebettet wurde, und b) es sich hier nur sehr wenige tumortragende Späne fanden, es somit also äußerst unwahrscheinlich ist, dass auch bei vollständiger Einbettung die 5%-Grenze überschritten wird. Finden sich bereits bei der ersten Einbettung deutlich > 5% tumortragender Gewebespäne ist ebenfalls unwahrscheinlich, dass sich dieser Prozentsatz durch eine vollständige Einbettung ändert. Ganz sicher ist man natürlich nur nach vollständiger</p>

Kommentar	Antwort
	Einbettung des Materials. Ein gewisser Ermessensspielraum ist aber durch die Formulierung der Empfehlung 4.38 sicher gegeben ("soll das Restmaterial komplett eingebettet werden, falls dies therapeutische Konsequenzen hat.")

Zu Empfehlung 5.1

Letzten Satz streichen (gilt analog und mit derselben Begründung für Empfehlung 5.7); Der Satz suggeriert in diesem Zusammenhang, nur Patienten, die die in der Leitlinie definierten AS-Kriterien erfüllen, sollten über das Konzept der verzögerten Intervention aufgeklärt werden. Das ist aus juristischer Sicht nicht haltbar. Das Patientenrechtegesetz schreibt in §630e vor, auch über Behandlungsalternativen aufzuklären. Die in der LL definierten Kriterien für AS basieren auf einem Expertenkonsens. In den AS-Kohorten differieren die Kriterien erheblich, ohne dass sich Unterschiede in den Outcomes zeigten. Die Studien, auf denen die Empfehlungen für AS beruhen, schließen also z.T. auch Patientengruppen, für die in der S3-LL keine AS empfohlen wird, für die sich aber aus Studien AS als Behandlungsalternative herleitet. (Dall’Era 2012, Ip 2012). Zudem sind selbst in der aktuell in Deutschland rekrutierenden PREFERE-Studie andere Einschlusskriterien definiert, was zeigt, wie uneinheitlich die Auffassung von der AS-Eignung national und international ist. Angesichts der erheblichen Unterschiede in den Interventionsrisiken ist der Ausschluss von Patientengruppen von der Aufklärung über AS nicht haltbar. Die Pflicht zur Aufklärung über konservative Therapien belegt auch das Urteil des OLG Naumburg vom 8.11.2012, AZ 1U62/12.

Die Empfehlung schließt die Aufklärung aller Patienten über alle Optionen ein. Die Aussage dass auch über die Kriterien der Aktiven Überwachung aufgeklärt werden soll bedeutet nicht, dass nur Patienten mit diesen Kriterien aufgeklärt werden sollen.

Zu Empfehlung 5.4

... gegen die Risiken der Aktiven Überwachung (Active Surveillance) abgewogen werden.

Unerwünschten Therapiefolgen einer kurativen Intervention sind mit hohem Evidenzgrad belegt und werden im Hintergrundtext zu 5.4 entsprechend zitiert. Als Schaden für AS ist belegt: Erhöhte ED-Rate durch wiederholte Biopsien, ARI 10% (Fujita 2010). Uneinheitliche Ergebnisse gibt es zu psychischer Belastung unter AS, wobei einige (u.a. Litwin 2002) eher auf ein höheres Ausmaß an Belastung unter AS hinweisen, die anderen hingegen keine Unterschiede beobachten (u.a. Punnen 2013, van den Bergh 2012, 2010, 2009, Burnett 2007, Steineck 2002). In der gesamten Literatur gibt es KEINEN Beleg für einen Schaden durch zu spät erkannten Progress. Es gibt Daten aus nicht vergleichenden Kohorten, die RP-Resektate untersuchen und bei Patienten mit präoperativ festgestellten AS-Einschlusskriterien postoperativ teilweise upstaging und upgrading beobachten (u.a. Suardi 2008, 2010).

Auch wenn die prognostische Bedeutung eines zu spät erkannten Progresses schwer zu belegen ist, ist eine Aufklärung über dieses Risiko zwingend. Eine Nicht-Information der Patienten über dieses Risiko ist in Anbetracht der verfügbaren Therapiealternativen keine Option.

Kommentar	Antwort
<p>Hier fehlt jedoch der Vergleich, zudem untersuchen die Studien Surrogate. In vergleichenden Kohorten konnte jedoch gezeigt werden, dass eine um 2,6 bzw. 2,9 bzw. 3,9 Jahre verzögerte Intervention nicht mit schlechteren Ergebnissen verbunden ist als die sofortige (van den Bergh 2013; Warlick 2006, van den Bergh 2010, Shappley 2009, Holmström 2010;). Und zwar trotz Selektionsbias, der eigentlich für einen Nachteil der verzögert operierten Gruppe spricht, da nur solche Patienten aus einem AS-Kollektiv verzögert operiert worden waren, die Anzeichen von Progress aufwiesen, während in der Gruppe der sofort Operierten alle, auch die mit günstiger Prognose, eingeschlossen wurden. Eine vergleichende Studie, die einen Vorteil zugunsten der sofortigen Intervention zeigt (O'Brien 2011), ist unausgewogen und statistisch anfällig, da aus einem Kollektiv von 1.111 Patienten nur 59 verzögert operiert worden waren aber 1.052 sofort.</p> <p>Der Hintergrundtext zu Empfehlung 5.4. erläutert zudem mit keinem Wort und keinem Beleg die Formulierung „Risiko einer nicht rechtzeitigen Behandlung im Falle einer Strategie der Aktiven Überwachung“, sondern betont vielmehr, dass im Vergleich der patientenrelevanten Outcomes keine Unterlegenheit der AS besteht. Weder aus dem eigenen Hintergrundtext, noch aus der vorhandenen Literatur ist die aktuelle Formulierung herzuleiten.</p>	

Zu Empfehlung 5.5

Fakt ist, dass keine prospektive randomisierte Studie jemals die therapeutische Gleichwertigkeit der radikalen Prostatektomie und der Strahlentherapie gezeigt hat; trotzdem werden in der Leitlinie beide Behandlungsverfahren praktisch gleichgesetzt.

Gleichzeitig positioniert die Leitlinie die radikale Prostatektomie und die Strahlentherapie als primär alternative Behandlungsoptionen. Sie berücksichtigt dabei nicht die Möglichkeit einer sequentiellen multimodalen kombinierten Therapie von Operation und Strahlentherapie. Diese Therapiestrategien sind bei kolorektalen Tumoren und beim Mammakarzinom heute selbstverständlich. Entsprechend sollten die Patienten über die unterschiedlichen Möglichkeiten einer adjuvanten oder Salvage Therapie nach Operation bzw. Bestrahlung aufgeklärt werden. Dies gilt gerade für die Patienten mit Hochrisikotumoren bzw. „very high risk“ Karzinomen.

In diesem Zusammenhang müssen Patienten auch über die individuelle Wertigkeit der Primärdiagnostik aufgeklärt werden. Insbesondere die Wahrscheinlichkeit eines Upgradings des Gleason Scores nach einer Substandard- bzw. Standard 12 TRUS gesteuerten transrektalen Biopsie.

Hier werden die Verfahren nicht als gleichwertig postuliert, lediglich die Aufklärung über beide Verfahren wird empfohlen. Das schließt die Aufklärung über ggf. multimodale Konzepte im individuellen Ansatz ein. Zur Verdeutlichung wurde im Hintergrundtext ein Satz zur Aufklärung über mögliche multimodale Therapiekonzepte ergänzt.

Kommentar	Antwort
<p>Zu Empfehlung 5.6</p> <p>Wichtig ist für die Beratung der Patienten die statistische Lebenserwartung. Der aufgeführte Charleston Score und ASA hilft einem nur bedingt weiter. Hier fehlt der Hinweis auf die aktuellen Sterbetafeln, bzw. online Internet basierte Tools (Sterbetafel des Statistischen Bundesamt Wiesbaden, Lebenserwartungsrechner der DIA (Denkfabrik für Altersvorsorge))</p> <p>Je genauer die Grundlage, gerne auch mit dem Charleston Score, desto unterschiedlicher die Lebenserwartung (Siehe "Lebenserwartung berechnen" von gesundheit.ch).</p>	<p>Die Empfehlung wurde bewusst schwach formuliert, um das Fehlen einer allgemein akzeptierten und für alle Fragen anwendbaren Komorbiditätsklassifikation in Rechnung zu stellen. Die ASA-Klassifikationen und der Charlson-Score wurden beim Prostatakarzinom mehrfach untersucht und werden in der aktuellen EAU-Leitlinie genannt. Daher wurde Konsens erzielt, diese beiden Klassifikationen zu erwähnen. Zusätzlich sind Komorbiditäten nur ein Faktor in der Beurteilung der wahrscheinlichen Lebenserwartung. Die Sterbetafeln und der Lebenserwartungsrechner der DIA sind sinnvoll zur Beurteilung der Lebenserwartung, berücksichtigen aber keine Komorbiditäten.</p>
<p>Zu Empfehlung 5.8</p> <p>Diese Empfehlungen entsprechen dem sog. Low risk Tumor in der NCCN Leitlinie. Die Integration von der Anzahl der befallenen Stenzen und der sog. Cancer Core Length ist sehr problematisch, da es davon abhängig ist, ob die Stanze den Tumor direkt in der Mitte trifft, bzw. ob es der Zufall will, dass ich bei der multifokalen Erkrankung zufällig noch weitere Ca Anteile treffe. Deshalb lieber nicht mit aufführen (siehe ANHANG)</p>	<p>Die Unsicherheiten in der Datenlage zur aktiven Überwachung sind im Hintergrundtext erwähnt. Die Kriterien für eine aktive Überwachung wurden sehr kontrovers diskutiert, ein Konsens war nur durch enge Anlehnung an vorhandene Empfehlungen erzielbar. Bei Vorliegend signifikanter neuer Evidenz können die Kriterien jederzeit aktualisiert werden.</p>
<p>Zu Empfehlung 5.10</p> <p>Bei Verschlechterung des Malignitätsgrades oder Verkürzung des PSA-DT auf weniger als drei Jahre oder bei lokaler Symptomatik soll zu einer Beendigung der Aktiven Überwachung geraten werden.</p> <p>Es gibt keine Evidenz und auch keine Plausibilität, dass ein asymptomatischer lokaler Progress bei gleichbleibenden Gleason Score und PSA-DT über 3 J einen Abbruch der Überwachung indiziert. Ziel einer Intervention ist entweder, eine Metastasierung zu</p>	<p>Ein symptomatischer Progress ist Hinweis auf ein fortgeschrittenes, dann nicht mehr heilbares Karzinom und fällt nicht unter den Begriff der aktiven Überwachung (es würde sich um ein „Watchful Waiting“ mit symptomorientiert-palliativer Intention handeln. Die fehlende Evidenz zur akti-</p>

Kommentar	Antwort
<p>verhindern oder durch das lokale Tumorstadium entstandene Beschwerden zu lindern. Lokaler Progress bei Gleason Score 6 stellt kein Risiko für Metastasierung dar (Ross 2012). Tumorumfängen als Einschlusskriterium für AS geht auf die alten Arbeiten von Epstein zurück, in denen er durch die Kombination der D'Amico-Kriterien und Tumorumfängen sogenannte insignifikante Tumore zu identifizieren versuchte, also Tumore, die nach klinischen Kriterien sicher als nicht progredient diagnostiziert werden können und daher keiner Überwachung bedürfen. Epstein selbst geht inzwischen dazu über, dem lokalen Tumorstadium geringe Bedeutung für AS-Fähigkeit zuzumessen, Johns Hopkins erweitert aktuell sogar seine Einschlusskriterien bezüglich Tumorumfängen (Reese, 2013).</p>	<p>ven Überwachung erlaubt gerade keine Aufweichung der Empfehlungen, da die fehlende Datenlage kein Beleg für die Sicherheit der aktiven Überwachung ist.</p>
<p>Zu Empfehlung 5.10</p> <p>Bei aller Vorsicht in der Anwendung der Aktiven Überwachungsstrategie sollte ein Therapiewechsel hin zu einer aktiven Therapie ausschließlich durch Nachweis eines histopathologischen Progress begründet werden (oder Wunsch des Patienten). Ein PSA Anstieg ist die Indikation zu dieser Re-Biopsie, kann jedoch kein alleiniger Grund für einen Therapiewechsel darstellen. Diese Empfehlung entbehrt jeder Logik und der Expertenkonsens sollte hier literaturbegründet sein. Diese zeigt aber keinen Hinweis auf die Richtigkeit der Empfehlung, vielmehr würde diese Empfehlung bei vielen BPH Patienten oder Patienten mit einer Prostatitis unter Überwachungsstrategie zu einer Operation oder Bestrahlung führen.</p> <p>Die Empfehlungen zum Abbruch sollten nicht den Empfehlungen der bundesweiten PREFERE Studie widersprechen. Diese sieht ebenfalls keinen Abbruch der AS nur aufgrund eines PSA Wert Anstiegs vor.</p>	<p>In Anbetracht der schwierigen Konsensfindung bei der Frage der aktiven Überwachung ist davon auszugehen, dass eine solche Aufweichung der Empfehlung keinen Konsens erzielen wird. Die Empfehlungen der Leitlinie schließen die Durchführung von Studien zur Überprüfung der Empfehlungen keinesfalls aus. Die Anpassung der Leitlinie an Studieneinschlusskriterien ist jedoch nicht möglich.</p>
<p>Zu Empfehlung 5.9</p> <p>Die Leitlinie stimmt nicht überein mit den neuesten Empfehlungen der NICE Leitlinie, die zu Beginn der Integration in die Active Surveillance Gruppe ein mpMRT empfiehlt und vor Biopsiekontrolle und/oder PSA Anstieg ebenfalls. Hierzu auch Empfehlung 4.11 (Patienten mit Tumorkategorie cT1 und low-risk-Parametern sollten keine bildgebenden Untersuchungen zum Staging (Sonografie, MRT, PET/CT) erhalten.)beachten</p>	<p>Die NICE-Leitlinie ist nach Anschluss der Konsentierung erschienen. Bei der anstehenden erneuten Aktualisierung steht die Rolle des MRT auf der Agenda. Die neuen Daten inklusive der NICE-Leitlinie werden dann einfließen.</p>
<p>Zu Empfehlung 5.13</p> <p>Streichen: Seit Verabschiedung dieser Formulierung haben sich die Anforderungen an Patienteninformation und Aufklärung auch auf gesetzlicher Grundlage geändert. Das Patientenrechtegesetz formuliert in §630c und 630e eindeutig die informations- und Aufklärungspflichten des Arztes bezüglich jeder Intervention. Ziel 11a des Nationalen Krebsplans definiert zudem die für Krebserklärung verbindlichen Anforderungen an Risikokommunikation.</p>	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung. Verzicht auf Aufklärung ist keine Option. In Anbetracht der wenigen randomisierten Studien zum frühen Prostatakarzinom erscheint eine Information der Patienten über die skandinavische Stu-</p>

Kommentar	Antwort
<p>In der aktuellen Formulierung ist der tatsächliche Effekt der Intervention nicht abzuschätzen, wie es lt. Ziel 11a NKP gefordert wird. Eine patientenverständliche Risikokommunikation auf der Basis der Bill-Axelson-Daten (2014) müsste lauten: „von 100 operierten Patienten waren nach 23 Jahren 18 Männer an Prostatakrebs gestorben. Ohne Operation waren es 29. Von 100 operierten Männern waren 80 langfristig impotent. Ohne Operation waren es 40.“ (Angaben Impotenz nach Holmberg 2013). Zudem müssen Patienten darüber informiert werden, dass es sich bei den eingeschlossenen Patienten um Männer mit klinisch auffälligen Prostatakarzinomen und teilweise hohem Risikoprofil handelte (PSA-Werte bis 50, Gleason bis 9), dass in dieser Studie ein Nutzen nur für Männer unter 65 Jahren beobachtet werden konnte und dass Watchful Waiting keine in der Leitlinie empfohlene Alternative für Männer ist, die für eine kurative Intervention in Frage kommen. Das sind sehr komplexe Inhalte, die viel Zeit zur Vermittlung brauchen und zudem geschulte Ärzte, denn auch viele Ärzte sind nicht in der Lage, Risiken korrekt einzuordnen und verständlich zu kommunizieren (Wegwarth, Gigerenzer 2012 & 2013). Vor diesem Hintergrund wird vorgeschlagen, die Empfehlung zur Aufklärung komplett zu streichen, da sie in der aktuellen Formulierung den gültigen Anforderungen nicht genügt.</p>	<p>die sinnvoll, wobei die Interpretation der Daten vorsichtig erfolgen sollte. Dem wird in der Empfehlung Rechnung getragen.</p>
<p>Zu Empfehlung 5.17</p> <p>Die Grad A Empfehlung für Mindestmengen entbehrt jeder Datenlage. Würde man sich an den publizierten Daten orientieren, müssten z. B. 75 radikale Prostatektomien pro Operateur und Jahr durchgeführt werden, um eine signifikante Verbesserung des BCR zu erreichen (MSKCC Daten). Die gewählten Grenzwerte sind willkürlich und orientieren sich an den DKG-Kriterien, die aber aus völlig anderen Gründen etabliert wurden. In einer Leitlinie kann man keine literatur-naiven Daten für eine solch problematische Situation empfehlen.</p>	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung. Möglicherweise sind höhere Mindestmengen medizinisch begründbar, jedoch nicht konsensfähig.</p>
<p>Zu Empfehlung 5.19</p> <p>Es fehlt die Erwähnung der inzwischen etablierten IMRT und IGRT Strahlentherapieverfahren. Es fehlt auch ein Hinweis auf die mögliche Gold Seeds Markierung vor IGRT.</p>	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung. IMRT und IGRT sind im Hintergrundtext erwähnt. Die Frage der Gold-Seeds wird bei der nächsten Aktualisierung berücksichtigt.</p>
<p>Zu Statement 5.25</p> <p>Die Protonentherapie kann alternativ zur konventionellen Strahlentherapie beim lokal begrenzten Prostatakarzinom angewendet werden.</p> <p>Die Protonentherapie ist eine von außen über die Haut auf den Patienten treffende Strahlenform mit einer ähnlichen biologischen Wirksamkeit (RBE 1,1) wie herkömmlich eingesetzte Photonen</p>	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung. Die gegenwärtige Datenlage lässt es unwahrscheinlich erscheinen, dass eine solche Empfehlung konsensfähig wäre. Die weitere Entwicklung wird ständig geprüft und ggf.</p>

Kommentar	Antwort
<p>(RBE 1,0). Die verwendeten Dosiskonzepte sind ähnlich denen der konventionellen Strahlentherapie. Im Gegensatz zu Photonen, die den gesamten Körper durchdringen, geben Protonen ihre maximale Energie am Ende ihrer Reichweite ab, die moduliert werden kann. Hinter dem Dosismaximum fällt keine weitere Strahlung an, so dass Normalgewebe besser geschont werden kann und ggf. Dosis-Eskalationen leichter umgesetzt werden können. Beide Strahlenarten wirken vorwiegend über Ionisationseffekte an den Zellen (DNA-Schäden). Die Strahlenbehandlung der Prostata geht mit einer Belastung von Risikoorganen wie Harnblase, Hüftköpfe und Rektum einher und kann Toxizitäten verursachen. Bei der Verwendung von Protonen resultiert eine geringere integrale Strahlenbelastung dieser Organe, so dass eine gute Verträglichkeit der Therapie erwartet und evtl. die Nebenwirkungen reduziert werden können.</p> <p>In der Vergangenheit war eine Protonenstrahlung nur an Forschungsanlagen möglich. Erstmals wurden Protonen 1954 am Menschen eingesetzt. 1990 wurde in Loma Linda, Kalifornien, USA eine Anlage rein für medizinische Anwendungen in Betrieb genommen. Seit den 90-er Jahren wurden über 3000 Patienten mit lokalisiertem Prostatakarzinom mit Protonen bestrahlt (Loma Linda, Jacksonville, Boston). Publierte Daten aus diesen Zentren zeigen sehr niedrige Raten von Spät-Nebenwirkungen. Eine Studie durchgeführt in Loma Linda, USA mit 1255 Prostatakarzinom-Patienten, die von 1991 bis 1997 mit Protonen allein oder in Kombination mit Photonen bestrahlt wurden ergab sehr geringe Grad 3 und 4 Toxizitäten. [1]. In einer neueren Arbeit hat man einen Zeitraum von 5 Jahren an 3 prospektive Studien ausgewertet. Nach einer 5-jährigen Nachsorgezeit der Prostatakarzinom-Patienten, welche mit Protonen bestrahlt wurden, war die Rate schwerer Toxizitäten (Grad 3) sehr niedrig; 0.5% der Patienten litten unter gastro-intestinalen Beschwerden und lediglich 1.0% Urin- und Miktionsbeschwerden. Es konnte in o.g. Studie gezeigt werden, dass diese Gruppe von 211 Männern 4 Jahre nach der Protonentherapie keinen Unterschied bemerkten hinsichtlich Stuhl, Urin oder Harnblasenfunktion im Vergleich zu der Zeit vor der Behandlung [2].</p> <p>In einem Vergleich dreier Studien unterschiedlicher Dosiskonzepte an Patienten der verschiedenen Risikogruppen wurden von August 2006 bis September 2007 an 211 Patienten Dosen zwischen 78-82 CGE appliziert. Die Hoch-Risikogruppe erhielt simultan eine wöchentliche Chemotherapie mit Docetaxel 20 mg/qm/KOF. Das progressionsfreie Überleben nach 2 Jahren lag bei 100 % für die Niedrig-Risiko Gruppe, bei 99 % für Gruppe des mittleren Risikos sowie 94 % für die Hochrisiko-Gruppe. Hinsichtlich der Nebenwirkungen gab es nach einem Zeitraum von 2 Jahren lediglich einen Fall mit CTC Grad 3 gastrointestinalen Reaktion und 4 Patienten mit Grad 3 genitourinärer Problematik. Hinsichtlich der Grad 2 gastrointestinalen Nebenwirkungen lagen diese nach 6, 12, 18 und 24 Monaten bei 0%, 5 %, 6% und 4 %</p>	<p>bei den anstehenden Aktualisierungen berücksichtigt.</p>

Kommentar	Antwort
<p>entsprechend einer kumulativen Inzidenz von 10 % nach 2 Jahren. Die Grad 2 Symptome rektale Blutung und Proktitis waren mit dem prozentualen Anteil der Rektumwand, welche Dosis zwischen 40-80 CGE erhalten hatte, vergesellschaftet. Die Nebenwirkungen in dieser Studie wurde nach CTCAE, v. 3.0) erfasst. Zur Einschätzung der Lebensqualität wurde eine Erfassung mittels EPIC, IPSS, IEFF-5 und IEFF-5m durchgeführt [3].</p> <p>Beim Prostatakarzinom wird von einer Dosis-Wirkungsbeziehung ausgegangen, was zu Bestrebungen geführt hat die Dosis zu erhöhen um die lokale Kontrolle zu verbessern. Verschiedene randomisierte Studien hatten einen Vorteil einer Dosisescalation auf 78-79 Gy für die externe Strahlentherapie beim lokal begrenzten Prostatakarzinom nachgewiesen [4]. Daten einer Einzelinstitution (Boston) lassen einen Vorteil einer weitergehenden Dosisescalation vermuten. In der Studie 03-12 des American College of Radiology wurde in einer Phase II-Studie an 84 Patienten die Sicherheit und Effizienz einer Dosis von 82 CGY appliziert mittels einer konformalen Strahlentherapie unter Verwendung von Protonen überprüft. Bei einem Beobachtungszeitraum von 31,6 Monaten traten hinsichtlich der Akuttoxizitäten vorwiegend Grad 1 (46%) und Grad 2 (23%) Toxizitäten auf, sowie 2% Grad 3-Toxizität. Hinsichtlich der Langzeit-Toxizität lag die Rate für Grad 1 Toxizität bei 33% und bei 26 % für Grad 2, sowie 8% Grad 3+4 Toxizitäten mit einem Fall einer Grad 4 Toxizität. Die Rate an Grad 3 und 4 Toxizität wird nach einem Zeitraum von 18 Monaten auf 6,08% geschätzt. Das Ziel der Studie war, zu überprüfen ob mit einer Strahlentherapie im genannten Dosisbereich eine Langzeit-Nebenwirkungsrate unter 10 % zu erreichen ist. Die erfassten Morbiditäten lassen die Autoren zu dem Schluss kommen dass eine Dosis von 82 GyE mit einer Einzeldosis von 2 GyE die vermutlich höchste mit Protonen sicher zu applizierende Dosis ist [5]. Ein unerwünschtes Begleitphänomen einer jeglichen Strahlentherapie ist eine mögliche Induktion von Zweitkarzinomen, so dass gefordert wird, die Strahlenbelastung von Normalgewebe so gering als möglich zu gestalten um diese Wahrscheinlichkeit zu minimieren. Auf Grund der geringeren Strahlenexposition von Normalgewebe kann das Risiko für eine Zweittumorentstehung nach einer Protonentherapie als niedriger eingeschätzt werden. Eine theoretische Studie aus MD Anderson Cancer Centre hat gezeigt, dass die Protonentherapie aufgrund der reduzierten Strahlenbelastung von Darm, Harnblase und Knochenmark, insbesondere im mittleren und Niedrigdosis-Bereich im Vergleich zur konventioneller Photonentherapie das theoretische Risiko von Zweittumoren um 26% senken kann bei Verwendung der spot-scanning-Technik [6].</p> <p><i>Literatur</i> 1. Jerry D. et al <i>Int J Radiat Oncol Biol Phys</i>, 2004; 2. N. P. Mendenhall, et al <i>Int J Radiat Oncol Biol Phys</i>, 2014; 3. Nancy P. et al <i>Int J Radiat Oncol Biol Phys</i>, 2012; 4. Anthony L. et al <i>JAMA</i> 2005; 5. John J. Coen, et al <i>Int J Radiat Oncol Biol Phys</i>, 2012; 6. Jonas D. et al <i>Int J Radiat Oncol Biol Phys</i>, 2009.</p>	

Kommentar	Antwort
<p>Zu Empfehlung 5.33</p> <p>Bei Patienten mit Prostatakarzinom und einem niedrigen Risiko (cT1c und PSA <10 und Gleason \leq 6) kann eine Lymphadenektomie nicht empfohlen werden</p> <p>Gleason 6-Karzinome metastasieren nicht. Die geringe Rate nachgewiesener Metastasen von 0,26% bzw. 0,03% ist auf die histologische Einschätzung zurückzuführen und darf nicht zu einer präventiven Ausweitung des Eingriffs (radikale Prostatektomie) führen (Ross et al Am J Surg Pathol 2012). Die Komplikationen der pLA sind im Hintergrundtext der Leitlinie gewürdigt.</p>	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung. Die Formulierung ändert inhaltlich wenig (kann-Empfehlung)</p>
<p>Zu Statement 5.34</p> <p>Je ausgedehnter die Lymphadenektomie durchgeführt wird, desto höher ist die Rate an nodal positiven Befunden. Dies ermöglicht ein exaktes Staging sowie die frühe Einleitung einer adjuvanten Therapie bei nachgewiesenen Lymphknotenmetastasen. Eine mögliche Alternative für ein exaktes Lymphknotenstaging stellt die gezielte Entfernung der sogenannten Sentinel-Lymphknoten, den ersten Lymphknoten im Lymphabstromgebiet der Prostata, dar. Die sLND verfolgt das Ziel, die mögliche Morbidität einer extendierten Lymphadenektomie zu reduzieren und dabei trotzdem eine hohe Sensitivität im Metastasenachweis sicherzustellen.</p> <p>Inzwischen liegen Ergebnisse zur sLND beim Prostatakarzinom von mehreren Tausend Patienten vor, welche eine sehr hohe Zuverlässigkeit des Verfahrens im Nachweis von Lymphknotenmetastasen zeigen konnten [1-6]. So ergaben sich für die sLND in einer Metaanalyse von Sadeghi et al. [7] eine gepoolte Detektionsrate von 93,8% und eine gepoolte Sensitivität von 94%. Die zielgerichtete sLND bietet dabei den Vorteil, dass im Vergleich zur extendierten Lymphadenektomie nur wenige Lymphknoten entfernt werden müssen und deshalb auch von einer geringen Morbidität auszugehen ist [8]. Aus den genannten Gründen wurde die sLND von den Europäischen Leitlinien bisher auch als Alternative zur extendierten Lymphadenektomie angesehen und findet dort auch aktuell (2014) Erwähnung (LE3).</p> <p><i>Literatur: 1. Wawroschek F, et al J Urol 2001; 2. Wawroschek F et al Eur Urol 1999; 3. Holl G et al Eur J Nucl Med Mol Imaging 2009; 4. Joniau S et al Eur Urol 2013; 5. Winter A et al Int J Urol 2014; 6. Rousseau C et al J Nucl Med 2014; 7. Sadeghi et al Nuklearmedizin. 2011; 8. Winter A, et al Aktuelle Urol 2011;</i></p>	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung, wird bei der nächsten Aktualisierung berücksichtigt.</p>

Kommentar	Antwort
<p>Zu Empfehlung 5.35</p> <p>Wird die Lymphadenektomie durchgeführt, so sollten mindestens zehn Lymphknoten entfernt werden bzw. alternativ Sentinel gesteuert lymphadenektomiert werden.</p> <p>Inzwischen liegen Ergebnisse zur sLND beim Prostatakarzinom von mehreren Tausend Patienten vor, welche eine sehr hohe Zuverlässigkeit des Verfahrens im Nachweis von Lymphknotenmetastasen zeigen konnten [1-6]. So ergaben sich für die sLND in einer Metaanalyse von Sadeghi et al. [7] eine gepoolte Detektionsrate von 93,8% und eine gepoolte Sensitivität von 94%. Die zielgerichtete sLND bietet dabei den Vorteil, dass im Vergleich zur extendierten Lymphadenektomie nur wenige Lymphknoten entfernt werden müssen und deshalb auch von einer geringen Morbidität auszugehen ist [8]. Aus den genannten Gründen wurde die sLND von den Europäischen Leitlinien bisher auch als Alternative zur extendierten Lymphadenektomie angesehen und findet dort auch aktuell (2014) Erwähnung (LE3).</p> <p><i>Literatur: 1. Wawroschek F, et al J Urol 2001; 2. Wawroschek F et al Eur Urol 1999; 3. Holl G et al Eur J Nucl Med Mol Imaging 2009; 4. Joniau S et al Eur Urol 2013; 5. Winter A et al Int J Urol 2014; 6. Rousseau C et al J Nucl Med 2014; 7. Sadeghi et al Nuklearmedizin. 2011; 8. Winter A, et al Aktuelle Urol 2011;</i></p>	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung, wird bei der nächsten Aktualisierung berücksichtigt.</p>
<p>Zu Kapitel 5.4.1</p> <p>Bei der Therapie des lokal fortgeschrittenen Prostatakarzinoms muss die multimodale Therapie genannt sein (radikale Prostatektomie gefolgt von Strahlen/Hormontherapie). In der jetzigen Formulierung steht die radikale Prostatektomie mit Lymphadenektomie als alleinige Option gegen die Strahlentherapie mit temporärer Hormontherapie. Dies gibt die klinische Realität und vor allem die möglichen Therapieoptionen nicht korrekt wieder.</p>	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung, wird bei der nächsten Aktualisierung berücksichtigt.</p>
<p>Zu Empfehlung 5.60</p> <p>Die Empfehlung könnte meines Erachtens mit einem höheren Level of Evidence abgesichert und ggf. präziser formuliert werden. In der Referenzliste fehlt eine systematische Übersichtsarbeit, die in Zusammenarbeit mit dem Deutschen Cochrane Zentrum in Freiburg erstellt wurde. Ich schätze diese als qualitativ hochwertig ein.</p> <p>Es fehlt relevante Literatur: Kunath F, et al BMC Cancer. 2013</p>	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung, wird bei der nächsten Aktualisierung berücksichtigt.</p>
<p>Zu Hintergrundtext zu Empfehlung 5.66</p> <p>Offene Fragen bestehen hinsichtlich der Art der hormonablativen Therapie (LH-RH-Analagon allein versus maximale Androgenblockade oder Testosteronrezeptorblockade allein oder LHRH-Antagonisten). In zwei Studien (Axcrona 2012 und Mason 2013) wurde gezeigt, dass Patienten, die eine neoadjuvante Hormonentzugstherapie mit Degarelix im Vergleich zu Goserelin und Bicalutamid (flare-up Prophylaxe) erhielten, bei gleicher Volumenreduktion eine signifikant stärkere Verbesserung von LUT-Symptomen erlebten. Diese Ergebnisse sollten bei der Wahl einer Hormonentzugstherapie für die neoadjuvante Therapie berücksichtigt werden.</p> <p>Es wurden statistisch signifikante Unterschiede hinsichtlich der</p>	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung, wird bei der nächsten Aktualisierung berücksichtigt.</p>

Kommentar	Antwort
<p>LUTS-Problematik gefunden, die gerade bei bestrahlten Patienten eine Rolle spielen <i>Axcrona K et al BJU international 2012</i></p>	
<p>Zu Kapitel 6.2ff</p> <p>Bei adipösen bzw. Osteoporose gefährdeten Patienten sollte ein Internist mit entsprechender Zusatzausbildung zwecks Abklärung und unterstützender Therapie hinzugezogen werden</p> <p>Nebenwirkung „Knochenbruch“ bei Testosteronmangel kann die Lebensqualität erheblich einschränken, Stichwort Sarkopenie z.B. Oberschenkelhalsbruch, ähnliches gilt für Diabetes Mellitus, Bluthochdruck, Mix der Medikamente nicht immer günstig</p>	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung, wird bei der nächsten Aktualisierung berücksichtigt.</p>
<p>Zu Empfehlung 6.14</p> <p>Die Salvage Operation wird nur in 1-2% der Patienten durchgeführt (s. Tran et al. Urol Oncol 2014 aus Kanada und Cary KC et al Cancer 2014 aus der CaPSURE Datenbank). In der Übersichtsarbeit von Chade et al. in Eur Urol 2012 (!), die nicht in der Literaturliste zu finden ist, gibt keinerlei Korrelation zwischen der „Erfahrung“ der Operateure einer Salvage-Prostatektomie und dem „outcome“. Es gibt allerdings eine Korrelation über alle publizierten Studien hinweg bezüglich der Kontinenzraten zwischen LDR-brachytherapierten und EBRT-therapierten Patienten. Diese Empfehlung entbehrt daher jeglicher Sinnhaftigkeit und/oder Literaturbasis. Entsprechend wird auch keine Literatur zitiert. Es liegen aber gute Daten vor, die gegen die Empfehlung der Leitlinienkommission sprechen, aber nicht zitiert wurden.</p>	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung. Die deutlich erhöhte Komplikationsrate dieses Eingriffes begründet diese Empfehlung, unterstrichen auch durch die vom Kommentator hervorgehobenen relativen Seltenheit dieses Eingriffes</p>
<p>Zu Empfehlung 6.23</p> <p>Die Leitlinie muss in jedem Fall die Phase III Studie der SWOG von Maha Hussain aufnehmen, in der die intermittierende gegen die kontinuierliche Androgendeprivation geprüft wurde. Es handelt sich um die größte Studie der Welt und wenn die Leitlinie bis 2016 gültig sein soll, muss diese Arbeit erwähnt werden. Zudem wurden präliminäre Ergebnisse bereits 2012 publiziert, fanden aber ebenfalls keine Erwähnung. <i>Tangen CM, et al J Urol. 2012; Hussain M et al N Engl J Med. 2013</i></p>	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung, wird bei der nächsten Aktualisierung berücksichtigt.</p>
<p>Zu Hintergrundtext zu Empfehlung 6.20</p> <p>In einer aktuellen gepoolten Analyse ausvergleichenden randomisierten Studien mit Degarelix wurde gezeigt, dass insbesondere Patienten mit einer kardialen Vorerkrankung von der Therapie mit einer absoluten Risikoreduktion von 8,2% weniger kardialen Ereignissen oder Tod im Vergleich zu LHRH- Agonisten Therapie profitierten (RR 56%; HR 0,44; 95% KI 0,26 – 0,74). Daraus ergab sich eine NNT von 12. Diese Daten bedürfen der Validierung durch eine prospektive Studie, jedoch sollten sie bei der Therapieentscheidung von Patienten mit kardialen Vorerkrankungen berücksichtigt werden. Da sich das Phänomen der kardiovaskulären Risikoreduktion in allen Degarelix-Studien zeigt, sollte in den Leitlinien darauf hingewiesen werden, dass das kardiovaskuläre Risiko vor Therapie erfasst werden soll und Antagonisten hier möglicherweise Vorteile bieten (Klotz L, et al Eur Urol 2014)</p>	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung, wird bei der nächsten Aktualisierung berücksichtigt.</p>

Kommentar	Antwort
<p>Zu Hintergrundtext zu Empfehlung 6.26</p> <p>Man sollte ergänzen, dass die Testosteronbestimmung auch unter Systemtherapie durchzuführen ist.</p>	<p>In der Empfehlung 6.30 steht: Bei Patienten mit progredienter Erkrankung unter chirurgischer oder medikamentöser Kastrationstherapie soll der Serumtestosteronspiegel kontrolliert werden.</p>
<p>Zu Empfehlung 6.33</p> <p>Bei dieser Empfehlung steht ein „soll“ für die Therapieoptionen Abirateron, Docetaxel und Sipuleucel-T. Hingegen wird im Hintergrundtext darauf hingewiesen, dass die Indikation zur Chemotherapie mit Docetaxel bei asymptomatischen oder mild symptomatischen Patienten Gegenstand kontroverser Diskussionen ist. Somit ist die „soll“ Empfehlung fragwürdig. In den weiteren detaillierten Ausführungen der einzelnen Substanzen 6.34 steht hingegen „sollte“ und die Empfehlungen 6.35 sowie 6.36 beschreiben ein „kann“. Das führt zu Verwirrungen für den Leser. Weiterhin sollte die aktuelle Studienlage mit Enzalutamid (PREVAIL Studie) berücksichtigt werden. Die Zulassung für Enzalutamid vor Chemotherapie wird im September 2014 erwartet und diese Substanz hat ebenfalls eine wichtige Relevanz im klinischen Alltag. Die S3 Leitlinie Prostatakarzinom wird bis 2016 Gültigkeit haben und wäre ansonsten mit dem Druck der S3 Leitlinie bereits veraltet.</p>	<p>Das „soll“ bezieht sich auf die Notwendigkeit einer Therapieempfehlung und nicht auf eine einzelne Substanz. Die einzelnen Substanzen bekommen dann ein „sollte“ wegen der differenzialdiagnostischen Überlegungen. Zur Verdeutlichung wird in der Empfehlung ein Hinweis auf die Empfehlungen zur Differenzialtherapie ergänzt.</p> <p>Enzalutamid ist für diese Indikation nicht zugelassen und ist daher an dieser Stelle nicht aufgenommen.</p>
<p>Zu Empfehlungen 6.33 und 6.36</p> <p>Sipuleucel: Es fehlt der Hinweis, dass zwar die europäische Zulassung erfolgt ist, aber fraglich die Zulassung in Deutschland 2014 vorliegen wird und die Therapie bei Drucklegung der S3 Leitlinie noch überhaupt nicht in Deutschland verfügbar ist.</p>	<p>Das Präparat hat eine Zulassung. Eine S3-Leitlinie kann sich nicht an der aktuellen Marktverfügbarkeit eines Präparates orientieren.</p>
<p>Zu Empfehlung 6.34 und 6.36</p> <p>Bei der Empfehlung 6.36 wird explizit darauf hingewiesen, dass die Indikation von Sipuleucel-T nur bei PC Patienten ohne viszerale Metastasen vorliegt. Dementsprechend muss auch bei der Empfehlung 6.34 darauf hingewiesen werden, dass die COU-302 Studie mit Abirateron ebenfalls nur Patienten ohne viszerale Metastasen eingeschlossen hat (Prevail Studie mit Enzalutamid hat hingegen auch PC Patienten mit viszeralen Metastasen eingeschlossen).</p>	<p>Sipuleucel-T ist explizit nur für nicht-viszerale Metastasierung zugelassen, während diese Einschränkung bei Abirateron nicht gemacht wird. Im Hintergrundtext zu Abirateron wird ergänzt, dass Patienten mit viszeralen Metastasen von der Studie ausgeschlossen wurden.</p>

Kommentar**ZU Hintergrundtext zur Empfehlung 6.34**

Der steroidale Androgen-Biosynthese-Inhibitor Abirateron hemmt die Androgenproduktion im Hoden, der Nebenniere und im Tumor durch Inhibierung von CYP17. Die Phase 3-Studie COU-AA-302 (n = 1088, 1:1 Randomisierung [Anmerkung ÄZQ: red. Fehler, wurde korrigiert]) zeigte einen Überlebensvorteil für Abirateron in Kombination mit Prednison im Vergleich zu Placebo mit Prednison (Medianes Gesamtüberleben: 35,3 Monate vs. 30,1 Monate, HR: 0,79, 95 % KI: 0,66-0,95, p = 0,0151) [Rathkopf et al Eur Urol 2014].

Das für die Interimsanalyse unter Berücksichtigung des koprimären Endpunktes vorgegebene Signifikanzniveau wurde in den bisher erfolgten Interimsanalysen nicht erreicht. Die finale Analyse der Studie steht derzeit noch aus. Da nach der vorzeitigen Entblindung der Studie nach der 2. Interimsanalyse ein Crossover vom Placebo- zum Abirateron-Arm erlaubt war und zudem zahlreiche nachfolgende Therapien in beiden Armen erfolgten, ist die Aussagefähigkeit der Studie hinsichtlich des Endpunktes Gesamtüberleben eingeschränkt.

Die bisher erreichte Verlängerung der progressionsfreien Überlebenszeit von etwa acht Monaten ist klinisch relevant. Im Vergleich zum Kontrollarm (Prednison und Placebo) zeigte Abirateron eine signifikante Verbesserung verschiedener klinischer und patientenrelevanter Endpunkte (progressionsfreies Überleben, biochemische und bildgebende Remission, Symptomatik, Zeit bis zur Opiattherapie, Zeit bis zur Einleitung einer Chemotherapie, und Zeit bis zur Verschlechterung des FACT-P Scores). Eingeschlossen wurden Patienten mit gutem Allgemeinzustand (ECOG 0-1). In der Studie hatten 35 % (n = 188) der Patienten mit Abirateron plus Prednison und 27 % (n = 146) der Patienten mit Placebo plus Prednison mindestens eine schwerwiegende Nebenwirkung. [Rathkopf et al. Eur Urol 2014]

Antwort

Die Formulierung ist zwar korrekt, aber unverhältnismäßig ausführlich.

Zu Empfehlung 6.37

Bei dieser Empfehlung steht ein „soll“ für die Therapieoptionen Docetaxel, Abirateron und Radium-223 bei ossärer Metastasierung. Abirateron wurde explizit nicht bei symptomatischen Patienten in der Erstlinientherapie untersucht und somit ist das „soll“ falsch. Es kann sich hier nicht um ein Empfehlungsgrad A und Level of Evidence 1+ handeln. Insbesondere ergab eine retrospektive Post-hoc Analyse der COU-302-Studie den klaren Hinweis, dass symptomatische Patienten mit einem BPI Score von 2-3 keine Überlebensverlängerung im Vergleich zu Placebo/Prednison zeigten.

Das „soll“ bezieht sich auf die Notwendigkeit einer Therapieempfehlung und nicht auf eine einzelne Substanz. Die einzelnen Substanzen bekommen dann jeweils unterschiedliche Empfehlungsgrade wegen der differenzialdiagnostischen Überlegungen. Zur Verdeutlichung wird in der Empfehlung ein Hinweis auf die Empfehlungen zur Differenzialtherapie ergänzt.

Zu Empfehlung 6.39

In dieser Empfehlung wird auf die Kritik von 6.37 eingegangen. Daher wurde hier die Empfehlung auf „kann“ abgeändert. Hier sollten die Empfehlungen 6.37 und 6.39 klarer und einheitlicher in ihrem Empfehlungsgrad definiert werden.

Dossier zur Nutzenbewertung nach §35a SGB V: Abirateronacetat (Zytiga) zur Behandlung des mCRPC bei erwachsenen Männern mit asymptomatischem und mild symptomatischem Verlauf der Erkrankung nach Versagen der Androgenentzugstherapie, bei denen eine Chemotherapie noch nicht klinisch indiziert ist. Janssen-

siehe Kommentar zu Empfehlung 6.37

Kommentar

Cilag GmbH; 14.1.13

Antwort**Zu Empfehlung 6.37**

Die Zulassung für Abirateron in der Erstlinientherapie ist beschränkt auf asymptomatische Patienten. Hier wird eine Off-Label-Indikation in Zusammenhang mit einer SOLL Empfehlung gebracht. Dies ist m.E. nach problematisch. Außerdem findet sich der korrekte Empfehlungsgrad weiter unten in Kapitel 6.3.9 (dort kann- Empfehlung) das ist kontradiktionär.

Die Zulassung sagt: "(.) mit asymptomatischem oder mild symptomatischem Verlauf der Erkrankung nach Versagen der Androgenentzugstherapie (.)". Die Empfehlung entspricht der Realität und lässt auch den notwendigen therapeutischen Spielraum.

Zu Empfehlung 6.42

Es sollte direkt in der Empfehlung darauf hingewiesen werden, dass bisher keine Studiendaten vorliegen. Zudem sollte explizit die Alternative einer Palliativbehandlung mit aufgenommen werden.

Empfehlung zu symptomatischen mCRPC Patienten mit ECOG > 2: Wie bereits im Hintergrundtext beschrieben, gibt es zu Abirateron nur Studiendaten (COU-301 und 302) mit ECOG 0-1 Status. Ebenso wurden in der ALSYMPCA Studie mit Radium-223 nur 10% aller Patienten mit einem ECOG = 2 eingeschlossen. Die aktuelle Bayer Studie 16216 erhärtet den Verdacht, dass ossär mCRPC Patienten mit ECOG > 2 nicht von der Behandlung profitieren, im Gegenteil - Toxizitäten mit Thrombocytopenie Grad 3-4 und Neutropenie G3-4 treten gehäuft auf.

Das „kann“ bezieht sich auf die Möglichkeit einer Therapieempfehlung und nicht auf eine einzelne Substanz. Bei dieser Empfehlung handelt es sich um eine offene Empfehlung, die auf einem Expertenkonsens beruht, da zu dieser Fragestellung keine Literatur gefunden wurde.

Zu Empfehlung 6.48

Wie bereits im Hintergrundtext beschrieben, gibt es zu Abirateron nur Studiendaten (COU-301 und 302) mit ECOG 0-1 Status. Ebenso wurden in der ALSYMPCA Studie mit Radium-223 nur 10% aller Patienten mit einem ECOG = 2 eingeschlossen. Die aktuelle Bayer Studie 16216 erhärtet den Verdacht, dass ossär mCRPC Patienten mit ECOG > 2 nicht von der Behandlung profitieren, im Gegenteil - Toxizitäten mit Thrombocytopenie Grad 3-4 und Neutropenie G3-4 treten gehäuft auf.

Eine Arbeit von Chi et al. ASCO 2013: Abstract 5013 untersucht die Prognosefaktoren für die Zweitlinientherapie mit Abirateron aus den COU-301 Daten. Im Hintergrundtext sollte die Literatur mit aufgeführt werden und die Prognosefaktoren erläutert werden.

Die genannten Daten sind nicht voll publiziert und so nicht bewertbar.

Kommentar**Antwort****Zu Hintergrundtext zu Empfehlung 6.44**

Unter Therapie mit Abirateron wurde nach einem medianen Follow-up von ca. zwölf Monaten in der 1. Interimsanalyse eine Verlängerung des Gesamtüberlebens um im Median 3,9 Monate im Vergleich zum Kontrollarm gezeigt [783]. In die randomisierte kontrollierte Studie (1.195 Patienten, 2:1-Randomisierung) waren asymptomatische und symptomatische Patienten mit sehr gutem Allgemeinzustand einbezogen (90 % ECOG 0-1), die vorher mindestens eine Chemotherapie erhalten hatten. Die Raten an Nebenwirkungen sind im Vergleich zu einer Chemotherapie geringer. Die Nebenwirkungen gründen vor allem auf der mineralokortikoiden Wirkung des Medikaments, zu nennen sind insbesondere Hypokaliämie, Hypertonie und Flüssigkeitsretention/Ödeme. In der Folgeauswertung [784] verstärkte sich der Vorteil bei einer Verlängerung der Gesamtüberlebenszeit von im Median 4,8 Monaten (15,8 Monate versus 11,2 Monate; HR: 0,74, 95 % KI: 0,64–0,86; $p < 0,0001$). Im Vergleich zum Kontrollarm zeigte Abirateron einen signifikanten Effekt auf verschiedene Endpunkte (progressionsfreies Überleben, biochemische und bildgebende Remission und Verbesserung des BPI-Scores (Schmerzurückgang)). Bei Patienten mit niedrigen Lebensqualitätswerten zu Beginn der Studie verbesserte sich die Lebensqualität bei mehr Patienten, die Abirateron erhielten im Vergleich zum Kontrollarm (Prednison und Placebo) (definiert als eine Verbesserung des FACT-P um 10 Punkte). Abirateron ist in Kombination mit Prednison/Prednisolon zur Behandlung des metastasierten kastrationsresistenten Prostatakarzinoms bei erwachsenen Männern, deren Erkrankung während oder nach einer Docetaxel-haltigen Chemotherapie progredient ist, zugelassen [773].

Die Formulierung ist zwar korrekt, aber unverhältnismäßig ausführlich.

Zu Empfehlung 6.55 ff

In Praxis stellt sich immer wieder die Frage, ob bei mCRPC Patienten mit asymptomatischer Harnstauungsniere unter der Chemotherapie mit Docetaxel oder Cabazitaxel eine Harnableitung erfolgen sollte. Zwar werden Taxane überwiegend hepatisch verstoffwechselt, aber die Gefahr einer fieberhaften Neutropenie mit Entwicklung einer Sepsis sollte bei diesen Patienten mit Harnstauungsniere zuvor bedacht werden. Hier wäre eine Empfehlung für die alltägliche Praxis sehr sinnvoll.

Dieser Themenbereich war nicht Bestandteil der Überarbeitung. Dieser Kommentar weist auf ein praxisrelevantes Problem hin. Durch die Empfehlung „Patienten mit symptomatischer Harnstauung sollen durch instrumentelle Harnableitung behandelt werden.“ ist diese Frage m. E. ausreichend behandelt. „Symptomatisch“ umfasst sowohl infizierte als auch nierenfunktionseinschränkende Harnstauungen.

Zu Hintergrundtext zu Empfehlung 6.64

Hier sollte im Hintergrundtext eine Stellungnahme zum Einsatz von Denosumab (Prolia) 60mg s.c zur Osteoporose und Androgenablation bei hormonsensiblen PC Patienten vorgenommen werden.

Dieser Themenbereich war nicht Bestandteil der Überarbeitung. Dies ist wahrscheinlich nicht konsensfähig, da die Nebenwirkungen den Nutzen wohl überwiegen würden.

Kommentar	Antwort
<p>Zu Hintergrundtext zu Empfehlung 6.64</p> <p>Die Indikation für Erythropoese-stimulierende Substanzen ist ungenau und teilweise falsch dargestellt. Hier verweise ich auf die EORTC Leitlinien (Aapro M, Eur J Cancer 2009). Wenn die Behandlung der Anämie in der S3 Leitlinie aufgenommen wird, dann sollte es auch korrekt und detailliert aufgelistet werden. Der Satz auf Seite 220 ist nicht korrekt „In jüngerer Zeit haben Studien Hinweise auf eine Stimulation des Tumorwachstums durch Erythropoietine gezeigt.“ Diese Aussage wurde widerlegt. Zahlreiche Studien hatten Erythropoietin in der falschen Indikation eingesetzt. Eine Re-Analyse ergab, dass bei korrektem Einsatz von ESA eine Stimulation des Tumorwachstums durch Erythropoietin nicht nachweisbar war. <i>Aapro et al, Br J Cancer 2008; Bohlius et al, Lancet 2009</i></p>	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung.</p>
<p>Zu Hintergrundtext zu Empfehlung 6.64</p> <p>In einem systematischen Review wurde eine gute Wirksamkeit von Tamoxifen zur Prävention und Behandlung von Brustschmerzen und Gynäkomastie festgestellt. In einem prospektiv randomisierten Vergleich war die Behandlung mit Tamoxifen der Strahlentherapie überlegen [863]. Tamoxifen ist jedoch für diese Indikation nicht zugelassen. 2012 wurde ein systematisches Review zu dieser Thematik publiziert: <i>Kunath F et al BMC Med. 2012</i></p>	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung, wird bei der nächsten Aktualisierung berücksichtigt.</p>
<p>Zu Hintergrundtext zu Empfehlung 6.65</p> <p>Es werden die Substanzen Docetaxel, Mitoxantron und insbesondere Estramustin (Stellenwert? Leitlinie Empfehlung?) aufgelistet. Es sollte Cabazitaxel hinzugefügt werden.</p>	<p>Text und Tabelle überarbeitet; Verweis auf Erstellung der S3 LL Supportive Therapie</p>
<p>Zu Hintergrundtext zu Empfehlung 6.65</p> <p>Anämie (Seite 224): Siehe hierzu Kommentar 6.64</p>	<p>Text und Tabelle überarbeitet; Verweis auf Erstellung der S3 LL Supportive Therapie</p>
<p>Zu Hintergrundtext zu Empfehlung 6.65</p> <p>Die Aussagen zur Neutropenie müssen in 3 Gruppen eingeteilt werden: (1)Therapie bei asymptomatischer Neutropenie (Antibiose, Wachstumsfaktoren), (2) Therapie bei febriler Neutropenie (Allgemeine Supportivmaßnahmen, Antibiose, Wachstumsfaktoren), (3)Prophylaxe zur Vermeidung der Neutropenie (Antibiose, Wachstumsfaktoren)</p> <p>Neutropenie (Tabelle 16 und Seite 224): Die Aussagen widersprechen sich: Tabelle sagt „prophylaktische Gabe von Antibiotika“ und im Text auf Seite 224 wird es verneint. Nach den aktuellen Leitlinien von Aapro, Eur J Cancer, 2011; Flowers, Clin Oncol 2013 und www.nccn.org 2013 muss eine wesentlich differenziertere Beschreibung zur Indikation und Behandlung von a.) Antibiotika und b.) Wachstumsfaktoren bei asymptomatischer Neutropenie und fieberhafter Neutropenie erfolgen. Der Text ist sehr allgemein gehalten und die Behandlung eher falsch dargestellt. Die Aussagen zur Neutropenie müssen in 3 Gruppen eingeteilt werden: (1)Therapie bei asymptomatischer Neutropenie (Antibiose, Wachstumsfaktoren), (2) Therapie bei febriler Neutropenie (Allgemeine Supportivmaßnahmen, Antibiose, Wachstumsfaktoren), (3)Prophylaxe zur Vermeidung der Neutropenie (Antibiose, Wachstumsfaktoren)</p>	<p>Text und Tabelle überarbeitet; Verweis auf Erstellung der S3 LL Supportive Therapie</p>

Kommentar	Antwort
<p>Zu Kapitel 7.1 ff</p> <p>Kapitel 7 Rehabilitation und Nachsorge: dieser Themenkomplex ist insbesondere in Bezug auf die Kontinenz nur oberflächlich abgearbeitet. Die Möglichkeiten einer präoperativen Vorbereitung der Patienten auf eine radikale Prostatektomie durch Beckenbodentraining sind überhaupt nicht erwähnt. In der postoperativen Situation fehlt jeder Hinweis auf die Differentialindikation zu einem konservativ vs. operativem Vorgehen bei persistierender Harninkontinenz. Die Möglichkeit einer medikamentösen off-label Therapie mit Duloxetin wird überhaupt nicht erwähnt.</p>	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung, der Kommentar wird bei der nächsten Aktualisierung berücksichtigt.</p>
<p>Zu Empfehlung 8.7</p> <p>Alle Patienten sollen ein Screening auf psychosoziale Belastungen erhalten. Die Erfassung der psychosozialen Belastung und der individuellen psychoonkologischen Behandlungsbedürftigkeit sollte so früh wie möglich und dann wiederholt im Krankheitsverlauf ,wenn klinisch indiziert und bei Veränderung des Erkrankungsstatus (Wiederauftretung oder Fortschreitung der Erkrankung) erfolgen. Zur Erfassung der psychosozialen Belastung sollen im Klinik- und Praxisalltag validierte Screeninginstrumente (z.B. Distressthermometer, HADS) verwendet werden. Diagnostik, psychosoziale Beratung und psychoonkologische Behandlung sollten nach der S3-Leitlinie „Psychoonkologische Diagnostik, Beratung und Behandlung von erwachsenen Krebspatienten“ (AWMF-Registernr. 032/051OL) erfolgen.; S3-Leitlinie Psychoonkologische Diagnostik, Beratung und Behandlung von erwachsenen Krebspatienten</p>	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung, der Kommentar wird bei der nächsten Aktualisierung berücksichtigt.</p>
<p>Zu Empfehlung 6.7 und Statement 6.12.</p> <p>Es fehlt die Erwähnung der Indikation zur PET-CT Untersuchung mit Cholin / Acetat ab einem PSA Wert > 1,5 ng/ml und des sehr modernen GA PMSA PET Ct bei einem Wert > 1ng/ml zum Abschluss einer systematischen Metastasierung.</p>	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung, wird bei der nächsten Aktualisierung berücksichtigt.</p>
<p>Zu Hintergrundtext zu Empfehlung 6.65</p> <p>Übelkeit und Erbrechen:</p> <p>1.) Einsatz von Metoclopramid: a.) Nach den aktuelleren Leitlinien MASCC/ESMO (Roila, Ann Oncol 2010), ASCO (Basch, J Clin Oncol 2011, NCCN (www.nccn.org) hat Metoclopramid keinen Stellenwert in der Chemotherapie.</p> <p>b.) Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) hat für alle Metoclopramidhaltigen, flüssigen Zubereitungen zur Einnahme mit einer Konzentration > 1 mg/ml die Zulassung widerrufen. Dies betrifft alle z.Zt. im Handel erhältlichen Tropfen zur Einnahme (siehe Anhang).</p>	<p>Text und Tabelle überarbeitet; Verweis auf Erstellung der S3 LL Supportive Therapie</p>
<p>Zur Leitlinie allgemein:</p> <p>Die Leitlinie erwähnt nicht die Möglichkeiten der onkologisch multimodalen Therapie des Prostatakarzinoms.</p>	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung, die Anmerkung ist prinzipiell richtig, wird bei der nächsten Aktualisierung berücksichtigt.</p>

Kommentar	Antwort
<p>Zur Leitlinie allgemein:</p> <p>Die Leitlinie berücksichtigt nicht, dass individuelle anatomische und funktionelle Voraussetzungen des unteren Harntrakts - insbesondere konkomitierende LUTS / BPS / Blasenspeicherstörungen - die Differentialindikation zu radikaler Prostatektomie oder Strahlentherapie deutlich beeinflussen können.</p>	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung, die Anmerkung ist prinzipiell richtig, wird bei der nächsten Aktualisierung berücksichtigt.</p>
<p>Zur Leitlinie allgemein:</p> <p>Ich möchte Ihnen darauf aufmerksam machen, das Prostatastanzbiopsien im wesentlichen überholt sind wenn verwendet um fest zu stellen ob Krebs ANWESEND ist. Die Nachteilen von Biopsien sind ihnen wohl bekannt, wie z.B. weniger als 63% Schlagechancen, immer ein Prostatitis Erfolg, Möglichkeit von Ent-metastasen durch Lymph- oder Blutbahn, usw. Im Beilage schicke Ich Ihnen mein Erfahrungen aus 2013 und bevor und hoffe dass Sie dem Verbrauch von Liquide Biopsien promoten werden als ein besseres und stabileres Alternative zum Stanzbiopsie. Zur Zeit wird hier in Holland den liquide Biopsie immer noch nur im zweit Instanz benutzt. (...)</p>	<p>Stanzbiopsien sind weltweit als Standard anerkannt. Eine Änderung der Empfehlungen ist nicht erforderlich.</p>
<p>Zur Leitlinie allgemein:</p> <p>Weiterhin möchte ich ihre Darstellung der HDR Monotherapie bei lokal begrenzten PCa - insbesondere in einer low oder intermediale Risk Konstellation - gerne um aktuelle Entwicklungen ergänzen, welche ich nicht in ihrem Text oder Literaturverzeichnis auffinden konnte.</p> <p>Es liegen durchaus Publikationen zur HDR Monotherapie vor - auch mit Langzeitergebnissen -, die anhand vieler hunderter Patienten die sehr hohe Wirksamkeit dieser Therapieoption gezeigt haben.</p> <p><i>Zamboglou N et al Int J Radiat Oncol Biol Phys. 2013; Demanes DJ et al Int J Radiat Oncol Biol Phys. 2011; Grimm P et al BJU Int. 2012</i></p>	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung. Die Datenlage zur HDR-Monotherapie wurde von der Leitliniengruppe als noch nicht ausreichend angesehen, um diese Therapie als Standardverfahren zu empfehlen. Eine weitere Prüfung in großen Zentren unter Studienbedingungen wurde empfohlen. Dies erscheint insbesondere in Hinblick auf die unklare Zukunft der LDR-Brachytherapie in Deutschland sinnvoll. Eine unkontrollierte Anwendung der HDR-Brachytherapie in kleinen Zentren kann auch aus diesem Grund nicht empfohlen werden.</p>
<p>Zur Leitlinie allgemein:</p> <p>Ich finde in den LL keine Empfehlung hinsichtlich folgender Situation: Patient mit R1, LO nach RPE zeigt nach 4 wo PSA 0,0 jedoch ultrasensitiv 0,028, nach weiteren 4 wo 0,042. mit blick auf die bessere Prognose bei früher SRT scheint mir in dieser speziellen Situation die ultrasensitive PSA-Bestimmung zur Interpretation der R Situation sinnvoll wenn nicht sogar notwendig.</p>	<p>Dieser Themenbereich war nicht Bestandteil der Überarbeitung. Es gibt nach Überzeugung der Leitliniengruppe keine Daten, die eine Überlegenheit einer Salvage-Strahlentherapie bei ultrasensitiver PSA-Messung belegen. Vielmehr besteht hier die Gefahr einer Überbehandlung.</p>

12.9. Formblatt der AWMF zur Erklärung von Interessenkonflikten

12.9.1. Erklärung über Interessenkonflikte

(S3-Leitlinie zur Früherkennung, Diagnose und Therapie der verschiedenen Stadien des Prostatakarzinoms, 043 - 022OL)

zu Händen

Prof. Dr. med. Dr. h.c. M. Wirth

Vorbemerkung

Die Entwicklung von Leitlinien für die medizinische Versorgung verlangt über die fachliche Expertise hinaus eine Vermeidung kommerzieller Abhängigkeiten oder anderer Interessenkonflikte, die die Leitlinieninhalte beeinflussen. Es gibt eine Vielzahl von materiellen (z.B. finanzielle oder kommerzielle) und immateriellen (z.B. politische, akademische oder persönliche) Beziehungen, deren Ausprägungsgrade und Bedeutungen variieren können. Interessenkonflikte sind somit zumeist unvermeidbar, aber nicht zwangsläufig problematisch in Hinblick auf eine Beeinflussung der Leitlinieninhalte.

Eine Erklärung zu den Beziehungen und den daraus entstehenden Interessenkonflikten durch die Autoren der Leitlinien und die Teilnehmer am Konsensusverfahren ist für die Qualitätsbeurteilung von Leitlinien, aber auch für ihre allgemeine Legitimation und Glaubwürdigkeit in der Wahrnehmung durch Öffentlichkeit und Politik entscheidend.

Die Erklärungen werden zu Beginn des Leitlinienprojekts gegenüber dem Leitlinienkoordinator abgegeben. Bei länger andauernden Projekten kann eine zusätzliche Abgabe im Verlauf erforderlich sein. Ob davon die erforderliche Neutralität für die Mitarbeit bei der Leitlinienentwicklung in Frage gestellt ist oder in welchen Bereichen das professionelle Urteilsvermögen eines Experten durch die Interessen Dritter unangemessen beeinflusst sein könnte, ist in der Leitliniengruppe zu diskutieren und zu bewerten.

Die Inhalte der Erklärungen und die Ergebnisse der Diskussion zum Umgang mit Interessenkonflikten sollten im Leitlinienreport offen dargelegt werden. In der Langfassung der Leitlinien ist auf das Verfahren der Sammlung und Bewertung der Erklärungen hinzuweisen.

Wir möchten Sie bitten, untenstehende Erklärung auszufüllen und zu unterzeichnen.

Erklärung

Die Erklärung betrifft finanzielle und kommerzielle (materielle) sowie psychologische und soziale (immaterielle) Aspekte sowie Interessen der Mitglieder selbst und/oder ihrer persönlichen/professionellen Partner innerhalb **der letzten 3 Jahre**. Bitte machen Sie **konkrete Angaben zu folgenden Punkten**:

1. Berater- bzw. Gutachtertätigkeit oder bezahlte Mitarbeit in einem wissenschaftlichen Beirat eines Unternehmens der Gesundheitswirtschaft (z.B. Arzneimittelindustrie, Medizinproduktindustrie), eines kommerziell orientierten Auftragsinstituts oder einer Versicherung

Nein

Ja

Falls ja, bitte konkrete Angabe:

2. Honorare für Vortrags- und Schulungstätigkeiten oder bezahlte Autoren- oder Co-Autorenschaften im Auftrag eines Unternehmens der Gesundheitswirtschaft, eines kommerziell orientierten Auftragsinstituts oder einer Versicherung

Nein

Ja

Falls ja, bitte konkrete Angabe:

3. Finanzielle Zuwendungen (Drittmittel) für Forschungsvorhaben oder direkte Finanzierung von Mitarbeitern der Einrichtung von Seiten eines Unternehmens der Gesundheitswirtschaft, eines kommerziell orientierten Auftragsinstituts oder einer Versicherung

Nein

Ja

Falls ja, bitte konkrete Angabe:

4. Eigentümerinteresse an Arzneimitteln/Medizinprodukten (z. B. Patent, Urheberrecht, Verkaufslizenz)

Nein

Ja

Falls ja, bitte konkrete Angabe:

5. Besitz von Geschäftsanteilen, Aktien, Fonds mit Beteiligung von Unternehmen der Gesundheitswirtschaft

Nein

Ja

Falls ja, bitte konkrete Angabe:

6. Persönliche Beziehungen zu einem Vertretungsberechtigten eines Unternehmens
Gesundheitswirtschaft

Nein

Ja

Falls ja, bitte konkrete Angabe:

7. Mitglied von in Zusammenhang mit der Leitlinienentwicklung relevanten Fachgesellschaften/Berufsverbänden, Mandatsträger im Rahmen der Leitlinienentwicklung

Nein

Ja

Falls ja, bitte konkrete Angabe:

8. Politische, akademische (z.B. Zugehörigkeit zu bestimmten „Schulen“), wissenschaftliche oder persönliche Interessen, die mögliche Konflikte begründen könnten

Nein

Ja

Falls ja, bitte konkrete Angabe:

9. Gegenwärtiger Arbeitgeber, relevante frühere Arbeitgeber der letzten 3 Jahre

Bewertung

Ergeben sich aus allen oben angeführten Punkten nach Ihrer Meinung für Sie oder die ganze Leitliniengruppe bedeutsame Interessenkonflikte?

Nein

Ja

Falls ja, bitte Angabe eines Vorschlags zur Diskussion in der Leitliniengruppe

(z.B. Stimmenthaltung zu speziellen Fragestellungen):

Ort, Datum

Name (bitte Druckschrift)
unterschrift

Un-

Adresse (Einrichtung, Strasse, Ort, Emailadresse)

12.10. Ergebnisse der Interessenkonflikterklärungen

12.10.1. Interessenkonflikterklärungen 2011

Name	1. Berater- bzw. Gutachtertätigkeit oder bezahlte Mitarbeit	2. Honorare für Vortrags- und Schulungstätigkeiten oder bezahlte Autorenschaften	3. Finanzielle Zuwendungen (Drittmittel)	4. Eigentümerinteresse	5. Besitz von Geschäftsanteilen, Aktien, Fonds	6. Persönliche Beziehungen	7. Mitglied relevanter Fachgesellschaften	8. Politische, akademische, wissenschaftliche oder persönliche Interessen	9. Gegenwärtiger Arbeitgeber, relevante frühere Arbeitgeber der letzten 3 Jahre
<i>Clemens Albrecht</i>	nein	nein	nein	nein	n.a.	nein	S3-LL Prosta-taCa, BVDST	nein	Gemeinschaftspraxis für Strahlentherapie, Nürnberg,
<i>Dirk Böhmer</i>	nein	Vortragstätigkeit für Takeda Pharma, Vortrags- und Schulungstätigkeit für Varian Medical Systems*	nein	nein	nein	nein	Vorstand AG Radioonkologie der DKG, Advisory Board der DEGRO	nein	Charité Universitätsmedizin, Berlin,
<i>A. Blana</i>	Mitglied Advisoryboard Amgen, Ferring, EDAP/TMS	Honorare für Vorträge Ferring, Astellas, EDAP/TMS	nein	nein	nein	nein	EAU, DGU	nein	Seit 7/2009 Klinikum Fürth, zuvor Caritas-krankenhaus St. Josef in Regensburg,
<i>Christof Börgermann</i>	nein	nein	nein	nein	nein	nein	DGU, BDU	nein	Klinik f. Urologie und Kinderurologie, urologische Onkologie, Düren,

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<i>Martin Burchardt</i>	nein	nein	Dr. Robert-Pfleger-Stif-tung – Andro-genrezeptor-forschung bei Prostatakarzi-nom → Dritt-mittel für Abteilung/ Forschungs-projekt	nein	habe die typischen „XXX- Aktien-fonds“ in überschauba-rem Maße. Ob darin irgend-welche Phar-mafirmen enthalten sind, entzieht sich meiner Kenntnis	nein	DGU	nein	Universitätsmedizin Greifswald, Klinik und Poliklinik für Urologie, Greifswald,
<i>Hans-Hermann Dubben</i>	nein	Vortrags- und Schulungstätig-keiten: Deutsche Gesellschaft f. wissenschaftliche und angewandte Kosmetik e.V., 2011, Thieme Verlag KG, Stutt-gart, 2008, Sana Kliniken AG, Ismaning, 2009, Roche Far-maceutska, Ljub-ljana, Slowenien, 2010	nein	nein	nein	nein	nein	nein	UK Hamburg-Eppen-dorf, Zentrum für psy-chosoziale Medizin, Institut für Allgemein-medizin, Hamburg,

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<i>Christian Doehn</i>	nein	Bayer HealthCare, Amgen, Pfizer, Wyeth, GSK, Novartis, Roche	Olympus	nein	AstraZeneca	nein	DGU	nein	Selbständig, bis 05/2011 UK Lübeck
<i>Paul Enders</i>	nein	nein	nein	nein	nein	nein	BPS	nein	Keine,
<i>Hanns-Jörg Fiebrandt</i>	nein	nein	nein	nein	nein	nein	BPS	nein	Keine
<i>Paolo Fornara</i>	nein	nein	GILUPI (Studie zur Detektion mittels Nanodetektorsonden von zirkulierenden Tumorzellen)	nein	nein	nein	DGU	nein	Martin-Luther-Universität Halle-Wittenberg, C4-Professur,
<i>Michael Fröhner</i>	nein	Pfizer, Apogepha, Takeda	nein	nein	nein	nein	DGU	nein	UK Dresden, Klinik und Poliklinik für Urologie,
<i>Marc-Oliver Grimm</i>	Beratertätigkeit für: Bayer Healthcare, Pfizer, Roche, Janssen Cilag	Vortragstätigkeit für: Bayer Healthcare AG, Pfizer AG, Novartis, Glaxo Smith	Novartis - Drittmittel für Forschungsvorhaben	nein	Aktienbesitz folgender Unternehmen: Bayer AG, Glaxo Smith	nein	DGU, AUA, EAU, BDU, DKG	nein	UK Jena (derzeitiger Arbeitgeber), UK Dresden (2006-2010),

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		Kline, Takeda Pharma, Apogepha			Kline				
<i>Markus Graefen</i>	nein	Honorar für Vortragstätigkeit: Ipsen, Amgen	nein	nein	nein	nein	DGU	nein	Universitätsklinik Hamburg-Eppendorf „Martini-Klinik“,
<i>Bernt Göckel-Beining</i>	nein	nein	nein	nein	nein	nein	Vorsitzender im Ausschuss für Evidence Based Medicine des Berufsverbandes der Deutschen Urologen (BDU)	nein	Selbständig (Facharzt f. Urologie),
<i>Marc-Oliver Grimm</i>	Bayer HealthCare, Pfizer, Roche, Janssen-Cilag	Bayer HealthCare, Pfizer, Novartis, Glaxo Smith Kline, Takeda, Apogepha, Roche, Janssen-Cilag	Novartis für Forschungsvorhaben	nein	Bayer HealthCare, Glaxo Smith Kline,	nein	DGU, AUA, EAU, BDU, DKG	nein	UK Jena, bis 2010 UK Dresden
<i>Oliver Hakenberg</i>	nein	nein	nein	nein	nein	nein	DGU, BDU	nein	UK Rostock / Universität,

Name	1. Berater- bzw. Gutachtertätigkeit oder bezahlte Mitarbeit	2. Honorare für Vortrags- und Schulungstätigkeiten oder bezahlte Autoren-schaften	3. Finanzielle Zuwend-ungen (Drittmittel)	4. Eigen-tümer-interesse	5. Besitz von Geschäfts-anteilen, Aktien, Fonds	6. Persön-liche Bezieh-ungen	7. Mitglied relevanter Fach-gesellschaften	8. Politische, akademische, wissenschaft-liche oder persönliche Interessen	9. Gegenwärtiger Ar-beitgeber, relevante frühere Arbeitgeber der letzten 3 Jahre
<i>Axel Heidenreich</i>	Astellas, Aventis, Ipsen, Novartis, Amgen	Amgen, Astellas, Sanofi-Aventis, Glaxo, Ipsen, Merck, Novartis, Roche, Pfizer, Takeda	Ipsen	nein	nein	nein	EAU, DGU, AUA, ASCO	nein	UK Aachen, UK Köln,
<i>Thomas Oliver Henkel</i>	nein	Kurse Brachytherapie	nein	nein	nein	nein	DGU, BDU, BUG	nein	Niedergelassener Urologe seit 1998
<i>Wolfgang Hinkelbein</i>	nein	nein	nein	nein	Beteiligung über Aktienfonds nicht auszuschließen	nein	DEGRO, DKG, BVDST	nein	Charité Berlin,
<i>Stefan Höcht</i>	Beratervertrag Sanofi Aventis 2008 (HNO-Bereich), Autorenvertrag Sanofi Aventis 2008 (HNO-Bereich)	Vortragshonorare Roche Pharma 2009/2010/2011 (Bronchial-Ca), Vortragshonorare „Roadshow S3-Leitlinie Prostata-Ca“ BDU/BVDST	nein	nein	nein	nein	DEGRO, BVDST	nein	Bis 2008 Charité Berlin, jetzt selbständig,
<i>Tobias Hölscher</i>	Klinische Reviews für Strahlentherapiepläne (HNO-Bereich), 3600 €/Jahr EQUAL-ESTRO	nein	nein	nein	nein	nein	DEGRO, ESTRO, BVDST	nein	Aktuell: UK Dresden und MVZ am UK Dresden, Zuvor: Med. Fakultät, TU-Dresden,

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<i>Bernd Joachim Krause</i>	nein	GE Healthcare 700 €, Hirnliga Symposium, 700€, 3. Round-Table-Diskussion „Forschungsprojekt DemenzdiagnostikLilly Pharma 2000 €, Lilly-Fortbildung, Takeda-Pharma 1000 €, PCA-Symposium, Solutionakademie 1000 €, Intensivkurs Uro-Onkologie, Ferring Arzneimittel GmbH 1000 €, Urologisches Live-Symposium	nein	nein	nein	nein	DGN	nein	UK Rostock, Klinik und Poliklinik für Nuklearmedizin,
<i>Michael Lein</i>	Advisory Board Novartis Pharma GmbH 2008-2011, Amgen 2010 Advisory Board	Vorträge 2009 Novartis, Vorträge 2008 Ferring + Novartis	Zeus Studie (Knochenmarkerbestimmung)	nein	nein	nein	nein	nein	Klinikum Offenbach GmbH, Charité Campus Mitte, Urologie,
<i>Hagen Loertzer</i>	nein	nein	nein	nein	nein	nein	nein	nein	Universitätsmedizin Göttingen, Klinik für

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									Urologie,
<i>Hans-Joachim Luboldt</i>	nein	nein	nein	nein	nein	nein	nein	nein	Selbständig: Klinikpra-xis für Urologie, Dins-laken,
<i>Gerd Lümmen</i>	Farco-Pharma	Medac, Lilly, Sanofi-Aventis	nein	nein	nein	nein	DGU, BDU	nein	St. Josef Hospital, Troisdorf
<i>Stefan Machtens</i>	nein	Vortragshonorare Bayer, Novartis, GE Healthcare, Sanofi Aventis, Pfizer, BARD Honorar Deutsche Krankenhausge-sellschaft für Gutachtertätigkeit im G-BA („Intersti-tielle Brachytherapie“ Vortragshonorar durch den Bundesverband Me-dizintechnik (BV Med)	50% Sekretari-atsstelle durch die Fa. BARD als Dokumen-tationsassis-tentin für die europäische Pro-Brachy Datenbasis.	nein	nein	nein	DGU	nein	Marienkrankenhaus Bergisch Gladbach gGmbH,
<i>Thomas Martin</i>	nein	Honorare für Vorträge (Roche, Merck)	nein	nein	nein	nein	DEGRO	nein	Klinikum Bremen-Mitte und Ambulanz Bremen GmbH,

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<i>Kurt Miller</i>	Amgen, AstraZeneca, Astellas, BMS, Janssen-Cilag, Novartis	Amgen, AstraZeneca, Astellas, BMS, Janssen-Cilag, Novartis	nein	nein	nein	nein	DGU	nein	UK Charité Berlin,
<i>Lutz Moser</i>	nein	nein	nein	nein	nein	nein	DEGRO	nein	UK Charité Berlin
<i>Ullrich G. Mueller-Lisse</i>	nein	Teilnahme an der Fortbildungsveranstaltung "Uro Update 2010" der Fa. Med Update GmbH, Hagenauer Str. 53, 65203 Wiesbaden einschl. Vortrag und Autorenschaft (Handbuch Urologie 2010, Springer Medizin Verlag)	nein	nein	nein	nein	Deutsche Röntgengesellschaft: Vorsitzender der AG Uroradiologie	nein	UK München, Institut für klinische Radiologie,
<i>Ullrich Otto</i>	nein	nein	nein	nein	nein	nein	nein	nein	Kliniken Hartenstein GmbH, Bad Wildungen,

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<i>Holger Palmedo</i>	nein	Honorar für Vortragstätigkeit der Firmen JBA, Covidien	nein	nein	nein	nein	DGN, BDN	nein	Seit 2008 freiberuflich tätig, Niederlassung,
<i>Karl Pummer</i>	Astellas Pharma	Astellas, Takeda, Ferring, Janssen-Cilag	nein	nein	nein	nein	DGU	nein	Medizinische Universität Graz, Klinik f. Urologie,
<i>Volker Rohde</i>	nein	Sanofi Aventis: „Palliativmedizin“ 2010	nein	nein	nein	nein	DGU	nein	Eigene Praxis für Urologie,
<i>Herbert Rübber</i>	Astellas, Fresenius, Innovacell, DKV, AOK	nein	Studien, interne Forschungsgelder der Universität	nein	nein	nein	DGU, BDU, NRWGU, EAU, AUA	nein	UK Essen
<i>Bernd Jürgen Schmitz-Dräger</i>	AstraZeneca, Astellas, Cmi, EDAP (Frankreich), Ferring, GPC Biotech, Janssen,, Novartis, SEP	Gen-Probe Inc. San Diego, Novartis, Takeda	nein	nein	nein	nein	DGU, DKG, AUA, SIU, URS, ESUR, EAU, IBCN, Classification on Urological Diseases (ICUD) Bladder Cancer 1999, 2005, 2010	nein	Selbständig (privatärztliche urologische Gemeinschaftspraxis, Fürth),

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<i>Martin Schostak</i>	Advisory Board Lilly Pharma und AstraZeneca, Klinischer Berater für EDAP TMG GmbH und CureVac GmbH	LKP bei multiplen Studien: bioMérieux, ProtecSys, Lilly, EDAP	nein	nein	nein	nein	nein	nein	Charité (Universitätsmedizin, Urologische Klinik) seit 15 Jahren,
<i>Mark Schrader</i>	nein	nein	nein	nein	nein	nein	nein	nein	UK Ulm, Klinik f. Urologie,
<i>Felix Sedlmayer</i>	nein	Honorare für firmen-initiierte Fortbildungsveranstaltungen	nein	nein	nein	nein	derzeit ÖGRO-Präsident	nein	Salzburger Landeskliniken GmbH (SALK),
<i>Axel Semjonow</i>	nein	Abbott, Ärztekammer Westfalen-Lippe, Beckman-Coulter, DAK, GenProbe, GlaxoSmithKline (EuMedCom) Labor Nordwest, Nordhorn, Novartis, Sanofi, Siemens, TAD, Takeda, Vivantes	Beckman-Coulter, Brahms, Epigenomics, Protagen, Siemens	Patent "Charakterisierung von Tumoren"	nein	Partnerin ist als Medical Director bei Phillips Health Care beschäftigt	DGU, European Group on Tumor Markers (EGTM), National Academy of Clinical Biochemists (NACB)	nein	UK Münster, Prostatazentrum,

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<i>Michael Stöckle</i>	nein	honoriertes Vor-trag im Rahmen des DGU-Kongresses 2011 (Fa. Janssen, Honorar 1000 €)	klinische Studien für fast alle Unter-nehmen, die Präparate für rologische Er-krankungen entwickeln, auch beim Prostatakarzi-nom. Zwei study nurses sind darüber finanziert.	nein	Aktienbesitz Fa. Intuitive Surgical	nein	DGU: Vor-stand	nein	UK des Saarlandes, Klinik für Urologie und Kinderurologie,
<i>Thomas-Alexander Vögeli</i>	Medac	Sanofi, Lilly, Takeda, Aventis, Farco Pharma	nein	nein	nein	nein	DGU	nein	Medizinisches Zentrum Städteregion Aachen, Universität Düsseldorf,
<i>Lothar Weißbach</i>	Der Urologe, Uro-News, Stif-tung Warentest, BMG	Vorträge Lilly, Akademie der DGU	Gazprom Germania	nein	Gazprom Germania	nein	DGU	nein	Stiftung Männerge-sundheit, Berlin
<i>Frederik Wenz</i>	nein	Sanofi, Astra-Zeneca, Elekta, Zeiss, Lilly, No-vartis	Forschungs-kooperationen mit den ge-nannten Fir-men	nein	nein	nein	DEGRO, BVDST	nein	Universität Heidelberg, Universitätsmedizin Mannheim,
<i>Nicolas Wernert</i>	nein	nein	nein	nein	nein	nein	Deutsche Gesellschaft für Pathologie	nein	Universität Bonn

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<i>Thomas Wiegel</i>	Bayer-Schering, Ipsen, Takeda, Novartis, Amgen, AstraZeneca	Ipsen, Takeda, Novartis	nein	nein	nein	nein	DEGRO	nein	UK Ulm,
<i>Manfred P. Wirth</i>	Akademie der Dt. Urologen, Amgen, Apogepha, Astellas, AstraZeneca, Ferring, GlaxoS-mithKline, Novartis, Orion, Pfizer, Pharmion, Sanofi Aventis, Takeda, TRM Oncology	Akademie der Dt. Urologen, Amgen, Apogepha, Astellas, AstraZeneca, Ferring, GlaxoS-mithKline, Novartis, Orion, Pfizer, Pharmion, Sanofi Aventis, Takeda, TRM Oncology	nein	nein	nein	nein	DGU, BDU	nein	UK Dresden
<i>Bernhardt Wörmann</i>	nein	nein	nein	nein	nein	nein	DGHO	nein	Klinikum Braunschweig bis 2009, DGHO sein 2010, Charite Berlin seit 2011
<i>Johannes M Wolff.</i>	Advisory Board: AstraZeneca (beendet), Sanofi, Janssen-Cilag, Ferring, Amgen	AstraZeneca (beendet), Sanofi, Janssen-Cilag, Ferring, Amgen, Astellas, Takeda, GSK	nein	nein	nein	nein	DGU, BDU, DKG-AUO	nein	AKH Viersen GmbH, Viersen

Name	1. Berater- bzw. Gutachtertätigkeit oder bezahlte Mitarbeit	2. Honorare für Vortrags- und Schulungstätigkeiten oder bezahlte Autorenschaften	3. Finanzielle Zuwendungen (Drittmittel)	4. Eigentümerinteresse	5. Besitz von Geschäftsanteilen, Aktien, Fonds	6. Persönliche Beziehungen	7. Mitglied relevanter Fachgesellschaften	8. Politische, akademische, wissenschaftliche oder persönliche Interessen	9. Gegenwärtiger Arbeitgeber, relevante frühere Arbeitgeber der letzten 3 Jahre
<i>Jens-Peter Zacharias</i>	BPS (Der BPS wird zu 50% durch Spenden finanziert. Davon kommen 3,5 % von der Arzneimittelindustrie. 95% sind Projektförderungen der Dt. Krebshilfe und der Krankenkassen.	nein	nein	nein	nein	nein	BPS Vorstand	nein	Rentner

Abkürzungen: AOK = Allgemeine Ortskrankenkasse, ASCO = American Society of Clinical Oncology, AUA = American Urological Association, BDN = Berufsverband Deutscher Neurologen, BDU = Bundesverband der deutschen Urologen, BMG = Bundesministerium für Gesundheit, BMS = Bristol-Myers Squibb, BPS = Bundesverband Prostatakrebs Selbsthilfe, BUG = Berliner Urologische Gesellschaft, BVDST = Berufsverbandes Deutscher Strahlentherapeuten, DAK = Deutsche Angestellten Krankenkasse, DEGRO = Deutsche Gesellschaft für Radioonkologie, DGHO = Deutsche Gesellschaft für Hämatologie und Onkologie, DGN = Deutsche Gesellschaft für Nuklearmedizin, DGU = Deutsche Gesellschaft für Urologie, DKG = Deutsche Krebsgesellschaft, DGK-AUO = Arbeitsgemeinschaft Urologische Onkologie der Deutschen Krebsgesellschaft, DKV = Deutsche Krankenversicherung, EAU = European Association of Urology, EqualEstrO = Independent Quality Assurance for Therapeutic Radiology and Oncology, ESTRO = European Society for Therapeutic Radiology and Oncology, ESUR = European Society for Urological Research, G-BA = Gemeinsamer Bundesausschuss, IBCN = International Bladder Cancer Network, MVZ = Medizinisches Versorgungszentrum, NRWGU = Nordrhein-Westfälische Gesellschaft für Urologie, SIU = Société Internationale d'Urologie, UK = Universitätsklinikum, URS = Urological Research Society

12.10.2. Interessenkonflikterklärungen 2013/2014

Name	1. Berater- bzw. Gutachtertätigkeit oder bezahlte Mitarbeit	2. Honorare für Vortrags- und Schulungstätigkeiten oder bezahlte Autorenschaften	3. Finanzielle Zuwendungen (Drittmitel)	4. Eigentümerinteresse	5. Besitz von Geschäftsanteilen, Aktien, Fonds	6. Persönliche Beziehungen	7. Mitglied relevanter Fachgesellschaften	8. Politische, akademische, wissenschaftliche oder persönliche Interessen	9. Gegenwärtiger Arbeitgeber, relevante frühere Arbeitgeber der letzten 3 Jahre	Selbsteinschätzung, ob Interessenkonflikt besteht
<i>Albrecht Clemens</i>	Nein	Nein	Nein	Nein	Ja: MIG Fonds ~ 50.000 Euro	Nein	Ja: DEGRO	Nein	Gemeinschaftspraxis für Strahlentherapie	Nein
<i>Andreas Blana</i>	Nein	Ja: Referententätigkeit: Conmed / Linvatec, EDAP TMS, Janssen	Nein	Nein	Nein	Nein	Ja: DGU, EAU, Bayerisch österreichische Urologenvereinigung	Nein	Klinikum Fürth	Nein

Name	1. Berater- bzw. Gutachtertätigkeit oder bezahlte Mitarbeit	2. Honorare für Vortrags- und Schulungstätigkeiten oder bezahlte Autorenschaften	3. Finanzielle Zuwendungen (Drittmitel)	4. Eigentümerinteresse	5. Besitz von Geschäftsanteilen, Aktien, Fonds	6. Persönliche Beziehungen	7. Mitglied relevanter Fachgesellschaften	8. Politische, akademische, wissenschaftliche oder persönliche Interessen	9. Gegenwärtiger Arbeitgeber, relevante frühere Arbeitgeber der letzten 3 Jahre	Selbsteinschätzung, ob Interessenkonflikt besteht
<i>Alfred Böcking, (Beobachter)</i>	Nein	Nein	Nein	Nein	Nein	Nein	Nein	Ja: 80 wissenschaftliche Publikationen zur diagnostischen/prognostischen DNA-Bildzytometrie. Entwicklung von Applikationssoftware zusammen mit dem Lehrstuhl für Bildverarbeitung an der RWTH Aachen, Prof. Dr. D. Meyer-Ebrecht	Emeritierter Hochschulprofessor seit 2010, Konsiliarium am Institut für Pathologie des Krankenhauses Düren	Nein
<i>Dirk Böhmer</i>	Nein	Ja: Takeda Pharma Vortragstätigkeiten	Ja: Varian Medical Systems Schulungskurs (4 x pro Jahr)	Nein	Nein	Ja: Hr. J. Schröder, Fa. BrachySolut ion	Ja: DKG, DEGRO, ARO	Nein	Charite Universitätsmedizin Berlin	Nein
<i>Christof Börgermann,</i>	Nein	Nein	Nein	Nein	Nein	Nein	Ja: BDU	Nein	Krankenhaus Düren	Nein

Name	1. Berater- bzw. Gutachtertätigkeit oder bezahlte Mitarbeit	2. Honorare für Vortrags- und Schulungstätigkeiten oder bezahlte Autorenschaften	3. Finanzielle Zuwendungen (Drittmitel)	4. Eigentümerinteresse	5. Besitz von Geschäftsanteilen, Aktien, Fonds	6. Persönliche Beziehungen	7. Mitglied relevanter Fachgesellschaften	8. Politische, akademische, wissenschaftliche oder persönliche Interessen	9. Gegenwärtiger Arbeitgeber, relevante frühere Arbeitgeber der letzten 3 Jahre	Selbsteinschätzung, ob Interessenkonflikt besteht
<i>Burchardt, Martin</i>	Nein	Nein	Nein	Nein	Nein	Nein	Nein	Nein	Universitätsmedizin Greifswald	Nein
<i>Carl, Ernst-Günther</i>	Nein	Nein	Nein	Nein	Nein	Nein	Ja: BPS Schatzmeister	Nein	Im Ruhestand seit 2008	Nein
<i>Dietz, Josef</i>	Nein	Nein	Nein	Nein	Nein	Nein	Nein	Nein	Als Rentner bin ich seit 6 Jahren als SHG-Leiter Mitglied im BPS e.V. und stellv. Vorstand im Landesverband Prostatakrebs Selbsthilfe Baden-Württemberg g.V. ehrenamtlich und gemeinnützig landes- und bundesweit engagiert.	Nein

Name	1. Berater- bzw. Gutachtertätigkeit oder bezahlte Mitarbeit	2. Honorare für Vortrags- und Schulungstätigkeiten oder bezahlte Autorenschaften	3. Finanzielle Zuwendungen (Drittmittel)	4. Eigentümerinteresse	5. Besitz von Geschäftsanteilen, Aktien, Fonds	6. Persönliche Beziehungen	7. Mitglied relevanter Fachgesellschaften	8. Politische, akademische, wissenschaftliche oder persönliche Interessen	9. Gegenwärtiger Arbeitgeber, relevante frühere Arbeitgeber der letzten 3 Jahre	Selbsteinschätzung, ob Interessenkonflikt besteht
<i>Doehn, Christian</i>	Ja: Advisory Boards: Roche, Pfizer, Bayer, GSK, Novartis, Janssen Cilag, Sanofi	Ja: Vorträge/Schulungen: Roche, Bayer, GSK, Novartis, Takeda	Ja: Olympus	Nein	Ja: Astra-Zeneca	Nein	Ja: DGU, BDU, EAU, AUA, ASCO, DKG	Nein	UKSH (Uni Lübeck) bis 05/2011 seitdem Freiberufler	Nein
<i>Donner-Banzhoff, Norbert</i>	Nein	Nein	Ja: Arriba-pro, AOK Ba-Wü, AOK Bundesverband 150.000 €	Nein	Nein	Ja: Ehefrau leitende Angestellte bei Novartis Vaccines & Diagnostics	Ja: Deutscher Hausärzteverband, DEGAM	Nein	Philipps-Universität Marburg Abteilung für Allgemeinmedizin	Nein

Name	1. Berater- bzw. Gutachtertätigkeit oder bezahlte Mitarbeit	2. Honorare für Vortrags- und Schulungstätigkeiten oder bezahlte Autorenschaften	3. Finanzielle Zuwendungen (Drittmitel)	4. Eigentümerinteresse	5. Besitz von Geschäftsanteilen, Aktien, Fonds	6. Persönliche Beziehungen	7. Mitglied relevanter Fachgesellschaften	8. Politische, akademische, wissenschaftliche oder persönliche Interessen	9. Gegenwärtiger Arbeitgeber, relevante frühere Arbeitgeber der letzten 3 Jahre	Selbsteinschätzung, ob Interessenkonflikt besteht
<i>Egidi, Günther</i>	Ja: 1000 € vom Profil-Institut für die Teilnahme an einem Experten-Workshop zu Patientenrelevanten Endpunkten in der Diabetes-Therapie	Ja: 1000 € von der AOK Bremen für die Erarbeitung eines Vortragsmoduls zu umsatzstarken Arzneimitteln.	Nein	Nein	Nein	Nein	Ja: Gesellschaft für Allgemeinmedizin und Familienmedizin (DEGAM)	Ja: Ich bin strenger Anhänger einer auf klinisch relevante Endpunkte orientierten evidenzbasierten Medizin und habe mich wiederholt kritisch gegenüber einem PSA-Screening geäußert.	selbständig	Ja: Aus meiner kritischen Grundhaltung gegen ein PSA-Screening ergibt sich vorab ein Interessenkonflikt, der m.E. nicht gegen meine Mitarbeit in der Leitliniengruppe spricht, sondern der nur gewusst und beachtet werden sollte.
<i>Enders, Paul</i>	Nein	Nein	Nein	Nein	Nein	Nein	Ja: Bundesverband Prostatakrebs Selbsthilfe e.V.	Nein	n/a	Nein
<i>Fiebrandt, Hanns-Jörg</i>	Nein	Nein	Nein	Nein	Nein	Nein	Ja: BPS	Nein	Rentner seit 2004	Nein

Name	1. Berater- bzw. Gutachtertätigkeit oder bezahlte Mitarbeit	2. Honorare für Vortrags- und Schultätigkeiten oder bezahlte Autorenschaften	3. Finanzielle Zuwendungen (Drittmitel)	4. Eigentümerinteresse	5. Besitz von Geschäftsanteilen, Aktien, Fonds	6. Persönliche Beziehungen	7. Mitglied relevanter Fachgesellschaften	8. Politische, akademische, wissenschaftliche oder persönliche Interessen	9. Gegenwärtiger Arbeitgeber, relevante frühere Arbeitgeber der letzten 3 Jahre	Selbsteinschätzung, ob Interessenkonflikt besteht
<i>Fornara, Paolo</i>	Nein	Nein	Nein	Nein	Nein	Nein	Ja:	Nein	MLU Universität Halle-Wittenberg Ernst-Grube-Str. 40 06120 Halle	Nein
<i>Fröhner, Michael</i>	Nein	Ja: Vortragshonorare erhalten von GlaxoSmithKline, Novartis.	Nein	Nein	Nein	Ja: Organisation eines Live-OP-Seminars mit der Firma Wolff im Rahmen des Mitteldeutschen Urologenkongresses 2013.	Ja: Deutsche Gesellschaft für Urologie	Nein	Universitätsklinikum Dresden A.ö.R.	Nein
<i>Ganswindt, Ute</i>	Nein	Ja: Gelegentlich Vortragshonorar oder Reisekostenunterstützung durch MERCK, TAKEDA, HEXAL	Nein	Nein	Nein	Nein	Ja: Marburger Bund, DEGRO, ESTRO, ASTRO, DKG	Nein	LMU München . Klinikum der Universität	Nein

Name	1. Berater- bzw. Gutachtertätigkeit oder bezahlte Mitarbeit	2. Honorare für Vortrags- und Schulungstätigkeiten oder bezahlte Autorenschaften	3. Finanzielle Zuwendungen (Drittmittel)	4. Eigentümerinteresse	5. Besitz von Geschäftsanteilen, Aktien, Fonds	6. Persönliche Beziehungen	7. Mitglied relevanter Fachgesellschaften	8. Politische, akademische, wissenschaftliche oder persönliche Interessen	9. Gegenwärtiger Arbeitgeber, relevante frühere Arbeitgeber der letzten 3 Jahre	Selbsteinschätzung, ob Interessenkonflikt besteht
<i>Göckel-Beining, Bernt</i>	Nein	Nein	Nein	Nein	Nein	Nein	Ja: Leitlinienbeauftragter des BDU	Nein	Selbständig	Nein
<i>Graefen, Markus</i>	Nein	Nein	Nein	Nein	Nein	Nein	Ja: DGU	Nein	Martini-Klinik, Universitätsklinik, Hamburg-Eppendorf	Nein
<i>Grimm, Marc-Oliver</i>	Ja: Pfizer Pharma (Berater), Astellas Pharma (Berater), GlaxoSmithKline Pharma (Berater), Bayer HealthCare (Berater)	Ja: Bayer HealthCare (Referent) Pfizer Pharma (Referent), Sanofi Aventis (Referent), Hexal AG (Referent), Novartis (Referent), Takeda (Referent), Janssen Cilag (Referent), Apogepha (Referent), AMS (Gastopereur)	Ja: Novartis Pharma GmbH	Nein	Nein	Nein	Ja: Deutsche Gesellschaft für Urologie, Berufsverband der Deutschen Urologen, Deutsche Krebsgesellschaft, European Association of Urology, American Urological Association, Thüringer Krebsgesellschaft, Arbeitskreis Urologische Onkologie Thüringen	Nein	Universitätsklinikum Jena Bachstr. 8 07740 Jena	Nein
<i>Grün, Arne</i>	Nein	Nein	Nein	Nein	Nein	Nein	Ja: DEGRO, DEG	Nein	Charité-Klinik für Radio-Onkologie	Nein

Name	1. Berater- bzw. Gutachtertätigkeit oder bezahlte Mitarbeit	2. Honorare für Vortrags- und Schultätigkeiten oder bezahlte Autorenschaften	3. Finanzielle Zuwendungen (Drittmitel)	4. Eigentümerinteresse	5. Besitz von Geschäftsanteilen, Aktien, Fonds	6. Persönliche Beziehungen	7. Mitglied relevanter Fachgesellschaften	8. Politische, akademische, wissenschaftliche oder persönliche Interessen	9. Gegenwärtiger Arbeitgeber, relevante frühere Arbeitgeber der letzten 3 Jahre	Selbsteinschätzung, ob Interessenkonflikt besteht
<i>Hakenberg, Oliver</i>	Nein	Nein	Nein	Nein	Nein	Nein	Ja: DGU, BDU	Nein	Universitätsmedizin Rostock	Nein
<i>Hartmann, Arndt</i>	Ja: Advisory Board Zylomed	Nein	Nein	Nein	Nein	Nein	Ja: Deutsche Gesellschaft für Pathologie, Bundesverband Deutscher Pathologen	Nein	Universitätsklinikum Erlangen	Nein
<i>Heidenreich, Axel</i>	Ja: Amgen, Astellas, IPSEN, Janssen Cilag, Sanofi Aventis	Ja: Amgen, Astellas, Ferring, IPSEN, Janssen Cilag, Sanofi Aventis, Takeda, Myriad	Ja: Astellas, Sanofi Aventis	Nein	Nein	Nein	Nein	Nein	Uniklinik Aachen	Nein
<i>Henkel, Thomas-Oliver</i>	Ja: Advisory Board Duodart/Firma GSK	Ja: Schulung für Ärzte: Brachytherapie Kurse Firma Bebig	Nein	Nein	Nein	Ja: Dr. Rainer Ott, Firma TEVA	Nein	Nein	Selbstständig	Nein
<i>Höcht, Stefan</i>	Nein	Nein	Nein	Nein	Nein	Nein	Ja: Vorstand ARO, Vorstand DEGRO	Nein	Selbstständig tätig	Nein
<i>Hoffmann, W.</i>	Nein	Nein	Nein	Nein	Nein	Nein	Ja: DEGRO-Vorstandmitglied	Nein	Klinikum-Braunschweig	Nein

Name	1. Berater- bzw. Gutachtertätigkeit oder bezahlte Mitarbeit	2. Honorare für Vortrags- und Schulungstätigkeiten oder bezahlte Autorenschaften	3. Finanzielle Zuwendungen (Drittmitel)	4. Eigentümerinteresse	5. Besitz von Geschäftsanteilen, Aktien, Fonds	6. Persönliche Beziehungen	7. Mitglied relevanter Fachgesellschaften	8. Politische, akademische, wissenschaftliche oder persönliche Interessen	9. Gegenwärtiger Arbeitgeber, relevante frühere Arbeitgeber der letzten 3 Jahre	Selbsteinschätzung, ob Interessenkonflikt besteht
<i>Hölscher, Tobias</i>	Ja: klinische Qualitätskontrolle für Bestrahlung im Rahmen klinischer Studien; EQUAL-ESTRO; 3600 €/Jahr	Nein	Nein	Nein	Nein	Nein	Ja: Mitgliedschaft DEGRO, ESTRO, Bundesverband Strahlentherapie., DGU	Nein	Klinik und Poliklinik für Strahlentherapie und MVZ für Strahlentherapie am Universitätsklinikum Dresden	Nein
<i>Klein, Tobias</i>	Nein	Ja: Dozent "Fachpflege Onkologie" im Rahmen der "Weiterbildung Onkologie für MFA Urologie" durch medac GmbH/DGU	Nein	Nein	Nein	Nein	Ja: KOK Beirat (Konferenz Onkologischer Kranken- & Kinderkrankenpflege) -> eine AG de DKG e.V.	Nein	DRK-Schwesternschaft Hamburg e.V. (Angestellter)	Nein
<i>Kotzerke, Jörg</i>	Nein	Nein	Nein	Nein	Nein	Nein	Ja: Präsident der deutschen Gesellschaft für Nuklearmedizin	Nein	Freistaat Sachsen	Nein

Name	1. Berater- bzw. Gutachtertätigkeit oder bezahlte Mitarbeit	2. Honorare für Vortrags- und Schulungstätigkeiten oder bezahlte Autorenschaften	3. Finanzielle Zuwendungen (Drittmittel)	4. Eigentümerinteresse	5. Besitz von Geschäftsanteilen, Aktien, Fonds	6. Persönliche Beziehungen	7. Mitglied relevanter Fachgesellschaften	8. Politische, akademische, wissenschaftliche oder persönliche Interessen	9. Gegenwärtiger Arbeitgeber, relevante frühere Arbeitgeber der letzten 3 Jahre	Selbsteinschätzung, ob Interessenkonflikt besteht
<i>Krause, Bernd</i>	Nein	Nein	Nein	Nein	Nein	Nein	Ja: Mitglied im Vorstand d. Deutschen Ges. für Nuklearmedizin, Task Group Coordinator der DGN, ist mit der Erstellung sämtlicher Leitlinien der DGN. Sei es im Sinne der Erstellung für die bei der AWMF einzustellenden Leitlinien der DGN oder eigene Leitlinien befasst, die entsprechend auch publiziert werden. Ist im Vorstand der European Association of Nuclear Medicine (EANM), Wien, als Committee Koordinator tätig. Daraus ergibt sich ebenfalls eine Involvierung in Leitlinienerstellungen der EANM.	Nein	Universitätsmedizin Rostock	Nein

Name	1. Berater- bzw. Gutachtertätigkeit oder bezahlte Mitarbeit	2. Honorare für Vortrags- und Schulungstätigkeiten oder bezahlte Autorenschaften	3. Finanzielle Zuwendungen (Drittmitel)	4. Eigentümerinteresse	5. Besitz von Geschäftsanteilen, Aktien, Fonds	6. Persönliche Beziehungen	7. Mitglied relevanter Fachgesellschaften	8. Politische, akademische, wissenschaftliche oder persönliche Interessen	9. Gegenwärtiger Arbeitgeber, relevante frühere Arbeitgeber der letzten 3 Jahre	Selbsteinschätzung, ob Interessenkonflikt besteht
<i>Kristian-Glen</i>	Nein	Ja: Vorträge Uro-Update	Nein	Nein	Nein	Nein	Ja: Mitglied: Deutsche Gesellschaft für Pathologie (DGP), Berufsverband deutscher Pathologen (BV)	Nein	Universitätsklinikum Bonn/Universität Bonn (seit 5/2011) Universität Zürich (2007-2011)	Nein
<i>Lein, Michael</i>	Ja: Advisory Board Novartis (2012 beendet), Meeting mit Fa. Amgen (Beratung)	Ja: Vortrag Fa. Amgen	Ja: VEG-Studie, Fa. GlaxoSmithKline; FINA007-Studie, Fa. Galenus	Nein	Nein	Nein	Nein	Nein	Klinikum Offenbach GmbH	Nein

Name	1. Berater- bzw. Gutachtertätigkeit oder bezahlte Mitarbeit	2. Honorare für Vortrags- und Schultätigkeiten oder bezahlte Autorenschaften	3. Finanzielle Zuwendungen (Drittmittel)	4. Eigeninteresse	5. Besitz von Geschäftsanteilen, Aktien, Fonds	6. Persönliche Beziehungen	7. Mitglied relevanter Fachgesellschaften	8. Politische, akademische, wissenschaftliche oder persönliche Interessen	9. Gegenwärtiger Arbeitgeber, relevante frühere Arbeitgeber der letzten 3 Jahre	Selbsteinschätzung, ob Interessenkonflikt besteht
<i>Loch, Tillmann</i>	Ja. Fresenius Kabi Deutschland (Honorar), TheraNostic (Honorar)	Ja: Vortrags- und Schultätigkeit, Takeda Pharma, GSK, Farco, etc. (nach Anfrage); Kongressvorträge a. Anfrage (i.d. Regel nicht produktbezogen)	Ja: Leihgeräte BK Medical, Olympus	Ja: Erfinder/Entwickler Ultraschall-diagnostikverfahren (Keine Zahlungen!)	Nein	Nein	Ja: DGU, EAU, Guideline Office, AK Bildgebende Systeme der Akademie, ESUV; Mitglied: AUA, DGU, BDU, DEGUM, EAU,	Nein	Diakonissenkrankenhaus Flensburg	Nein
<i>Loertzer, Hagen</i>	Nein	Nein	Nein	Nein	Nein	Nein	Ja: DGU, DBU	Nein	Westpfalz-Klinikum Kaiserslautern, Universitätsklinikum Göttingen	Nein
<i>Luboldt, Hans-Joachim</i>	Nein	Nein	Nein	Nein	Nein	Nein	Ja: DGU, BDU, AUA, SIU, EAU	Nein	Selbstständig	Nein

Name	1. Berater- bzw. Gutachtertätigkeit oder bezahlte Mitarbeit	2. Honorare für Vortrags- und Schultätigkeiten oder bezahlte Autorenschaften	3. Finanzielle Zuwendungen (Drittmitel)	4. Eigentümerinteresse	5. Besitz von Geschäftsanteilen, Aktien, Fonds	6. Persönliche Beziehungen	7. Mitglied relevanter Fachgesellschaften	8. Politische, akademische, wissenschaftliche oder persönliche Interessen	9. Gegenwärtiger Arbeitgeber, relevante frühere Arbeitgeber der letzten 3 Jahre	Selbsteinschätzung, ob Interessenkonflikt besteht
<i>Lümmen, Gerd</i>	Ja: FARCO Pharma GmbH, Köln; Innovacell Biotechnologie AG, Innsbruck, Österreich	Nein	Nein	Nein	Nein	Nein	Ja: DGU, BDU	Nein	St. Josef-Hospital Troisdorf	Nein
<i>Machtens, Stefan</i>	Ja: Advisory Board Tätigkeit für Sanofi, Pfizer, Bayer	Ja: Bezahlte Vortragstätigkeit für Sanofi, BARD, Pfizer, GSK, Astellas, Bayer, Amgen	Ja: Drittmittel für Study Nurse durch Fa. BARD	Nein	Nein	Nein	Ja: Mitglied in DGU	Nein	Chefarzt in der Abteilung für Urologie und Kinderurologie am Marienkrankenhaus Bergisch Gladbach; Dr.-Robert-Koch-Str. 18; 51465 Bergisch Gladbach	Nein
<i>Martin, Thomas</i>	Nein	Ja: Vortragshonorare von Roche Pharma	Nein	Nein	Nein	Nein	Ja: DEGRO, ARO	Nein	Ambulanz Bremen GmbH, MVZ Sektion Radioonkologie; Klinikum Bremen-Mitte, Klinik für Strahlentherapie	Nein

Name	1. Berater- bzw. Gutachtertätigkeit oder bezahlte Mitarbeit	2. Honorare für Vortrags- und Schulungstätigkeiten oder bezahlte Autorenschaften	3. Finanzielle Zuwendungen (Drittmitel)	4. Eigentümerinteresse	5. Besitz von Geschäftsanteilen, Aktien, Fonds	6. Persönliche Beziehungen	7. Mitglied relevanter Fachgesellschaften	8. Politische, akademische, wissenschaftliche oder persönliche Interessen	9. Gegenwärtiger Arbeitgeber, relevante frühere Arbeitgeber der letzten 3 Jahre	Selbsteinschätzung, ob Interessenkonflikt besteht
<i>Miller, Kurt</i>	Ja: Amgen, Novartis, Astellas, Janssen-Cilag, Ferring, Sanofi-Aventis, GSK, BMS, Roche	Ja: Amgen, Novartis, Astellas, Janssen-Cilag, Ferring, Sanofi-Aventis, GSK, BMS, Roche	Ja: Novartis	Nein	Nein	Nein	Ja: DGU, DKG	Nein	Charité	Nein
<i>Moser, Lutz</i>	Nein	Nein	Nein	Nein	Nein	Nein	Ja: Mitglied der DEGRO, Deutsche Gesellschaft der Radioonkologen	Nein	Charité Berlin Universitätsmedizin	Nein

Name	1. Berater- bzw. Gutachtertätigkeit oder bezahlte Mitarbeit	2. Honorare für Vortrags- und Schulungstätigkeiten oder bezahlte Autorenschaften	3. Finanzielle Zuwendungen (Drittmitel)	4. Eigentümerinteresse	5. Besitz von Geschäftsanteilen, Aktien, Fonds	6. Persönliche Beziehungen	7. Mitglied relevanter Fachgesellschaften	8. Politische, akademische, wissenschaftliche oder persönliche Interessen	9. Gegenwärtiger Arbeitgeber, relevante frühere Arbeitgeber der letzten 3 Jahre	Selbsteinschätzung, ob Interessenkonflikt besteht
<i>Mueller-Lisse, Ulrich</i>	Nein	Ja: Vorträge / Seminare für Bracco Deutschland GmbH, Konstanz (Hersteller von Kontrastmitteln für die Radiologie) und für Saegeling Medizintechnik GmbH, Heidenau (Medizinproduktehersteller, Vertrieb und Service)	Nein	Nein	Nein	Nein	Ja: Mitglied und Vertreter der Deutschen Röntgen-gesellschaft e.V. (Berlin), Vorsitzender der Arbeitsgemein-schaft Urogenitale Radiologie der Deutschen Röntgen-gesellschaft e.V.	Nein	Klinikum der Universität München (fortlaufend seit 07/1993)	Nein
<i>Otto, Ullrich</i>	Nein	Nein	Nein	Nein	Nein	Nein	Nein	Nein	Klinikum Hartenstein, Bad Wildungen	Nein
<i>Palmedo, Holger</i>	Nein	Nein	Nein	Nein	Nein	Nein	Ja: DGN	Nein	freiberuflich	Nein

Name	1. Berater- bzw. Gutachtertätigkeit oder bezahlte Mitarbeit	2. Honorare für Vortrags- und Schultätigkeiten oder bezahlte Autorenschaften	3. Finanzielle Zuwendungen (Drittmitel)	4. Eigentümerinteresse	5. Besitz von Geschäftsanteilen, Aktien, Fonds	6. Persönliche Beziehungen	7. Mitglied relevanter Fachgesellschaften	8. Politische, akademische, wissenschaftliche oder persönliche Interessen	9. Gegenwärtiger Arbeitgeber, relevante frühere Arbeitgeber der letzten 3 Jahre	Selbsteinschätzung, ob Interessenkonflikt besteht
<i>Pummer, Karl</i>	Ja: Astellas, Takeda, Janssen (jeweils Advisory Board)	Ja: Astellas, Takeda, Ferring, Novartis, Janssen (jeweils Vorträge)	Ja: Takeda (Studienprotokoll: Millennium C21004)	Nein	Nein	Nein	Nein	Nein	Medizinische Universität Graz Auenbruggerplatz 5/6 8036 Graz	Nein
<i>Rohde, Volker</i>	Nein	Ja: Vorträge für Firmen: Hexal, Apogepha, Medac, Jansen (keine Zusammenhänge zu Produkten)	Nein	Nein	Nein	Nein	Nein	Nein	Eigenständige Praxisführung	Nein
<i>Roth, Wilfried</i>	Nein	Nein	Nein	Nein	Nein	Nein	Ja: DGP, BV Deutscher Pathologen	Nein	Universitätsklinikum Heidelberg DKFZ Heidelberg	Nein
<i>Rübben, Herbert</i>	Ja: DKV, AOK, Innovacell	Nein	Nein	Nein	Nein	Nein	Ja: DGU, BDU	Nein	Land NRW	Nein

Name	1. Berater- bzw. Gutachtertätigkeit oder bezahlte Mitarbeit	2. Honorare für Vortrags- und Schultätigkeiten oder bezahlte Autorenschaften	3. Finanzielle Zuwendungen (Drittmitel)	4. Eigentümerinteresse	5. Besitz von Geschäftsanteilen, Aktien, Fonds	6. Persönliche Beziehungen	7. Mitglied relevanter Fachgesellschaften	8. Politische, akademische, wissenschaftliche oder persönliche Interessen	9. Gegenwärtiger Arbeitgeber, relevante frühere Arbeitgeber der letzten 3 Jahre	Selbsteinschätzung, ob Interessenkonflikt besteht
<i>Schmitz-Dräger, Bernd Jürgen</i>	Ja: Novartis: Studententätigkeit, Referent, Advisory Board; Takeda: Referent; Hexal: Referent, Advisory Board	Ja: Novartis Pharma, Astra-Zenaca	Ja: Novartis Pharma	Nein	Nein	Nein	Ja: EAU, International Bladder Cancer Network (IBCN)	Nein	Selbstständig	Nein
<i>Schostak, Prof. Dr. med. Martin</i>	Ja: Berater für die Firma EDAP-TMS	Ja: Vortragender für EDAP-TMS	Nein	Nein	Nein	Nein	Ja: Mitglied DGU	Nein	Universitätsklinikum Magdeburg seit 06/2011 Charité Berlin 1994-2011	Nein
<i>Schrader, Prof. Mark</i>	Nein	Nein: Astellas, Bayer, Pierre Fabre	Ja: Janssen	Nein	Nein	Nein	Nein	Nein	aktuell: Universitätsklinikum Ulm vorher: Charité	Nein

Name	1. Berater- bzw. Gutachtertätigkeit oder bezahlte Mitarbeit	2. Honorare für Vortrags- und Schultätigkeiten oder bezahlte Autorenschaften	3. Finanzielle Zuwendungen (Drittmitel)	4. Eigentümerinteresse	5. Besitz von Geschäftsanteilen, Aktien, Fonds	6. Persönliche Beziehungen	7. Mitglied relevanter Fachgesellschaften	8. Politische, akademische, wissenschaftliche oder persönliche Interessen	9. Gegenwärtiger Arbeitgeber, relevante frühere Arbeitgeber der letzten 3 Jahre	Selbsteinschätzung, ob Interessenkonflikt besteht
<i>Sedlmayer, Felix</i>	Nein	Ja: firmengetragene Wissenschafts-Symposien (je 1x) Takeda, Astellas, Sandoz	Ja: Forschungs Kooperation mit d. Firmen Elekta, C-Re (Medizintechnikhersteller)	Nein	Nein	Nein	Ja: ÖGRO, DEGRO	Nein	Land Salzburg	Nein
<i>Seitz, Gerhard (Beobachter)</i>	Nein	Nein	Nein	Nein	Nein	Nein	Ja: DGP	Nein	Niedergelassen als Pathologe, Chefarzt in Teilzeit (13 h) der Sozialstiftung Bamberg	Nein

Name	1. Berater- bzw. Gutachtertätigkeit oder bezahlte Mitarbeit	2. Honorare für Vortrags- und Schultätigkeiten oder bezahlte Autorenschaften	3. Finanzielle Zuwendungen (Drittmitel)	4. Eigentümerinteresse	5. Besitz von Geschäftsanteilen, Aktien, Fonds	6. Persönliche Beziehungen	7. Mitglied relevanter Fachgesellschaften	8. Politische, akademische, wissenschaftliche oder persönliche Interessen	9. Gegenwärtiger Arbeitgeber, relevante frühere Arbeitgeber der letzten 3 Jahre	Selbsteinschätzung, ob Interessenkonflikt besteht
<i>Semjonow, Axel</i>	Ja: Beckman-Coulter, Janssen-Cilag	Ja: Abbott, Astellas, Beckman-Coulter, Dr. Pfleger, Ferring, GlaxoSmithKline, Ipsen, Novartis, Pfizer, Roche, Siemens, Takeda, TEVA	Ja: Beckman-Coulter, Protagen, Roche	Ja: Patent "Method for characterizing primary tumors" DE10 2171 02A1, DE10 2171 02B4, EP149 7657 A2, US200 6014 7911, US200 9003 5774 A1, WO20 0308 7405	Nein	Ja: Familiäre Beziehung: Medical Director Philips Healthcare	Ja: Arbeitskreis Labordiagnostik, DGU; European Group on Tumor Marker (EGTM); National Academy of Clinical Biochemists (NACB)	Nein	UK Münster, Prostatazentrum	Nein

Name	1. Berater- bzw. Gutachtertätigkeit oder bezahlte Mitarbeit	2. Honorare für Vortrags- und Schultätigkeiten oder bezahlte Autorenschaften	3. Finanzielle Zuwendungen (Drittmitel)	4. Eigentümerinteresse	5. Besitz von Geschäftsanteilen, Aktien, Fonds	6. Persönliche Beziehungen	7. Mitglied relevanter Fachgesellschaften	8. Politische, akademische, wissenschaftliche oder persönliche Interessen	9. Gegenwärtiger Arbeitgeber, relevante frühere Arbeitgeber der letzten 3 Jahre	Selbsteinschätzung, ob Interessenkonflikt besteht
				A2, WO20 0308 7405 A3						
<i>Steuber, Thomas</i>	Ja: Advisory-Board Aktivität bei Janssen, Amgen, Sanofi-Aventis	Ja: Honorarvorträge (Sat-Symposien) für Amgen und Janssen	Nein	Nein	Nein	Nein	Nein	Nein	Martini-Klinik am UKE GmbH	Nein
<i>Stöckle, Michael</i>	Nein	Nein	Ja: Prostata-Ca Studie, Janssen, Studienleiter Dr. Oltmann	Nein	Ja: 50 Aktien von intuitive surgical	Nein	Ja: Präsident DGU	Ja: Robotischer Operateur (Da Vinci Operationen)	Uniklinikum des Saarlandes	Nein
<i>Vögeli, Thomas-Alexander</i>	Nein	Ja: Vortragstätigkeit: Medac, Takeda, Lilly, Sanofi, Teleflex	Nein	Nein	Nein	Nein	Ja: DGU, AUA, SIU, EAU	Nein	Medizinisches Zentrum Städteregion Aachen	Nein

Name	1. Berater- bzw. Gutachtertätigkeit oder bezahlte Mitarbeit	2. Honorare für Vortrags- und Schulungstätigkeiten oder bezahlte Autorenschaften	3. Finanzielle Zuwendungen (Drittmitel)	4. Eigentümerinteresse	5. Besitz von Geschäftsanteilen, Aktien, Fonds	6. Persönliche Beziehungen	7. Mitglied relevanter Fachgesellschaften	8. Politische, akademische, wissenschaftliche oder persönliche Interessen	9. Gegenwärtiger Arbeitgeber, relevante frühere Arbeitgeber der letzten 3 Jahre	Selbsteinschätzung, ob Interessenkonflikt besteht
<i>Wagner, Sigrid</i>	Nein	Nein	Nein	Nein	Nein	Nein	Nein	Nein	Bis 2011 Uni Halle, Ernst-Gruber-Str. 40, 06120 Halle Ab 2011 Klinikum Ingolstadt GmbH	Nein
<i>Wedding, Ulrich</i>	Nein	Ja: Novartis, Roche, Janssen-Cilag, Amgen, Pro.. (nicht lesbar), Cephalon, Pfizer, Chugai, Sanofi	Nein	Nein	Ja: Bayer AG 50 Aktien	Nein	Ja: DGHO, DGP, DGIM, DKG, AIO, DGG	Nein	Universitätsklinikum Jena	Nein
<i>Weißbach, Lothar</i>	Ja: Wissenschaftlicher Beirat Hexal	Ja: Vortragshonorare Fa. Lilly	Ja: Fa. Gazprom für die HAROW-Studie; Fa. Janssen für die IBuTu-Studie	Nein	Nein	Nein	Nein	Nein	Ja: Novartis, Roche, Janssen-Cilag, Amgen, Pro.. (nicht lesbar), Cephalon, Pfizer, Chugai, Sanofi	Nein

Name	1. Berater- bzw. Gutachtertätigkeit oder bezahlte Mitarbeit	2. Honorare für Vortrags- und Schultätigkeiten oder bezahlte Autorenschaften	3. Finanzielle Zuwendungen (Drittmitel)	4. Eigentümerinteresse	5. Besitz von Geschäftsanteilen, Aktien, Fonds	6. Persönliche Beziehungen	7. Mitglied relevanter Fachgesellschaften	8. Politische, akademische, wissenschaftliche oder persönliche Interessen	9. Gegenwärtiger Arbeitgeber, relevante frühere Arbeitgeber der letzten 3 Jahre	Selbsteinschätzung, ob Interessenkonflikt besteht
<i>Wenz, Frederik</i>	Ja: Elekta, Berater Zeiss, Berater	Ja: Vortragshonorare Celegene, Elekta, Zeiss, Roche, Amgen, Novartis	Ja: Forschungs-kooperation Elekta, Zeiss	Nein	Nein	Nein	Ja: DEGRO, DGU, ARO, BVDST	Nein	Universitätsmedizin Mannheim	Nein
<i>Wernert, Nicolas (Berater)</i>	Nein	Nein	Nein	Nein	Nein	Nein	Ja: Deutsche Gesellschaft für Pathologie	Nein	Universität Bonn/Universitätsklinikum Bonn	Nein
<i>Wiedemann, Andreas</i>	Nein	Ja: Vortragstätigkeit: FA. Pfizer, Fa. Dr. Pfleger, Fa. Berlin-Chemie	Ja: AMS-Deutschland	Nein	Nein	Nein	Ja: Deutsche Gesellschaft für Geriatrie Vorsitz AG Inkontinenz	Nein	Ev. Krankenhaus Witten gGmbH	Nein
<i>Wiegel, Thomas</i>	Ja: Advisory Board Ipsen, Siemens	Ja: Ferring, Hexal, Takeda, Siemens, Ipsen, Janssen	Nein	Nein	Nein	Nein	Ja: DEGRO	Nein	Land Baden-Württemberg	Nein

Name	1. Berater- bzw. Gutachtertätigkeit oder bezahlte Mitarbeit	2. Honorare für Vortrags- und Schultätigkeiten oder bezahlte Autorenschaften	3. Finanzielle Zuwendungen (Drittmitel)	4. Eigentümerinteresse	5. Besitz von Geschäftsanteilen, Aktien, Fonds	6. Persönliche Beziehungen	7. Mitglied relevanter Fachgesellschaften	8. Politische, akademische, wissenschaftliche oder persönliche Interessen	9. Gegenwärtiger Arbeitgeber, relevante frühere Arbeitgeber der letzten 3 Jahre	Selbsteinschätzung, ob Interessenkonflikt besteht
<i>Wirth, Manfred</i>	Ja: Amgen GmbH, Apogepha Arzneimittel GmbH, Astra-Zeneca GmbH, Bayer Vital GmbH, Dendreon Cooperation, Ferring Arzneimittel GmbH, Janssen Cilag GmbH, Orion Pharma GmbH, Sanofi-Aventis Deutschland GmbH, Siemens AG, Takeda Pharma	Ja: Amgen GmbH, Apogepha Arzneimittel GmbH, Astra-Zeneca GmbH, Bayer Vital GmbH, Dendreon Cooperation, Ferring Arzneimittel GmbH, Janssen Cilag GmbH, Orion Pharma GmbH, Sanofi-Aventis Deutschland GmbH, Siemens AG, Takeda Pharma	Nein	Nein	Nein	Nein	Ja: Mitglied der DGU und des BDU	Nein	Universitätsklinikum Carl Gustav Carus Dresden	Nein
<i>Wolff, Johannes M.</i>	Ja: Astra Zeneca, Amgen, Bayer, Ferring, Janssen, Sanofi	Ja: Astra Zeneca, Astellas, Bayer, Ferring, Hexal, Ipsen, Janssen, Sanofi, Takeda	Nein	Nein	Nein	Nein	Ja: DGU, BDU, DGHO, DKG	Nein	AKH Viersen Heesstraße 10 41751 Viersen	Nein

Name	1. Berater- bzw. Gutachtertätigkeit oder bezahlte Mitarbeit	2. Honorare für Vortrags- und Schulungstätigkeiten oder bezahlte Autorenschaften	3. Finanzielle Zuwendungen (Drittmitel)	4. Eigentümerinteresse	5. Besitz von Geschäftsanteilen, Aktien, Fonds	6. Persönliche Beziehungen	7. Mitglied relevanter Fachgesellschaften	8. Politische, akademische, wissenschaftliche oder persönliche Interessen	9. Gegenwärtiger Arbeitgeber, relevante frühere Arbeitgeber der letzten 3 Jahre	Selbsteinschätzung, ob Interessenkonflikt besteht
<i>Wörmann, Bernhard</i>	Nein	Nein	Nein	Nein	Nein	Nein	Ja: Deutsche Gesellschaft für Hämatologie und Medizinische Onkologie (DGHO), verantwortlich für Leitlinien	Nein	Deutsche Gesellschaft für Hämatologie und Medizinische Onkologie (DGHO); Charité Berlin	Nein
<i>Zacharias, Jens-Peter</i>	Nein	Nein	Nein	Nein	Nein	Nein	Ja: BPS Vorstandsmitglied, Vertreter im G-BA (siehe Geschäftsbericht)	Ja: ebm Fördermitglied, Vertreter des BPS	Rentner	Ja: Wegen der Interessenlage wurde ich eingeladen.
<i>Zastrow, Stefan</i>	Ja: Sanofi-Aventis, Pfizer, Apogepha	Ja: Janssen, Sanofi-Aventis, Pfizer, Apogepha	Nein	Nein	Nein	Nein	Ja: DGU	Nein	Universitätsklinikum Dresden	Nein
<i>Zips, Daniel</i>	Nein	Nein	Ja: Bayer Pharma Berlin Forschungs-kooperation	Nein	Nein	Nein	Ja: ESTRO	Nein	Klinikum Tübingen seit 04/2012, zuvor Uniklinikum Dresden	Nein

13. Literatur

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