

The notion of PICO for synthesis: planning the grouping of studies for meta-analyses and other syntheses

Cochrane Methods Symposium

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Declaration of interest

I am employed by Cochrane Australia (CA), School of Public Health and Preventive Medicine, Monash University. CA is funded by the Australian Government through the National Health and Medical Research Council (NHMRC) to support the conduct and use of systematic reviews, research translation, and methodological development in evidence synthesis.

I am the director of the Melbourne GRADE Centre.

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I am co-author on four chapters of the new Cochrane Handbook.



() Cochrane

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Defining the criteria for including studies and how they will be grouped for the synthesis

Joanne E McKenzie, Sue E Brennan, Rebecca E Ryan, Hilary J Thomson, Renea V Johnston, James Thomas

KEY POINTS

- The scope of a review is defined by the types of population (participants), types of interventions (and comparisons), and the types of outcomes that are of interest. The acronym PICO (population, interventions, comparators and outcomes) helps to serve as a reminder of these.
- The population, intervention and comparison components of the question, with the
 additional specification of types of study that will be included, form the basis of the
 pre-specified eligibility criteria for the review. It is rare to use outcomes as eligibility
 criteria: studies should be included irrespective of whether they report outcome data,
 but may legitimately be excluded if they do not measure outcomes of interest, or if
 they explicitly aim to prevent a particular outcome.
- Cochrane Reviews should include all outcomes that are likely to be meaningful and not include trivial outcomes. Critical and important outcomes should be limited in number and include adverse as well as beneficial outcomes.
- Review authors should plan at the protocol stage how the different populations, interventions, outcomes and study designs within the scope of the review will be grouped for analysis.

3.1 Introduction

One of the features that distinguishes a systematic review from a narrative review is that systematic review authors should pre-specify criteria for including and excluding studies in the review (eligibility criteria, see MECIR Box 3.2.a).

When developing the protocol, one of the first steps is to determine the elements of the review question (including the population, intervention(s), comparator(s) and

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Origins of PICO for synthesis



Three levels of PICO

- **1. Review PICO** (planned at protocol stage) on which *eligibility of studies* is based [Chapters 2 and 3]
- 2. PICO for each synthesis (planned at protocol stage) which defines the question that each synthesis aims to answer. [Chapters 2 and 3]
- **3. PICO of included studies** (determined at the review stage) which defines the questions investigated in the included studies [Chapter 9]

The questions we ask

Does exercise increase bone density in postmenopausal women?

What is the comparative efficacy and acceptability of different psychological therapies for panic disorder?

What is the effect of **psychosocial interventions** for supporting women to stop smoking in pregnancy?

PICO characteristics of studies identified by the search



PICO for the review

(i.e. the criteria for including studies)

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The questions we answer

Does exercise increase bone density in postmenopausal women?

Any exercis	se	.aan (SD)	Control N	Mean (SD)	Mean Difference IV,Random,95% CI	Weight	Mean Ditterence IV,Random,95% CI
Bemben 2000	17	0.37 (16.45)	8	-1.06 (21)	• •	+ 0.4%	1.43 [-15.09, 17.95]
Bocalini 2009	15	-0.09 (1.9)	10	-1.58 (0.36)		11.7 %	1.49 [0.50, 2.48]
Bravo 1996	61	0.27 (19.6)	63	-0.53 (20.8)	• •	→ 1.7 %	0.80 [-6.31, 7.91]
Chan 2004	54	-0.94 (3.85)	49	-1.8 (3.52)		10.4 %	0.86 [-0.56, 2.28]
Chilibedk 2002	10	-0.1 (2.85)	12	-0.4 (2.77)		7.6 %	0.30 [-2.06, 2.66]
Chuin 2009	8	0 (12.43)	7	0 (10.24)	•	→ 0.7 %	0.0 [-11.48, 11.48]
Ebrahim 1997	49	-0.25 (16)	48	-2.75 (20.77)	• •	➡ 1.6 %	2.50 [-4.89, 9.89]
Englund 2005	21	0 (12.46)	19	0 (18.13)	•	→ 1.0 %	0.0 [-9.74, 9.74]
Going 2003	71	0.57 (4.14)	59	-0.47 (4.12)		10.4 %	1.04 [-0.39, 2.47]
Kerr 2001	54	0.47 (9.11)	36	-0.11 (15.6)	• •	→ 2.5 %	0.58 [-5.07, 6.23]
Korpelainen 2006	84	-0.59 (1.23)	76	-1.04 (1.16)		13.0 %	0.45 [0.08, 0.82]
Lau 1992	11	-6.6 (2.86)	12	-1.1 (0.54)	+	9.5 %	-5.50 [-7.22, -3.78]
Lord 1996	68	1.52 (5.19)	70	3.12 (6.52)		8.8 %	-1.60 [-3.56, 0.36]
Maddalozzo 2007	29	-1.46 (16.84)	29	-3.19 (17.03)	• •	→ 1.2 %	1.73 [-6.99, 10.45]
Nelson 1994	20	0.9 (4.5)	19	2.5 (3.8)	• •	7.0 %	-1.60 [-4.21, 1.01]
Newstead 2004	23	0 (9.67)	26	-1.27 (17.9)	• •	→ 1.4 %	1.27 [-6.66, 9.20]
Pruitl 1996	15	0.07 (18.12)	11	0.79 (16.3)	• •	→ 0.5 %	-0.72 [-14.02, 12.58]
Smidt 1992	22	1.06 (4.02)	27	-0.25 (3.84)		8.0 %	1.31 [-0.91, 3.53]
Tolomio 2009	58	0 (18.18)	67	-1.18 (14.56)	• •	→ 2.4 %	1.18 [-4.65, 7.01]
Total (95% CI) Heterogeneity: Tau ² – 1.96; Chi ² – Test for overall effect: Z – 0.15 (P – Test for subgroup differences: Not	690 58.64, d1 0.88) applicable	- 18 (P⊲0.00001	648 i); l≊ - 69%		-	100.0 %	-0.08 [-1.08, 0.92]

Does non-weight bearing, high force exercise increase bone density ... The ques Study or subgroup Exercise Mean Difference Weight Mean Difference - ITO N Mean (SD) N Mean(SD) IV.Fixed.95% CI IV.Fixed.95% CI Bemben 2000 0.77 (22.6) 0.2 % 1.83 [-18.37, 22.03] 10 8 -1.06 (21) Bocalini 2009 64.7 % 1.49 [0.50, 2.48] -0.09 (1.9) 10 -1.58 (0.36) 15 Chilibeck 2002 12 -0.4 (2.77) 11.3 % 0.30 [-2.06, 2.66] -0.1 (2.85) 10 Chuin 2009 0.5 % 0.0[-11.48, 11.48] 0 (12.43) 0 (10.24) 8 Kerr 2001 1.04 (13.77) 36 -0.11 (15.6) 1.1 % 1.15 [-6.35, 8.65] 24 Any exercise Nelson 1994 20 0.9 (4.5) 19 2.5 (3.8) 9.3 % -1.60 [-4.21, 1.01] .aan(SD) Pruitt 1996 -0.49 (22.28) 11 0.79 (16.3) 0.2 % -1.28 [-19.48, 16.92]

27

130

-0.25 (3.84)

0.7%

1.6 %

12.8 %

100.0%

1.31 [-0.91, 3.53]

1.03[0.24, 1.82]

Does exercise increase bone density in postmenopausal women?

Study or subgroup	Exercise N	Mean (SD)	N	Mean (SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% Cl
Bemben 2000	7	-0.11 (24.5)	8	-1.06 (21)	_+	7.2 %	0.95 [-22.31, 24.21
Kerr 2001	30	0.03 (12.16)	36	-0.11 (15.6)	-	86.6 %	0.14 [-6.56, 6.84
Pruitl 1996	7	1.16 (31.13)	11	0.79 (16.3)	-+	6.2 %	0.37 [-24.62, 25.36
Total (95% CI) Heterogeneity: Chi ² = 0.00, o Test for overall effect: Z = 0.0 Test for subgroup differences	44 d1 = 2 (P = 1.00) 7 (P = 0.95) 5: Not applicable	; lº =0.0%	55		•	100.0 %	0.21 [-6.02, 6.45

1.06 (4.02)

117

Heterogèneity: Chi² = 5.26, dt = 7 (P = 0.63); l² =0.0%.

Test for overall effect: Z = 2.54 (P = 0.011)

0 (10.24)

-2.75 (20.77)

Test for subgroup differences: Not applicable

Does dynamic weight bearing, low force exercise increase bone density ...

0.0 [-11.48, 11.48]

2.50 [-4.89, 9.89]

Study or subgroup Exercise Control Mean Difference Mean(SD) N Mean (SD) IV.Fixed.95% CI N Going 2003 0.57 (4.14) -0.47 (4.12) 59 Maddalozzo 2007 29 1.46 (16.84) 29 -3.19 (17.03) Newstead 2004 -1.27 (17.9) 23 0 (9.67) 26 Total (95% CI) 123 114 -1 Heterogeneity: Chi² = 0.03, dt = 2 (P = 0.99); l² = 0.0% Test for overall effect: Z = 1.51 (P = 0.13) Test for subgroup differences: Not applicate

Heterogeneity: Tau² = 1.96; Chi² = 58.64, d1 = 18 (P<0.00001); I²

≪0.00001); I≊	Study or subgroup	Exercise N	Mean (SD)	N	Mean(SD)	Mean Difference IV,Random,95% Cl	Weight	Mean Difference IV,Random,95% Cl
-	Bravo 1996	61	0.27 (19.6)	63	-0.53 (20.8)	_	11.9 %	0.80 [-6.31, 7.91]
Weight	Chan 2004	54	-0.94 (3.85)	49	-1.8 (3.52)	#	26.2 %	0.86 [-0.56, 2.28]
· .	Ebrahim 1997	49	-0.25 (16)	48	-2.75 (20.77)		11.4 %	2.50 [-4.89, 9.89]
94.4 %	Lau 1992	11	-6.6 (2.86)	12	-1.1 (0.54)	.	25.6 %	-5.50 [-7.22, -3.78]
2.5 %	Lord 1996	68	1.52 (5.19)	70	3.12 (6.52)	-#-	25.0 %	-1.60 [-3.56, 0.36]
3.0 %								
00.0 %	Total (95% CI) Heterogeneity: Tau ² = 10.0 Test for overall effect: Z = 0. Test for subgroup difference	243 0; Chi² = 32.90, o 72 (P = 0.47) s: Not applicable	di - 4 (P⊲0.00001)	242); l² - 88%		•	100.0 %	-1.20 [-4.45, 2.05]

Does dynamic weight bearing, high force exercise increase bone density ...

Bemben 2000

Bocalini 2009

Bravo 1996

Chan 2004

Chilibeck 2002

Ebrahim 1997

Englund 2005 Going 2003 Kerr 2001

Korpelainen 2006 Lau 1992 Lord 1996

Maddalozzo 2007 Nelson 1994 Newstead 2004 Pruitt 1996 Smid1 1992

Tolomio 2009

Total (95% CI)

Test for overall effect: Z = 0.15 (P = 0.88) Test for subgroup differences: Not applicable

Chuin 2009

0.37 (16.45)

-0.09 (1.9)

0.27 (19.6)

-0.94 (3.85)

-0.1 (2.85)

0 (12.43)

-0.25 (16)

Smid1 1992

Total (95% CI)

48

17

15

61

54

10

49

690

Cochrane Database of Systematic Reviews

Exercise for preventing and treating osteoporosis in postmenopausal

women

Cochrane Systematic Review - Intervention Version published: 06 July 2011 see what's new https://doi.org/10.1002/14651858.CD000333.pub2 🗗

Used in 11 guidelines View article information New search Conclusions changed [Am] score { 119

PICO: Diverse and overlapping interventions

🛫 Tracey E Howe Beverley Shea Lesley J Dawson Fiona Downie Ann Murray Craig Ross Robin 🕻			
Lynn M Caldwell Gisela Creed		Category	Description
	9	DWB-HF	Supervised aerobic, weight-bearing (e.g. walking, jog, skipping, stair
Dynamic			climb) and weight-lifting exercise (e.g. dumbbell presses)
What are the	16	DWB-HF	Progressive multidirectional jumping, increasing jump heights and
Going 2003			repetitions
Newst characteristics (oritoria)	3	DWB-LF	Rapid walking, stepping up/down or aerobic dancing. Localised
Dyn characteristics (criteria)			exercise (limbs, abdomen, back)
that differentiate each	1	NWB-HF	Weight lifting (Quadriceps extension, hamstring flexion, leg press,
Bravo 16 group?			shoulder press, biceps curl, triceps extension, seated row and
Exahim			latissimus pull) – high load, low repetitions
Lau 1992 Lord 1996	10	NWB-HF	Resistance weight training (wrist curl, reverse curl, biceps curl, triceps
Non-weight page exercise	10		pushdown hip flexion hip extension latissimus dorsi pull down and
N			calf raise: loading increase)
Bemben 2000 10 0.77 (22.6) 8 -1.06 (21)	1	NWB-LF	Weight lifting (Quadriceps extension, hamstring flexion, leg press,
Chilibed 2002 10 -0.1 (2.85) 12 -0.4 (2.77)	-		shoulder press, biceps curl, triceps extension, seated row and
Non-weight hearing low force exercise			latissimus pull) – low load, high repetitions
Study or subgroup Exercise Mean Ditterence	17	NWB-LF	Bench press lateral pull down military press bicens curl knee
N Mean(SD) N Mean(SD) IV,Fixed,95% CI Bember 2000 7 0.11 (24.5) 8 1.02 (21) 1.02 (21)	17		extension knee flexion hin adduction and adduction leg press back
Kerr 2001 30 0.03 (12.16) 36 -0.11 (15.6)			extension, knee hexion, hip abduction and adduction, leg press, back
Pruitf 1996 7 1.16 (31.13) 11 0.79 (16.3)			extension (more repetitions, lower force)
Total (95% Cl) 44 55 🔶	100.0 %	0.21 [-6	6.02, 6.45]

 Total (95% CI)
 44

 Heterogeneity: Chi² = 0.00, d1 = 2 (P = 1.00); l² = 0.0%
 Test for overall effect: Z = 0.07 (P = 0.95)
 Test for subgroup differences: Not applicable

0.21 [-6.02, 6.45]

PICO characteristics of each included study



PICO for each synthesis

(i.e. the criteria for including studies)

Study or subgroup	Experimental n/N	Control n/N	Risk Rato M-H,Random,95% Cl
1 Single interventions Baric 1976	9/63	2/47	
Dunkley 1997	4/50	0/50	
Haug 1994	42/229	8/93	+
Lawrence 2003 (AvB)	13/297	2/141	
McLeod 2004	37/163	14/109	
Moore 2002	88/523	108/567	-
Panjari 1999	33/476	31/537	-
Pberl 2004	5/26	2/18	
Price 1991 (AvB)	2/52	0/35	
Price 1991 (AvC)	4/71	1/35	
Tappin 2000	2/48	2/49	
Tappin 2005	17/347	19/409	_
Valbo 1996	5/52	8/78	_ _
Subtotal (95% Cl) Total events: 261 (Experimenta Heterogeneity: Tau ² = 0.05; Ch Test for overall effect: Z = 2.06 (2397), 197 (Control) i² = 16.38, d1 = 12 (P P = 0.040)	2168 ■ 0.17); l ^a =27%	•
2 Multiple interventions Gielen 1997	12/193	11/198	<u> </u>
Harimann 1996	27/113	16/106	
Kendrick 1995	48/822	65/1063	-
Lawrence 2003 (AvC)	17/311	2/141	· · · · · ·
Lillington 1995	7/16	4/18	
Mayer 1990 (AvC)	8/72	2/77	
Secker-Walker 1994	29/255	26/258	
Stotts 2004	3/24	5/30	
Tsoh 2010	6/23	2/19	
Windsor 1985 (AvB)	6/103	1/52	
Windsor 1985 (AvC)	14/102	1/52	I
Subtotal (95% CI) Total events: 177 (Experimenta Heterogeneity: Tau ² = 0.06; Ch Test for overall effect: Z = 2.21 (2034), 135 (Control) ² = 13.81, d1 = 10 (P P = 0.027)	2014 - 0.18); l² -28%	•
3 Tailored interventions Eades 2012	1/124	2/107	
Hajek 2001	80/365	73/367	+
Hegaard 2003	23/327	7/320	

PICO for each synthesis

Does dynamic weight bearing, low force exercise increase bone density

Study or subgroup	Exercise N	Mean (SD)	Control N	Mean (SD)	Mean Difference IV,Random,95% Cl	Weight	Mean Difference IV,Random,95% Cl
Bravo 1996	61	0.27 (19.6)	63	-0.53 (20.8)	e	11.9%	0.80 [-6.31, 7.91]
Chan 2004	54	-0.94 (3.85)	49	-1.8 (3.52)	#	26.2 %	0.86 [-0.56, 2.28]
Ebrahim 1997	49	-0.25 (16)	48	-2.75 (20.77)		11.4 %	2.50 [-4.89, 9.89]
Lau 1992	11	-6.6 (2.86)	12	-1.1 (0.54)	-	25.6 %	-5.50 [-7.22, -3.78]
Lord 1996	68	1.52 (5.19)	70	3.12 (6.52)	-	25.0 %	-1.60 [-3.56, 0.36]
Total (95% CI) Heterogeneity: Tau ^e = 10.00 Test tor overall effect: Z = 0.7 Test tor subgroup difference	243 c; Chi² = 32.90, c ²2 (P = 0.47) s: Not applicable	ii - 4 (P⊲0.00001)	242); I≊ - 88%		•	100.0 %	-1.20 [-4.45, 2.05]



Should we pre-specify our PICO for each synthesis?



Ideally, yes!

(new guidance in 2019 Cochrane Handbook) training.cochrane.org/handbook

... almost always some important variants (dose, duration of treatment ...)

Why specify PICO for synthesis?*

Minimise bias & increase reproducibility

Improve interpretation

Increase utility

*Cochrane Handbook, Chapter 3, Table 3.2.b

Why specify PICO for synthesis?

Minimise bias & increase reproducibility	The way in which studies are grouped for synthesis influences findings . A decision to include a study (or not) in a given MA (or other synthesis) will change the result, and possibly the conclusion			
	 Careful planning of groups may help avoid decisions influenced by the findings of individual studies increase the reproducibility of findings 			
Improve interpretation	 Provides a 'standardised' terminology for interventions and outcomes that overcomes the varied descriptions used by study authors enables comparison and synthesis of PICO characteristics across studies provides a consistent language for reporting that aids interpretation 			
Increase utility	 Helps ensure that we make best use of available data produce a review focused on questions relevant to decision makers (especially if involved in planning) 			

A process for planning PICO for each synthesis^{*}

- Identify intervention characteristics that may modify the effect of the intervention
- Label and define intervention groups (+ define levels for group based on 'how much')
- 3. Check whether there is an existing system for grouping
- 4. Plan how the groups will be used in synthesis and reporting
- 5. Decide how to group interventions with multiple components or co-interventions
- Build in contingencies by specifying both specific and broader intervention groups

Suggests steps and the decision points at each step

- Aim is to capture the 'behind the scenes' work
- Not intended to be prescriptive, may be iterative, and some steps may be concurrent
- Includes principles for developing a flexible plan, that maximises the potential to synthesise

A process for planning intervention groups for synthesis^{*}

Considerations

- Identify intervention characteristics that may modify the effect of the intervention
- Label and define intervention groups (+ define levels for group based on 'how much')
- 3. Check whether there is an existing system for grouping
- 4. Plan how the groups will be used in synthesis and reporting
- 5. Decide how to group interventions with multiple components or co-interventions
- Build in contingencies by specifying both specific and broader intervention groups

*Cochrane Handbook, Chapter 3, Table 3.2.b

1. Identify intervention characteristics that may modify the effect of the intervention.

Step

Consider whether differences in interventions characteristics might modify the size of the intervention effect importantly. Content-specific research literature and expertise should inform this step.

The TIDieR checklist – a tool for describing interventions – outlines the characteristics across which an intervention might differ (Hoffmann et al 2014). These include 'what' materials and procedures are used, 'who' provides the intervention, 'when and how much' intervention is delivered. The iCAT-SR tool provides equivalent guidance for complex interventions (Lewin et al 2017).

2a. Label and define intervention groups to be considered in the synthesis.

For each intervention group, provide a short label (e.g. supportive psychotherapy) and describe the core characteristics (criteria) that will be used to assign each intervention from an included study to a group.

Groups are often defined by intervention content (especially the active components), such as materials, procedures or techniques (e.g. a specific drug, an information leaflet, a behaviour change technique). Other characteristics may also be used, although some are more commonly used to define subgroups (see Chapter 10, Section 10.11.5): the purpose or theoretical underpinning, mode of delivery, provider, dose or intensity, duration or timing of the intervention (Hoffmann et al 2014).

In specifying groups:

 focus on 'clinically' meaningful groups that will inform selection and implementation of an intervention in practice;

Exercise interventions differ across multiple characteristics, which vary in importance depending on the review.

In a review of exercise for osteoporosis, whether the exercise is weight-bearing or non-weight-bearing may be a key characteristic, since the mechanism by which exercise is thought to work is by placing stress or mechanical load on bones (Howe et al 2011).

Different mechanisms apply in reviews of exercise for knee osteoarthritis (muscle strengthening), falls prevention (gait and balance), cognitive function (cardiovascular fitness).

The differing mechanisms might suggest different ways of grouping interventions (e.g. by intensity, mode of delivery) according to potential modifiers of the intervention effects.

In a review of psychological therapies for coronary heart disease, a single group was specified for meta-analysis that included all types of therapy. Subgroups were defined to examine whether intervention effects were modified by intervention components (e.g. cognitive techniques, stress management) or mode of delivery (e.g. individual, group) (Richards et al 2017).

In a review of psychological therapies for panic disorder (Pompoli et al 2016), eight types of therapy were specified:

1) psychoeducation;

Examples

- supportive psychotherapy (with or without a psychoeducational component);
- 3) physiological therapies;
- 4) behaviour therapy;
- 5) cognitive therapy;
- 6) cognitive behaviour therapy (CBT);
- 7) 7. third-wave CBT; and

A process for planning outcome groups for synthesis^{*}

	Fully specify outcome domains	Step	Considerations	Examples
	Determine whether there is an existing system for identifying and grouping important outcomes	1. Fully specify outcome domains.	For each outcome domain, provide a short label (e.g. cognition, consumer evaluation of care) and describe the domain in sufficient detail to enable eligible outcomes from each included study to be categorized. The definition should be based on the concept (or construct) measured, that is 'what' is measured. 'When' and 'how' the outcome is measured will be considered in subsequent steps. Outcomes can be defined hierarchically, starting with very broad groups (e.g. physiological/clinical outcomes, life impact, adverse events), then outcome domains (e.g. functioning and perceived health status are domains within 'life impact'). Within these may be narrower domains (e.g. physical function, cognitive function), and then specific outcome measures (Dodd et al 2018). The	In a review of computer-based interventions for sexual health promotion, three broad outcome domains were defined (cognitions, behaviours, biological) based on a conceptual model of how the intervention might work. Each domain comprised more specific domains and outcomes (e.g. condom use, seeking health services such as STI testing); listing these helped define the broad domains and guided categorization of the diverse outcomes reported in included studies (Bailey et al 2010). In a protocol for a review of social media interventions for improving health, the rationale for synthesizing broad groupings of outcomes (e.g. health behaviours, physica health) was based on prediction of a common underlyin mechanism by which the intervention would work, and the review objective, which focused on overall health
3.	Define the outcome time points			
	Specify the measurement tool or measurement method			
	Specify how multiplicity of outcomes will be handled		level at which outcomes are grouped for synthesis alters the question addressed, and so decisions should be guided by the review objectives.	rather than specific outcomes (Welch et al 2018).
5.	Plan how the specified outcome domains will be used in the synthesis		 definitions should reflect existing systems if available, or relevant literature and terminology understood by decision makers; where outcomes are likely to be inconsistently labelled and described, listing examples may convey the scope of the domain; consider the level at which domains will be defined (broad versus narrow) and the implications for reporting and synthesis: combining diverse outcomes may lead to unexplained heterogeneity whereas narrowly specified outcomes may prevent synthesis when few studies report specific measures; 	
	Build in contingencies by specifying both specific and broader outcome domains			

*Cochrane Handbook, Chapter 3, Table 3.2.c

Thank you!