

## Appendix 2

This appendix was part of the submitted manuscript and has been peer reviewed. It is posted as supplied by the authors.

Appendix 1 to: Bourne AM, Whittle SL, Richards BL, et al. The scope, funding and publication of musculoskeletal clinical trials performed in Australia. *Med J Aust* 2014; 200: xxx-xxx. doi: 10.5694/mja13.10907.

Appendix 2. 2011 and 2012 Australia and New Zealand Clinical Trial Registry (ANZCTR) and World Health Organization (WHO) registered clinical trials with Australian recruitment showing details of condition, intervention, controls, trial size and funding sources

Condition	Intervention category	Trial Design <sup>‡</sup>	Intervention(s)	Control(s)	Trial Size	Funding Source
Rheumatoid arthritis	Drugs	RCT-PB (A)	Adalimumab	Placebo	60	Industry
		RCT-PB*	PF-05280586	Two other brands of rituximab	195	Industry
		RCT-PB*	Certolizumab pegol + methotrexate for early active RA	Placebo	800	Industry
		RCT-PB (A)	Methotrexate + MK-8457	Methotrexate + Placebo	178	Industry
		SCT (A)	Oral low dose prednisolone	Uncontrolled	36	Charity
		RCT-O (A)	Biologic disease modifying antirheumatic drug (DMARD)	Conventional disease- modifying antirheumatic therapy	104	Self-funded/Un- funded
		RCT-PB*	Enbrel	Placebo	168	Industry
		RCT-PB*	Baricitinib	Placebo	525	Industry
		RCT-PB*	Baricitinib; Adalimumab	Placebo	1280	Industry
		RCT-PB*	BI 655064	Placebo	130	Industry
		RCT-PB*	Sarilumab	Placebo	522	Industry

		RCT-PB*	Baricitinib	Placebo	525	Industry
		RCT-PB*	Baricitinib	Placebo	660	Industry
		SCT-PB*	Sarilumab SAR153191 (REGN88)	Placebo	522	Industry
		RCT-PB*	Methotrexate (MTX); MK- 8457	Placebo	178	Industry
		RCT-PB*	Sirukumab	Placebo	990	Industry
		RCT-PB*	Rituximab	PF-05280586; Rituximab	210	Industry
		RCT-O*	Adalimumab + Methotrexate	Certolizumab Pegol + Methotrexate	892	Industry
		RCT-PB*	Rituximab-EU+ Rituximab- Pfizer	Rituximab-Pfizer (PF- 05280586); Rituximab-US + Rituximab-Pfizer	157	Industry
		RACT-PB*	Adalimumab (high levels)	Adalimumab (current levels)	61	Industry
	Physical	RCT-O (A)	Conventional periodontal examination, treatment and follow-up	No examination, treatment or follow-up	90	National Health and Medical Research Council project grant
	Psychological	SCT (A)**	Questionnaire	Uncontrolled	330	Industry
Osteoarthritis#	Drugs	RCT-PB (A)	Autologous adipose derived stem cells injection	Placebo	40	Industry

RCT-PB (A	) Hyaluronidase powder	No hyaluronidase powder	180	Hospital; Charity
RCT-PB (A	) Platelet-rich plasma injections	Hylan G-F 20 injections	39	Self-funded/Un- funded
RCT-PB	<5,000 molecular weight Fraction Human Albumin 5% (Ampion) + lignocaine + betamethasone; Ampion + betamethasone	Placebo + lignocaine + betamethasone	60	Industry
RCT- PB(A	) Stromal vascular fraction containing adipose-derived stem cells injection	Hylan G-F 20 injections	60	University
RCT-PB*	Humanized anti-nerve growth factor (NGF) mAb (ABT-110) + Naprosyn®	Placebo + Naprosyn®	390	Industry
RCT-PB (A	) Adalimumab for hand osteoarthritis	Placebo	40	Industry
RCT-PB*	Strontium ranelate	Placebo	1206	Industry
RCT-O (A)	Polyethylene glycol with electrolytes (Movicol) for post-operative constipation after major joint replacement	Usual care	320	Hospital
RCT-O (A)	Green-Lipped Mussel extract	Glucosamine sulphate	40	Self-funded/Un- funded

	SCT (A)	New Zealand Green-Lipped Mussel extract	Uncontrolled	20	Industry
	RCT-PB*	FX006	Triamcinolone acetonide	152	Industry
	RCT-PB*	FX006	Triamcinolone acetonide	24	Industry
Surgery	RCT-O (A)	Modified Genesis II Slim for knee replacement	Genesis II	1060	Industry
	RCT-O (A)	Laparoscopic adjustable gastric banding prior to joint replacement in obese patients with osteoarthritis	Joint replacement alone	120	National Health and Medical Research Council project grant
	RCT-O (A)	Patient matched Instrumentation for total knee replacement	Standard intramedullary alignment systems	200	Industry
	SCT (A)	Patient matched instrumentation for total knee arthroscopy	Uncontrolled	30	Industry
	RCT-O (A)	Negative pressure wound therapy during hip arthroplasty	Standard dressing	80	University
	RCT-PB (A)	Knee arthroscopy under low pressure (30mmHg)	Standard pressure (80mmHg)	50	University
	RCT-O (A)	MACNAV positioning system for hip joint replacement	Other navigation system; no navigation system	60	Industry

9	SCT	Avascular necrosis (AVN) Cage Prosthesis for hip replacement	Uncontrolled	77	Industry
F	RCT-O (A)	Topical negative pressure dressing for orthopaedic surgery	Standard dressing	1500	University
9	SCT (A)	Reinfusion of cell-salvaged whole blood for total hip arthroplasty	Uncontrolled	25	Industry
F	RCT-PB (A)	Intra-operative cerebral oximetry for lower limb arthroplasty	Placebo	40	Hospital
9	SCT (A)	Multi-modal analgesic pathway for knee arthroplasty	Uncontrolled	100	Self-funded/Un- funded
S	SCT (A)	Collarless Polished Tapered stem for hip arthroplasty	Uncontrolled	50	Hospital
S	SCT (A)	Mindfulness training for joint arthroplasty	Uncontrolled	30	Self-funded/Un- funded
5	SCT (A)	Radiopaque tantalum bead markers for Hip osteoarthritis	Uncontrolled	35	Industry
F	RCT-PB*	Posterior stabilised knee implant	Posterior cruciate retaining knee implant	120	Hospital

	RCT-O (A)	Dexmedetomidine for sedation during hip and knee arthroplasty	Propofol	40	Self-funded/Un- funded
	SCT (A)	Short stem femoral components for hip replacement	Uncontrolled	25	Hospital
	RCT-PB*	Multiple cancellous screws fixation	Sliding hip screw	100	University
Physical	RCT-O (A)	Two booster physiotherapy sessions + home exercise	Home exercises	60	National Health and Medical Research Council program grant
	RCT-O (A)	Gait retraining (gait group); High protein, low glycaemic load diet (diet group); Progressive resistance training (PRT group); Gait + Diet + PRT (Combined group)	Lifestyle Advice	125	National Health and Medical Research Council project grant
	RCT-BP (A)	Donjoy unloader knee brace; anterior-posterior support without frontal plane adjustment (unadjusted) for post-traumatic knee osteoarthritis	No treatment	40	University
	RCT-O (A)	Neuromuscular training program following	No exercise	62	National Health and Medical

	arthroscopic partial medial meniscectomy			Research Council project grant
RCT-O (A)	McConnell taping	Vitamin E cream	30	Self-funded/Un- funded
RCT-O (A)	Genutrain knee brace	Neoprene knee orthosis	90	Self-funded/Un- funded; Industry
RCT-O (A)	Forearm strengthening exercises (hand)	No exercises	66	Self-funded/Un- funded
RCT-O (A)	Adjustments to the entire kinetic chain (five areas) (hip)	Adjustments to one area	60	Self-funded/Un- funded
RCT-O (A)	Independent home exercise program following total hip replacement	Supervised exercise class	120	University
RCT-PB (A)	Low voltage electrical stimulation of muscles following total knee replacement	Sham stimulation	72	Self-funded/Un- funded
RCT-O (A)	Nintendo Wii-Fit exercises following total knee replacement	Standard treatment	128	Self-funded/Un- funded; Other collaborative funding; Charity
RCT-O (A)	Extensive rehabilitation	Standard rehabilitation	60	Hospital
SCT (A)	Pre-operative Education and Exercise program for hip and	Uncontrolled	40	Self-funded/Un-

			knee replacement			funded
		RCT-O*	Hospital Inpatient Rehabilitation	Hybrid Home Programme	220	Industry
	Psychological	RCT-O (A)	Mindfulness training for patients undergoing total hip or knee replacement	No treatment	150	Australian Research Council
	Education/ Self- management	RCT-O (A)	Additional interpreter sessions following total knee replacement	Usual care	44	Hospital
		RCT-O (A)	Self-efficacy based education DVD for joint replacement pain and anxiety management	No DVD	100	Hospital
		SCT (A)	Pre-admission education program for total hip or knee joint replacement	Uncontrolled	200	Hospital
		RCT-O (A)	Telephone coaching + physiotherapist-delivered physical activity program	Physiotherapist-delivered physical activity program	168	National Health and Medical Research Council program grant
		SCT (A)	Pre-operative Education and Exercise program for hip or knee replacement	Uncontrolled	20	Self-funded/Un- funded
Polymyalgia	Drugs	RCT-PB*	Lodotra	Placebo	400	Industry

rheumatica						
Spondyloarthritis	Drugs	RCT-PB*	Apremilast	Placebo	456	Industry
Juvenile Arthritis	Drugs	SST*	Enbrel	Uncontrolled	123	Industry
		SCT*	Tocilizumab	Uncontrolled	20	Industry
		SCT*	Etanercept	Uncontrolled	100	Industry
Gout	Drugs	SCT (A)	Various doses of Allopurinol	Uncontrolled	30	National Health and Medical Research Council Safety Grant; Charity
		SCT*	Lesinurad	Uncontrolled	200	Industry
		RCT-PB*	Lesinurad	Placebo	315	Industry
		RCT-PB*	Lesinurad	Placebo	200	Industry
		RCT-PB*	Lesinurad	Placebo	600	Industry
		SCT*	Canakinumab	Uncontrolled	200	Industry
		SCT*	Allopurinol	Uncontrolled	1743	Industry
Psoriatic arthritis	Drugs	RCT-BP*	Secukinumab	Placebo	600	Industry
		RCT-PB*	Apremilast; Etanercept	Placebo	240	Industry
		RCT-PB*	BMS-945429	Placebo	150	Industry

Fibromyalgia	Physical	RCT-PB (A)	Transcranial direct current stimulation	Placebo	32	University
Systemic Sclerosis	Drugs	RCT-PB*	Pomalidomide	Placebo	88	Industry
Sj <b>ö</b> grens Syndrome	Physical	RCT-O (A)	High intensity humidifier machine (AIRVO)	Look alike machine	20	Hospital
Systemic lupus	Drugs	RCT-PB*	Soluble Fc-gamma receptor	Placebo	50	Industry
erythematosus		SCT*	LY2127399	Uncontrolled	1276	Industry
		SCT	Epratuzumab	Uncontrolled	400	Industry
		RCT-PB	Epratuzumab	Placebo	1053	Industry
		SCT (A)	Therapeutic drug monitoring (TDM) guided dosing of EC-MPS	Uncontrolled	32	Hospital; Industry
		SCT*	Anti-Macrophage Migration Inhibitory Factor (Anti-MIF) Antibody	Uncontrolled	<b>4</b> <sup>B</sup>	Industry
		RCT-PB*	AMG 557	Placebo	32	Industry
		RCT-PB*	BMS-188667 + Mycophenolate mofetil; BMS-188667 + Prednisone for Lupus Nephritis	Placebo + Mycophenolate mofetil; Placebo + Prednisone	400	Industry

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		RCT-PB*	BIIB023 for Lupus Nephritis	Placebo	300	Industry
Osteoporosis	Drugs	RCT-PB (A)	Zoledronic acid for anti- epileptic drug-induced bone loss	Placebo	60	Industry
		RCT-PB (A)	Intravenous zoledronic acid for people with osteoporosis and minimal trauma fracture	Placebo	60	Industry
		RCT-PB (A)	Cholecalciferol liquid for bone loss in chronic kidney disease	Placebo	62	Industry
		RCT-PB*	MK-0822 for postmenopausal osteoporosis	Placebo	1630 0	Industry
		RCT-O (A)	Zoledronic acid for low bone mineral density in HIV-infected adults taking tenofovir	Switch from tenofovir to another potent anti-HIV drug (without commencing zoledronic acid)	84	National Health and Medical Research Council project grant
		RCT-PB (A)	Calcium + vitamin D for low bone density	Placebo	60	University
		RCT –PB (A)	Vitamin D for vitamin D deficiency	Placebo	30	University
		RCT-PB*	AMG785 + denosumab for postmenopausal osteoporosis	Placebo	5600	Industry

	RCT-BP*	AMG 785; AMG 785 + alendronate for post- menopausal osteoporosis	Alendronate	4000	Industry
	RCT-PB*	Teriparatide for low trauma femoral neck fracture (1)	Placebo	1220	Industry
	RCT-PB*	Teriparatide for low trauma femoral neck fracture (2)	Placebo	1220	Industry
	RCT-O (A)	Vitamin D3 for decreasing number of fractures	No treatment	250	Hospital
	RCT-PB*	Denosumab; Zoledronic acid	Placebo	620	Industry
	RCT-PB*	Romosozumab; Denosumab	Placebo + Denosumab	6000	Industry
	RCT-PB*	Teriparatide; Vitamin D; Calcium	Placebo	122	Industry
Physical	RCT-O (A)	Pilates exercise program; Pilates exercise program + home exercise	Usual care	80	University
	RCT-O (A)	Rehabilitation program post surgically treated hip fracture & living in high care aged facility	Standard care	236	National Health and Medical Research Council project grant
	RCT-O (A)	Whole body vibration therapy for bone metabolism in breast cancer patients undergoing aromatase	No treatment	50	Charity

			inhibitor therapy			
		RCT-O (A)	Whole body vibration therapy for bone metabolism in prostate cancer with androgen therapy	No treatment	50	Charity
	Education/ Self- management	RCT-O (A)	Sheets with bone health related education	Standard care	10	Charity
Low back pain	Drugs	RCT-PB (A)	Dexamethasone for low back pain and lumbosacral radiculopathy	Placebo	100	Hospital
		RCT-PB*	ABT-110 + Naprosyn® for chronic low back pain	Placebo + Naprosyn®	390	Industry
		RCT-PB (A)	Low-dose amitriptyline for chronic neuropathic low back pain	Placebo	150	National Health and Medical Research Council project grant
	Surgery	RCT-PB (A)	Minimally invasive decompressive laminectomy for degenerative lumbar canal stenosis	Standard decompressive laminectomy	30	Self-funded/Un- funded
	Physical	RCT-O (A)	McKenzie method exercises for chronic low back pain	Motor control exercises	70	Charity
		RCT-O*	Back Strain Monitor device with bio-feedback	Back Strain Monitor device with no bio-feedback	96	Industry

	RCT-PB (A)	Acupuncture of lumbar spine with sensory discrimination for chronic low back pain	Acupuncture of Lumbar spine without sensory discrimination	25	University
	RCT-PB (A)	Usual chiropractic care for non-specific spinal pain	De-tuned ultrasound and random spinal de-tuned activator treatment	180	Industry
	RCT-O	Hip strengthening; Hip stretching	Hip rotation only	30	Self-funded/Un- funded
	RCT-O (A)	Exercise rehabilitation program for chronic low back pain	General exercise	52	University
	RCT-O (A) <sup>B</sup>	Postural re-education; Progressive resisted back extension exercise; both for thoracic kyphosis	No intervention	160	National Health and Medical Research Council PhD Scholarship; Hospital; Industry
	RCT-PB (A)	Manipulation of the thoracic, abdominal and pelvic organs and their associated supportive ligaments, connective tissue and fascia	Sham manipulation	64	Self-funded/Un- funded
	RCT-PB*	Boston Scientific Precision Plus spinal cord stimulation therapy	ND	<b>1</b> <sup>B</sup>	Industry
Psychological	RCT-PB (A)	Novel psychotherapeutic	Sham psychotherapeutic	250	National Health and Medical

			intervention	intervention		Research Council project grant
	Education/ Self- management	RCT-O (A)	Pamphlet only; Pamphlet with education delivered by pharmacists	Usual care	360	Department of Health WA
Neck pain	Drugs	RCT-PB (A)	Benztropine for acute non- traumatic neck pain	Placebo	30	Self-funded/Un- funded
	Physical	RCT-PB (A)	Passive positioning of the participant	Sham positioning	85	Self-funded/Un- funded
		RCT-O (A)	High force mobilisation for chronic non-specific neck pain	Low force mobilisation; Laser	66	Charity
		RCT-PB (A)	Sustained natural apophyseal glides for dizziness and pain from cervical spine problems	Detuned machine	90	Other collaborative funding
		RCT-O (A)	Workplace based exercise and ergonomic advice for non-specific neck pain	Ergonomic advice	640	National Health and Medical Research Council project grant
		RCT-O (A)	Sensorimotor and kinematic exercises + interactive virtual reality exercises for chronic neck pain	Sensorimotor and kinematic exercises	60	University
		RCT-O (A)	Gradual removal of orthosis for cervical spinal trauma	Immediate removal of	80	Hospital

			including fractures and ligamentous injuries	orthosis		
		SCT (A)	Manual therapy treatment	Uncontrolled	20	Self-funded/Un- funded
Shoulder/arm	Drugs	RCT-PB (A)	Glucocorticoid injection+ hydrodilatation for stiff painful shoulder	Glucocorticoid injection	80	Self-funded/Un- funded
		RCT-PB*	Autologous conditioned plasma for Rotator Cuff injury	Placebo	60	NR
		RCT-PB (A)	Glucocorticoid + local anaesthetic for shoulder pain	Usual care	64	Allied Health Workforce & Coordination Unit, Australia
	Surgery	RCT-PB (A)	Varying does of ropivacaine for shoulder surgery	Dose control	120	Hospital
		RCT-O	Addition of an implanted collagen scaffold for partial thickness, larger partial thickness or small full thickness supraspinatus tendon tears	No collagen scaffold; Standard subacromial decompression and/or repair alone	36	Industry
		RCT-O (A)	External rotation brace for anterior shoulder dislocations	Arthroscopic stabilization surgery	50	Hospital

Pł	nysical	RCT-O (A)	Nine physiotherapy sessions for anterior shoulder dislocation	Seven physiotherapy sessions	200	University
		RCT-O (A)	Supervised physiotherapy program + pulsed ultrasound + massage for primary anterior shoulder dislocation	Supervised physiotherapy program	200	Hospital; Other collaborative groups; Queensland Health
		RCT-O (A)	Supervised exercise program for shoulder pain due to accessory nerve injury after surgery	Usual care	60	Hospital
		RCT-O (A)	Ultrasound-guided shockwave therapy for painful soft tissue calcification including tendinopathy	Patient-guided shockwave treatment	120	Industry
		RCT-O (A)	Collar & cuff sling under clothing 90 degrees elbow flexion; posterior plaster of Paris backslab and collar and cuff sling over clothing 50 degrees elbow flexion for supracondylar humeral fracture	Collar and cuff sling under clothing with elbow flexion at 120 degrees	180	Hospital
		RCT-PB (A)	Electrical stimulation therapy for frozen shoulder	Placebo stimulation therapy	40	University

Elbow/forearm	Drugs	RCT-O (A)	Prolotherapy injection for lateral epicondylalgia	Physiotherapy and therapeutic Exercise	120	Charity
	Physical	RCT-PB (A)	Titanium volar locking plate for distal radius fractures	Stainless Steel volar locking plate	130	Hospital
		RCT-O (A)	Immobilisation periods of one and three weeks	Immobilisation period of six weeks	135	Hospital
		RTC-O (A)	Professional advice plus a progressive exercise program	Professional advice	30	Self-funded/Un- funded
Hip/thigh	Drugs	SCT (A)	Autologous tenocyte implantation for gluteal tendinopathy	Uncontrolled	20	Industry
	Surgery	RCT-PB (A)	Intramedullary nail for hip fractures	Sliding hip screw	736	Industry
		SCT (A)	19 gauge spinal needle + air arthrogram for femoroacetabular impingement	Uncontrolled	40	Self-funded/Un- funded
	Physical	RCT-O (A)	Physiotherapy exercise Intervention; glucocorticoid injection for gluteal tendinopathy	No treatment	210	National Health and Medical Research Council project grant t
Knee/leg	Drugs	RCT-PB (A)	Glucosamine sulphate for undiagnosed knee pain	Placebo	60	University; Industry

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	Physical	RCT-O (A)	Prefabricated, commercially available, full length in-shoe orthoses for anterior knee pain	No treatment	40	Australian Research Council
		RCT-O (A)	Partial immobilisation for patella dislocation	Full immobilisation	60	Self-funded/Un- funded
		RCT-O (A)	One-on-one and group physiotherapy for lower limb orthopaedic surgery	One-on-one sessions only	89	Hospital
	Surgery	RCT-O (A)	Atorvastatin, Ivabradine for neck of femur fracture	No treatment	200	Hospital
		RCT-O (A)	Limited transthoracic echocardiography for femur surgery	Standard clinical assessment of cardiovascular function	180	University
Wrist/hand	Drugs	SCT*	Xiapex for Dupuytren's contractures	Uncontrolled	600	Industry
		SCT*	AA4500 collagenase clostridium histolyticum for Dupuytren's contractures	Uncontrolled	60	Industry
	Physical	RCT-O (A)	Nerve and tendon gliding exercises for carpal tunnel syndrome	No treatment	30	National Health and Medical Research Council project grant

		RCT-O (A)	Splint which allows wrist motion in the Dart Throwing Plane for scapho-lunate ligament injury	Static splint	20	Hospital
		RCT-O (A)	Nerve and tendon gliding exercises for carpal tunnel syndrome	Splinting	30	Queensland Health Practitioner Research Scheme; NHMRC project grant
		SCT (A)	Custom-made ulnar gutter splint for wrist pain	Uncontrolled	20	Hospital
Foot/ankle	Physical	RCT-O (A)	Weight-bearing mobilising for ankle fractures	Non weight-bearing mobilising	50	Self-funded/Un- funded
		RCT-O (A)	Low cost, off-the-shelf footwear for foot pain	Usual treatment	120	Australian Department of Veterans' Affairs
	Physical	RCT-O (A)	Contoured flip-flops; contoured in-shoe orthosis for heel pain	Flat flip-flops	150	National Health and Medical Research Council program grant; Industry
	Surgery	RCT-O (A)	Dexamethasone for foot or ankle surgery	No dexamethasone	90	Hospital
	Education/ self-	SCT (A)	Questionnaire for Plantar Fasciitis	Uncontrolled	150	Charity

	management					
		SCT (A)	Multimedia patient education module for foot and ankle surgery	Uncontrolled	500	Charity
Musculoskeletal adverse effects of drugs	Drugs	RCT-PB (A)	Crystalline glucosamine sulphate for Letrozole induced arthralgia in breast cancer patients	Placebo	143	Other collaborative funding
		RCT-PB (A)	Teriparatide + Calcium + Vitamin D for osteonecrosis of the jaw	Placebo + Calcium + Vitamin D	68	National Health and Medical Research Council project grant
	Physical	RCT-PB (A)	Acupuncture for arthralgia due to aromatase inhibitor therapy for breast cancer	Sham acupuncture	30	Charity
Un-specified/	Drugs	RCT-PB (A)	Ketamine + ibuprofen for	Ibuprofen	80	Charity
Other		SCT (A)	limb injuries Intranasal ketamine for MSK injuries	Uncontrolled	60	Hospital
	Education/ Self- management	SCT (A)	Exercise DVD for performance-related musculoskeletal disorders	Uncontrolled	150	Australian Research Council; Australia Council of the Arts

RCT-O (A)	Exercise class; Alexander Technique for performance- related musculoskeletal disorders	No intervention	150	Australian Research Council; Australia Council of the Arts
SCT (A)	Physiotherapist advice for Performance-related musculoskeletal disorders	Uncontrolled	150	Australian Research Council; Australia Council of the Arts

<sup>&</sup>lt;sup>†</sup>Trial Design Legend: Randomised controlled trial – participant-blinded (RCT-PB); randomised controlled trial - open (RCT-O); single arm clinical trial (SCT); \* European Union – Clinical Trial Registry (EU-CTR) registered trials; (A) - Australian-investigator initiated trial. <sup>#</sup>Knee osteoarthritis unless otherwise indicated; <sup>B</sup> indicates trial was terminated; \*\* Questionnaire also for Psoriatic Arthritis and Ankylosing spondylitis; NR – not reported