LSAW Demography and Data Overview

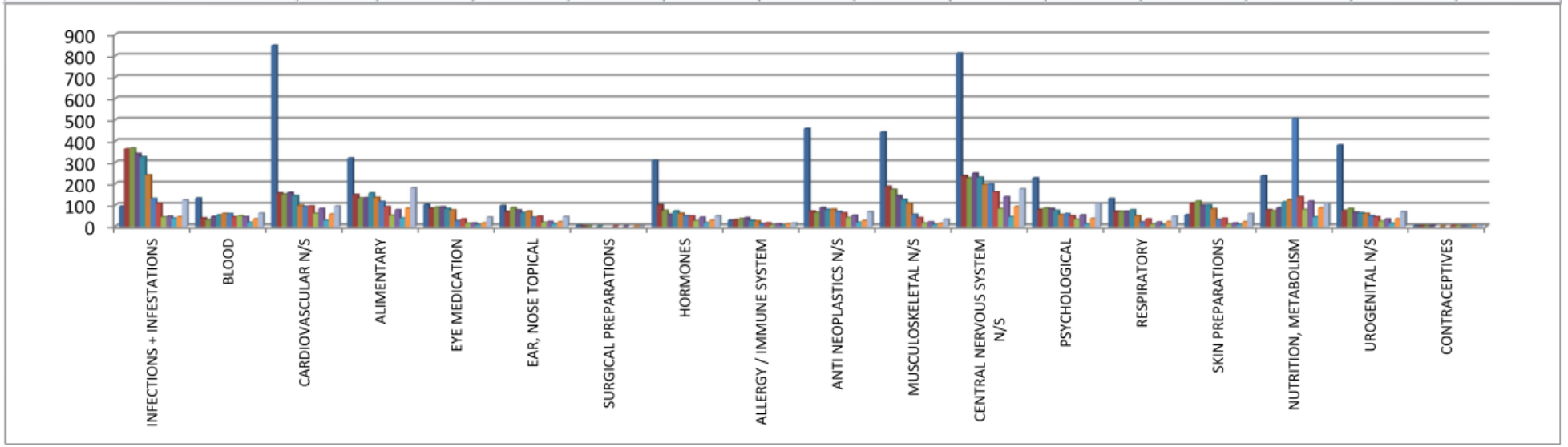
Description	Variable	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2010	2013
		B/L	12 mo	24 mo	36 mo	48 mo	60 mo	72 mo	84 mo	96 mo	114 mo	120 mo	144 mo	180 mo
Diary Returns	**Medications record – see table below**	1500	1375				1136		1012			829		495
Diary Returns	**Adverse event recording - see table below**	1500	1364	1334	1297	1198	1161	1102	1031	977	990	889	657	495
Lifestyle	**Demographic questionnaire**	1500			1290		1201		1022			843	631	495
	Smoking history	1493					1233							
	Employment and finances	1498												
	Socioeconomic status	1488												
	Joint Pain Questionnaire	1476					1187							
	Falls Questionnaire	1476					1024							
	HRT and menopause	1500												
	Children and breastfeeding questionnaire	1498												
	Age of parents death	1460												
	Language and Country of Birth	1500												
	Physical activity	1500			1291		1233		1024			847	630	495
	SF-36 questionnaire	1477					1198		1020			843	630	483
	Barthel	1496					1212		1020			893	651	297
	Urinary Symptoms					718								
	WOMAC					1255			1025					

	Epworth Sleepiness Scale					718								
	PHQ9											839	622	
	Community Service						1233							
Clinical	**Examination**	1500	1375				1136		1012			829		495
Anthropometry	**Height, weight and body mass index**	1498	1374	1317	1276	1206	1167		989			821	588	495
Data linkage for all 1500 participants	**Deaths**													Complete 1998-2013*
	Death certificate cause of death (Primary and contributing causes of death)													Complete 1998-2013*
	Cancer registry data by site and recurrence and pathology reports													Complete 1998-2013*
	Hospital and day surgery discharge diagnosis coding all 23,000 admissions													Complete 1998-2013*
	Emergency department admissions													Complete 1998-2013*
	Hospital admissions													
Whole blood			1375											
Fasting Serum and Plasma		1479	1375				1136		1012			829		495
Fasting urine		1479					1136		1012			829		495

* For “Complete 1998-2013” variables please contact admin@lsaw.com.au for further information

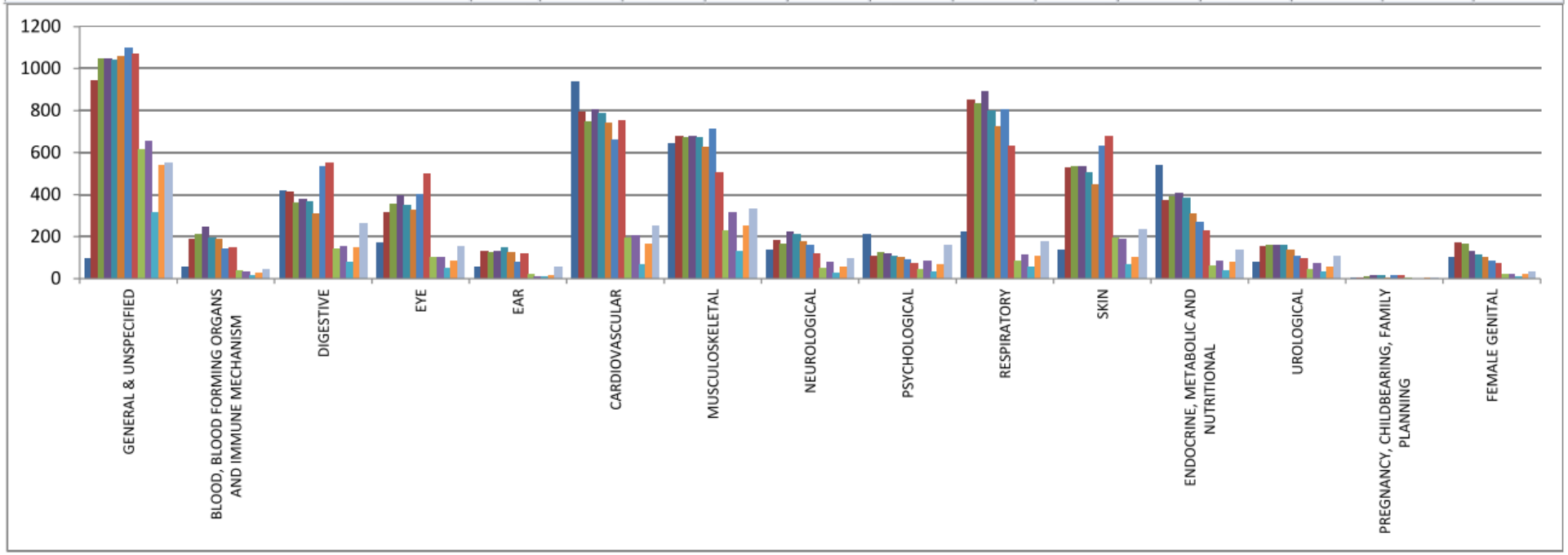
Medication

Medication	Baseline	12 months	24 months	36 months	48 months	60 months	72 months	84 months	96 months	114 months	120 months	144 months	180 months
INFECTIONS + INFESTATIONS	94	363	366	341	326	241	130	107	44	47	38	45	123
BLOOD	132	39	31	46	53	60	59	44	49	45	18	35	62
CARDIOVASCULAR N/S	849	156	151	159	144	98	93	95	61	83	28	57	95
ALIMENTARY	320	149	132	133	156	135	116	92	51	77	39	85	180
EYE MEDICATION	102	85	90	91	83	76	26	34	14	15	7	16	43
EAR, NOSE TOPICAL	97	69	88	76	64	71	42	47	18	22	12	21	46
SURGICAL PREPARATIONS	4	1	1		1			1		1		1	1
HORMONES	309	100	74	56	72	61	49	48	26	42	17	29	49
ALLERGY / IMMUNE SYSTEM	29	31	36	40	28	25	12	16	6	11	2	12	15
ANTI NEOPLASTICS N/S	459	71	65	88	79	80	69	63	41	51	18	27	68
MUSCULOSKELETAL N/S	442	187	173	144	126	107	56	40	15	20	8	14	33
CENTRAL NERVOUS SYSTEM N/S	812	237	227	249	230	196	198	162	83	138	45	93	176
PSYCHOLOGICAL	227	79	86	83	74	55	59	49	33	53	11	37	108
RESPIRATORY	130	70	70	70	77	49	20	34	10	19	6	22	47
SKIN PREPARATIONS	54	108	118	98	99	82	32	37	9	15	8	21	59
NUTRITION, METABOLISM	237	77	73	87	114	125	506	138	79	118	44	87	109
UROGENITAL N/S	381	74	83	65	63	60	49	44	24	34	14	35	68
CONTRACEPTIVES	3	2	3	4		1		3	3	2	1	3	6



Adverse Events

Events	Baseline	12 months	24 months	36 months	48 months	60 months	72 months	84 months	96 months	114 months	120 months	144 months	180 months
GENERAL & UNSPECIFIED	97	943	1048	1047	1038	1059	1096	1072	612	652	317	539	548
BLOOD, BLOOD FORMING ORGANS AND IMMUNE MECHANISM	53	185	213	247	194	185	143	146	36	34	12	29	46
DIGESTIVE	421	415	360	379	366	308	532	550	142	155	77	148	261
EYE	168	314	353	394	347	326	400	499	101	100	49	83	156
EAR	57	132	124	129	145	127	79	120	18	7	7	14	58
CARDIOVASCULAR	939	793	749	807	787	738	658	754	196	204	66	166	249
MUSCULOSKELETAL	644	677	671	679	674	624	711	505	228	317	130	251	333
NEUROLOGICAL	135	180	167	225	209	176	158	117	50	81	27	58	95
PSYCHOLOGICAL	209	109	122	118	109	99	92	74	42	86	30	66	161
RESPIRATORY	221	848	832	892	800	725	803	631	83	112	54	106	174
SKIN	133	529	535	533	505	449	632	675	195	188	64	103	235
ENDOCRINE, METABOLIC AND NUTRITIONAL	537	373	388	407	382	307	269	229	62	85	38	78	136
UROLOGICAL	77	151	161	159	160	138	106	93	46	71	31	58	107
FEMALE GENITAL	102	171	168	134	116	102	87	72	23	25	9	23	35



Overview

Participants

The participants involved in this study were recruited in 1998 to a 5-year, randomized, controlled trial of oral calcium supplements to prevent osteoporotic fractures as described previously [1]. Briefly, women were recruited from the Western Australian general population of women aged over 70 years by mail using the electoral roll a requirement of citizenship. Over 99% of Australians of this age are registered on the roll. Of the 5,586 women who responded to a letter inviting participation 1,510 women were willing and eligible and of these 1,500 women were recruited for the study. Participants were ambulant and did not have any medical conditions likely to influence 5-year survival. They were excluded if they were receiving bone-active agent, including hormone replacement therapy. Participants were similar in terms of disease burden and pharmaceutical consumption to whole populations of this age but they were more likely to be from higher socio-economic groups [2]. In the 5 years of the trial, participants received 1.2 g of elemental calcium as calcium carbonate daily or a matched placebo.

Overview of CAIFOS randomized controlled trial

1460 patients received calcium carbonate tablets, 0.6g twice per day (with morning and evening meals), or identical placebo tablets (Wyeth Consumer Healthcare, Baulkham Hills, Australia), 40 patients received calcium carbonate tablets, 0.6g twice per day (with morning and evening meals) plus 1000IU vitamin D. The randomization list was produced by generating 146 blocks of 10 numbers. In each block, 5 positions representing placebo and 5 positions representing calcium treatment were ordered using a letter code according to a random number generator. The numbered blocks were ordered according to randomly generated numbers, and an identification number was assigned in order to each letter code in the randomized list. The Pharmacy Department of the Sir Charles Gairdner Hospital, Nedlands, Australia, assigned a treatment to the letter code and assigned the appropriate medications to the patient according to this list. The randomization was stratified by allocating patients to blocks according to whether a prevalent non-traumatic fracture had occurred after age 50 years, ensuring that an equal number of patients with and without a prevalent fracture received placebo or calcium. Medication compliance was checked at the completion of the study by counting returned tablets at each 12-month review and was calculated as a percentage of the optimum. Average yearly compliance of less than 80% was classified as non-compliant.

Ethics statement

The Human Ethics Committee of the University of Western Australia approved the study and written informed consents were obtained from all participants. Approval number: 05/06/004/H50. Human ethics approval for the use of linked data for the project was provided by the Western Australian Department of Health Human Research Ethics Committee (DOHWA HREC), project number #2009/24.

Variables

Medications use and adverse events

At baseline the participants provided their previous medical history and current medications verified by their General Practitioner where possible. For the first 10 years diaries were completed at the time of medication change or adverse event. For the first five years diaries were returned every 4 months photocopied and returned. For year's 6 to 10 .they were returned every 6 months. For the final 5 years the participant were interviewed by telephone at 6 monthly intervals.

These data were coded using the International Classification of Primary Care – Plus (ICPC-Plus) method [3]. The coding methodology allows aggregation of different terms for similar pathologic entities as defined by the ICD-10 coding system. These data were then used to determine the presence of pre-existing diabetes (T89001-90009) and all emergent adverse events as determined by the participant.

All medications consumed were recorded including start and stop dates coded by 4 monthly intervals.

Demographic questionnaire

At baseline participants completed a questionnaire in which they were asked to report their age and date of birth, prevalent fractures was recoded if occurring after the age of 50 years and due to minimal trauma as defined by falling from a height less than one meter, and not of the face, skull or phalanges, years since menopause were calculated for each patient using reported age at last menstrual period, age at hysterectomy and ovariectomy or the onset of hot flushes.

Smoking history
Smoking status was coded as non-smoker or ex-smoker/current smoker if they had consumed more than 1 cigarette per day for more than 3 months at any time in their life.

Employment and finances
At baseline participants completed a questionnaire in which they were asked to report whether the rented or owned their own home, their income (1=pension, 2=superannuation, 3=a wage, 4=business income and 5=other sources of income), occupation at baseline (1=professional, 2=teacher/nurse, 3=clerical, 4=domestic, 5=factory/agricultural, 6=none of the above),age at highest level of education and whether or not they were in paid employment at baseline.

Socioeconomic status
An index of socioeconomic disadvantage (SES; range 1-6) was derived from the postcode according to the method developed by the Australian Bureau of Statistics[4], a higher score on the index indicates that the area has a higher proportion of families on high income and reflects levels of education, occupation, and economic status.

Children and breastfeeding questionnaire
At baseline participants completed a questionnaire in which they were asked to report the number of live births, and how many of their children were breastfed.

Physical activity
Physical activity was assessed by a demographic questionnaire where participants reported their type of activity and hours per week[5] in the question "Please list any sports recreation or regular physical activity, including walking, that you undertook in the last three months". The energy cost of such activities is given in METs[6] (1 MET accounts for an individual's basal metabolic rate and equals ~ 1kcal/kg/h). Activity levels (kcal/day) were calculated multiplying frequency, duration, energy cost of the activities and the body weight of individuals.

SF-36 questionnaire
Quality of Life (QOL) was assessed by the Medical Outcome Study Short Form-36 (SF-36) questionnaire, which has been validated for use in Australia[5], at baseline and 5 years. Standardized instructions were given to the participants but no extra direct assistance was given. The domains of Physical Functioning, Role-Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role-Emotional and Mental Health were calculated. The SF-36 summary statistics, the physical component score (PCS) and mental component score (MCS)[6] were derived from these domains using Australian normative data[5].

Barthel index
The modified Barthel Index was used to determine proficiency with activities of daily living; scores were dichotomized as being normal (100%) or reduced (<100%).

Height weight and BMI
Body weight (kg) was assessed using digital scales with participants wearing light clothes and no shoes. Height (cm) was assessed by using a stadiometer, and body mass index (BMI) was calculated as weight in kilograms divided by the square of height in meters. Body composition was measured in a randomly selected subgroups of participants by whole body Dual energy X-ray absorptiometry (DXA), using a Hologic 4500A bone densitometer (Hologic Corp., Waltham, MA) with CVs under 2% in our laboratory. All data and analyses presented exclude the head. Lean body mass refers to bone-free lean mass. The lean mass of the arms and legs were summed to provide the appendicular skeletal muscle mass.

Data linkage
Nb: There have been three data extractions of the Hospital Data Morbidity Collection, Mortality Registry, Emergency Data Collection and Cancer Registry to date (2010, 2012 and 2014). The numbers may vary between data extraction as more sensitive and specific linkage methodologies have been implemented and therefore, we recommend using the most up to date data extraction available.

Prevalent and incident disease status
Prevalent (1980 -1998) and incident diseases (1998 -2013) were retrieved from the Western Australian Data Linkage System (WADLS) for each of the study participants from 1980-2013. WADLS provides a complete validated record of every participant's hospitalizations from the coded records of each participant's hospital admissions. Events were defined using the principal discharge diagnosis codes from the International Classification of Diseases, Injuries and Causes of Death Clinical Modification (ICD-9-CM) [3]. Specific ICD codes were used for specific diseases (see system based outcome folders).

Death certificate cause of death (Primary cause of death with contributing causes of death)
Mortality data was available form 2 sources, that reported by relatives who agreed to send us a copy of the death certificate and death certificate data recorded in the Western Australian Data Linkage System. Mortality was defined using code death certificate data from the International Classification of Diseases, Injuries and Causes of Death Clinical Modification (ICD-9-CM) [3] and the International Statistical Classification of Diseases and Related Health Problems, 10th Revision, Australian Modification (ICD-10-AM) [4]. These codes included: ICD-9-CM codes 390-459 and ICD-10-AM codes I00-I99. Cancer mortality records were retrieved from WADLS from the Western Australian Cancer registry. The search for ICD codes included all available diagnostic information that comprised Parts 1 and 2 of the death certificate. All diagnosis text fields from the death certificate were used to ascertain the cause(s) of deaths where these coded data were not yet available from the WADLS.

Cancer registry data by site and recurrence and pathology reports
Incident cancers were defined as the first cancer diagnosed after inception of the study. Diagnoses of incident cancers and cancer deaths for individual studies were coded according to the *International Classification of Diseases, Ninth and Tenth Revision for cancers (C010 – C96).* Information on cancer incidence and mortality was obtained from the Western Australia Data Linkage System.

Fasting serum and plasma
Venous blood samples were collected between 08:30 and 10:30 h after overnight fasting and stored at -80C. Urine samples were collected between 08:30 and 10:30 h after overnight fasting and stored at -20C. Different sample types and availability is listed in the sample registry.

References

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