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RESEARCH ARTICLE

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Survey of community and hospital pharmacist involvement in outpatient chemotherapy using Japanese health information data

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ABSTRACT

In this study, information on injectable anticancer drug use and additional fee for enhanced collaboration (AEC) and additional fee for specific drug management guidance 2 (ASD2) claims from the NDB Open Data Japan (NODJ) dataset and the number of patients with cancer according to sex and age from the National Cancer Registry (NCR) dataset were integrated and evaluated to determine the current status and challenges in pharmacist interventions for patients receiving cancer treatment. The NODJ data, including receipt data billed from 2020 to 2021, were obtained from the Ministry of Health, Labour and Welfare website. The use of injectable anticancer drugs decreased relative to the number of cancer patients aged ≥ 75 years compared to those aged < 75 years. Regarding injectable anticancer drug use, the number of AEC claims was similar between men and women, but the number of ASD2 claims was lower in men than in women. The number of times community pharmacists claimed their ASD2 was approximately 5% of the number of times hospital pharmacists claimed their AEC. This study revealed that several patients did not receive sufficient guidance from community pharmacists compared to hospital pharmacists, suggesting a potential insufficiency in the collaboration between the two groups.

KEYWORDS Outpatient chemotherapy; hospital pharmacist; community pharmacist; additional fee for enhanced collaboration; additional fee for specific drug management guidance 2; NDB Open Data Japan

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Background

According to the World Health Organization (WHO), cancer is the second leading cause of death globally, accounting for an estimated 10 million deaths, or 1 in 6 deaths, in 2020 (World Health Organization, n.d.). In Japan, cancer has been the leading cause of death since 1981, and the estimated number of cancer deaths in Japan in 2022 was approximately 380,400, or approximately one in three people, die from cancer, and approximately one in two people will be diagnosed with cancer in their lifetime (Foundation for Promotion of Cancer Research, 2023). In Japan, the average length of stay for patients discharged from cancer-specialized hospitals and general clinics was 35.7 days in 2002 and 17.1 days in 2017 (Ministry of Health, Labour and Welfare, 2021b). The number of patients with cancer has increased from 139,400 inpatients and 119,700 outpatients in 2002 to 126,100 inpatients and 183,600 outpatients in 2017, with more patients receiving outpatient treatment (Ministry of Health, Labour and Welfare, 2021b). Given that side effects associated with outpatient chemotherapy are diverse and occur at different times (Ministry of Health, Labour and Welfare, 2009, 2019, 2021a, 2022a, 2023).

Multidisciplinary care is organised around the patient, and medical professionals collaborate and have access to a variety of shared information. In Japan, hospital pharmacists interview patients before visiting their doctors to check for side effects, suggest dosage adjustments of anticancer drugs, and provide supportive care; the efficacy of this approach has been reported (Kimura et al., 2017; Tanaka et al., 2019; Yoshimi et al., 2013).

There are several reports of community pharmacists monitoring adverse events and providing feedback to hospital pharmacists that have been useful (Rubira et al., 2021; Urakawa et al., 2021). A survey conducted in France reported that patients are willing to share information with community pharmacists in cancer treatment, to report side effects to the hospital, and to take effective solutions for their management (Hébert et al., 2018). In addition, there have been several reports on the early detection of side effects and changes in prescriptions during outpatient anticancer treatment owing to the involvement of pharmacists (Colombo et al., 2017; Gatwood et al., 2017; Herledan et al., 2023a, 2023b). To the best of our knowledge, reports about the involvement of community pharmacists with patients undergoing outpatient chemotherapy are rare.

Japan has universal health insurance; hence, all residents are required to be covered by some form of public insurance. The work of healthcare professionals is paid for by the medical and dispensing fees collected. In 2015, the Ministry of Health, Labour and Welfare (MHLW) presented the 'Pharmacy Vision for Patients.' It stated that it is important for community pharmacists to communicate with patients, provide patient guidance to improve adherence and avoid adverse events, and report to physicians on medication and side

effects (Ministry of Health, Labour and Welfare, 2015). The Basic Plan for the Promotion of Cancer Control (2017) stated that the necessary measures should be taken to strengthen cooperation between hospitals and pharmacies to support outpatients undergoing drug therapy in medication management and countermeasures against adverse effects (Ministry of Health, Labour and Welfare, 2018). Therefore, in April 2020, an 'additional fee for enhanced collaboration' (AEC) was established for hospital pharmacist services as an addition to the medical treatment fee. An 'additional fee for specific drug management guidance 2' (ASD2) was then established for community pharmacist services aside from the pharmacy administrative fee (Ministry of Health, Labour and Welfare, n.d.-e). These additional fees are paid when a pharmacist provides special patient guidance in addition to basic services for patients with cancer.

The AEC and ASD2 focus on developing facilities and equipment systems for the safe delivery of outpatient chemotherapy and collaboration between hospital and community pharmacists to manage the side effects experienced by patients. Therefore, this additional fee indicates that pharmacists contribute to safe drug treatment.

The MHLW started operating the National Database of Health Insurance Claims and Specific Health Checkups of Japan (NDB) by enacting the Act on Assurance of Medical Care for Elderly People in 2008. The NDB stores data on health insurance claims and specific health checkups (Ministry of Health, Labour and Welfare, n.d.-d). The NDB is one of the largest health-related databases worldwide, containing digitised data on health insurance claims and specific health checkup data collected from all medical institutions, including hospitals, clinics, pharmacies, and dental clinics, covering medical information on almost all individuals (over 100 million) in Japan. The NDB has been used in multiple studies in health economics, pharmacoepidemiology, clinical epidemiology, and other fields. The MHLW released the NDB Open Data Japan (NODJ) online, which provides various summary tables from the NDB that have been freely available to the general public since 2016. The NODJ includes basic summary tables created from medical inpatient claims, medical outpatient claims, diagnosis procedure combination (DPC) claims, dispensing claims, dental inpatient claims, dental outpatient claims, and specific health checkups (Ministry of Health, Labour and Welfare, 2022b). The NODJ has been used in several studies to identify trends in drugs prescribed by the Japanese insurance system (Mukai et al., 2020; Suzuki et al., 2023; Tanaka et al., 2022; Tanito, 2022). Furthermore, Japan enacted the Cancer Registration Promotion Act in 2013, where the registration of diagnosed cancer cases was started in 2016 under the new National Cancer Registry (NCR) system (Ministry of Health. Labour and Welfare, n.d.-a). The results of this survey are publicly available and can be obtained from the MHLW and the e-Stat website.

In this study, information on injectable anticancer drug usage, AEC, and ASD2 from the NODJ dataset and the number of patients with cancer according to sex, age, and cancer site from the NCR dataset were integrated and evaluated to determine the current status and problems associated with pharmacist interventions.

Methods

Data sources

1) National Database of Health Insurance Claims and Specific Health Checkups of Japan Open Data Japan

The 7th NODJ dataset, which includes receipt data billed from April 2020 to March 2021, was obtained from the MHLW website (Ministry of Health. Labour and Welfare, n.d.-f). The 7th NODJ includes eight tables containing statistics on 'medical treatments,' 'prescriptions,' and 'drug data,' among others. In the 'medical treatments' table, the number of medical treatments, classified into 'basic medical fee,' 'medical management,' and other parameters, stratified by prefecture, sex, age, and month of treatment, were summarised according to the score table prepared by the MHLW.

The 'prescriptions' table summarises the number of claims for each dispensing act, stratified by 'prefecture,' 'sex,' and 'age.'

In the 'drug data' table, the top 100 drugs regarding prescription quantity for each drug category were summarised by prefecture, sex, and age, based on information from medical inpatient/outpatient receipts, DPC receipts, and dispensing receipts. The 'drug data' tables were classified by dosage form: 'oral,' 'topical,' and 'injection.' The prescription quantities were reported as the number of days (times) multiplied by the amount used per day (per dose).

2) National Cancer Registry (NCR) system

In the NCR system, cancer sites are classified according to the WHO International Statistical Classification of Diseases and Related Health Problems (ICD) (Ministry of Health, Labour and Welfare, n.d.-b). The NCR registers primary cancers; if two or more independent cancers are detected in one person, each one is counted independently.

The number of patients with cancer categorised according to cancer site in 2019 was obtained from the NCR 'incidence by age group: by the site and sex (excluding epithelial cancers)' (Data Table 2019_2-a), which is available on the e-Stat website. The classification of cancer sites followed the C00 – C96 coding system. The number of patients was aggregated based on 5-year age groups for each sex. The population data were obtained from the 2020 'Population by Year, Sex, and Age' from the Current Population Survey available on the e-Stat website (Statistics Bureau of Japan, n.d.).

Medical remuneration points

1) Additional fee for enhanced collaboration (AEC)

The AEC can be claimed when a hospital pharmacist is notified, based on the instructions provided by the physician, to provide patients receiving injectable outpatient chemotherapy with a document on the occurrence of side effects and treatment plans and provide the necessary guidance based on the patient's condition. The contents of the document include the implementation status of the treatment regimen, dosage of anticancer agents, and the occurrence of major adverse reactions (including the severity scale [grade] of adverse reactions based on the Common Terminology Criteria for Adverse Events v5.0 Japanese translation JCOG [Japan Clinical Oncology Group] version and the results of relevant blood and biochemical tests). Hospital pharmacists instruct patients to present this document to community pharmacists. Several patients also carry a personal medication notebook. This notebook contains the patient's medication history, including prescription medications and allergy and adverse reaction history. The personal medication notebook is also submitted when patients present a prescription at a community pharmacy. The community pharmacist may record the prescribed medication before returning the personal medication notebook to the patient. When claiming the AEC, the hospital pharmacist is supposed to use the medication notebook or other documentation to inform the community pharmacist of the patient's treatment status. The conditions for the claim include making chemotherapy regimens available on the website and conducting training sessions for pharmacists and others working in community pharmacies at least once a year. The AEC is claimed at 150 points once a month. A point is added to each item for each medical procedure performed. The unit price per point is claimed at 0.67 USD (10 JPY).

For the AEC, the number of claims for medical practice (code: 130013570) was extracted from the data table '000986909.xlsx,' which is published in 'Number of claims by sex and age' of item G (injection, injection [addition]) of 'medical treatment.' (Ministry of Health. Labour and Welfare, n.d.-f, Table S1).

2) Additional fee for specific drug management guidance 2 (ASD2)

The ASD2 can be claimed when a community pharmacist confirms the patient regimen, provides the necessary pharmacological management and guidance, confirms the medication status of the patients and the presence of side effects via telephone or other means, and provides the hospital with the necessary information in writing. The conditions include that the community pharmacist must participate at least once a year in a hospital training session related to chemotherapy with antineoplastic agents to be able to guide patient in collaboration with hospital pharmacists. The ASD2 can be claimed at 100 points once a month.

The basic dispensing fee, dispensing fee, and pharmacy admin fee are stated in the 'prescriptions' section. The number of prescriptions for the 'basic dispensing fee' and ASD2 were extracted from the data table '000987605.xlsx,' which is published in 'Number of claims by sex and age' under 'prescriptions' (Ministry of Health. Labour and Welfare, n.d.-f, Table S2). Given that the basic dispensing fee represents the points claimed upon accepting a prescription at a pharmacy, it can be considered as the number of accepted prescriptions. The total number of times the basic dispensing fee was claimed is the sum of the dispensing act codes 410004110, 410004210, 410004610, 410004810, and 410005410. ASD2 was listed as 'pharmacy admin fee (addition and subtraction).' For ASD2, the total number of claims was based on the dispensing act codes 440008670 and 440009370. When a patient who brought a prescription within the past three months also brings their personal medication notebook, the pharmacy claims the pharmacy admin fee using the dispensing act codes 440007810 and 440008910. However, if the patient does not bring their medication notebook, dispensing act codes 440007910 and 440009010 were used for claiming. The number of times these codes were claimed was extracted to calculate the percentage of patients who brought their personal medication books.

Injectable anticancer drug usage in outpatient (in-hospital) and inpatient settings was extracted from the data table '000987622.xlsx,' which is published in 'Number of claims by sex and age' in the 'drug data_ injection' table (Ministry of Health. Labour and Welfare, n.d.-f, Table S3). The therapeutic categories described in the Standard Commodity Classification Number of Japan were used (Ministry of Internal Affairs and Communications, n.d.). Injectable anticancer drugs were classified according to the therapeutic category as specified by the top three digits of the therapeutic category code: alkylating agents (code: 421), antimetabolites (code: 422), antitumor antibiotics (code: 423), plant extract preparations (code: 424), and miscellaneous (code: 429). In the present study, the number of injectable anticancer drugs used was totalled for each drug category according to sex and five-year age groups.

In the data table, the number of claims < 10 or injection drugs were excluded from the analysis owing to the absence of numerical values for items with a usage < 400.

Data analysis procedures

Several analyses were performed using the data obtained from the 7th NODJ, NCR (2019), and e-Stat (Figure 1). Bivariate analysis was performed to examine the relationship between the number of patients and injectable anticancer drug usage for all registered cancer sites (C00 – C96). Injectable anticancer

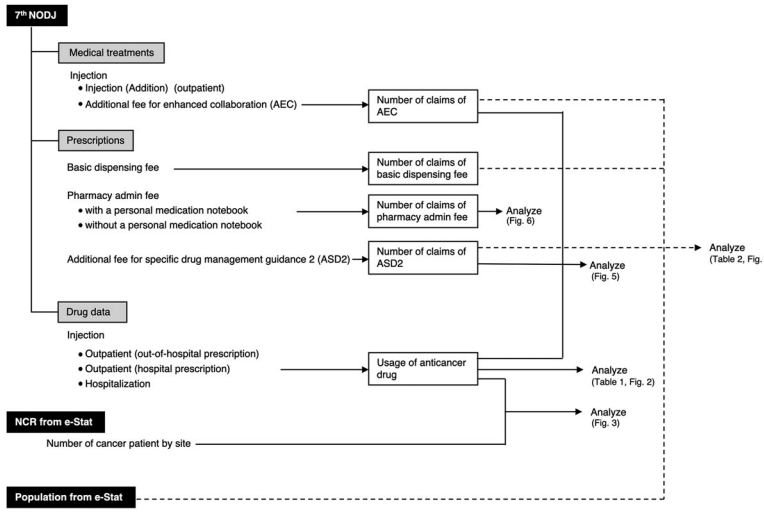

Figure 1. Flow chart of the data analysis.

drug usage was calculated according to inpatient and outpatient settings, sex, and 5-year age groups and graphed according to drug category. A mosaic plot was created to visualise the population and the number of claims of the basic dispensing fee, AEC, and ASD2 according to sex and age group.

A linear regression analysis was conducted to examine the relationship between the amount of injectable anticancer drugs used (outpatient) and the involvement of hospital and community pharmacists. The analysis focused on the relationship between the amount of injectable anticancer drugs used (outpatient) and the number of AEC and ASD2 claims. The ratio of the number of AEC and ASD2 claims for each 5-year age group was also calculated.

Data was analyzed using JMP Pro16 software (SAS Institute, Cary, NC, United States).

Ethics statement

The study is not subject to ethical examination as the study was an observational study without any research subjects. In addition, no consent to participate was required owing to the retrospective nature of the study.

Results

Table 1 summarises the number of injectable anticancer drugs used based on the 7th NODJ dataset and the cancer incidence based on NCR. Over 95% of

Table 1. Injectable anticancer drugs usage and cancer incidence by age group.

				Injectable anticancer drug usage (bottle) /outpatients (therapeutic category code)						Injectable anticancer drug usage (bottle) /inpatients (therapeutic category code)						
	Age	Percentage of outpatients to total (%)	Injectable anticancer drug usage (bottle) /total of outpatients and inpatients	Alkylating agents (421)	Antimetabolites (422)	Antibiotics (423)	Plant extract preparations (424)	Miscellaneous (429)	Total	Alkylating agents (421)	Antimetabolites (422)	Antibiotics (423)	Plant extract preparations (424)	Miscellaneous (429)	Total	Cancer incidence (C00–C96)
Total	0–4	1.92	50,324	0	0	0	967	0	967	5,935	31,985	0	6,098	5,337	49,357	926
	5–9	2.85	55,179	0	0	0	1,164	408	1,572	8,065	32,494	428	6,616	6,003	53,607	554
	10–14	1.52	62,860	0	0	0	953	0	953	11,697	33,689	1,759	8,735	6,024	61,907	637
	15–19	4.30	61,792	1,528	0	0	659	470	2,657	13,434	25,970	2,959	9,235	7,535	59,135	966
	20–24	12.09	51,602	2,755	411	533	1,219	1,320	6,239	10,241	16,293	3,914	8,164	6,748	45,363	1,621
	25–29	27.99	69,177	5,121	3,750	1,509	2,686	6,294	19,362	9,476	15,697	5,900	8,770	9,970	49,815	2,683
	30–34	48.03	129,217	7,843	11,374	6,963	11,644	24,232	62,058	11,467	17,977	9,876	11,730	16,107	67,159	5,290
	35–39	65.51	262,398	14,875	25,592	18,877	38,251	74,304	171,900	13,893	28,753	11,141	15,370	21,339	90,498	10,064
	40–44	71.05	529,642	27,000	57,950	35,719	84,914	170,744	376,329	23,405	42,715	15,846	27,444	43,901	153,313	19,515
	45–49	72.61	1,038,008	44,918	129,415	59,471	175,962	343,918	753,686	27,427	84,876	28,033	55,058	88,926	284,322	33,093
	50–54	72.72	1,399,737	45,918	210,463	61,544	233,921	466,030	1,017,878	31,301	115,897	32,580	78,610	123,469	381,859	40,076
	55–59	70.68	1,864,665	49,708	317,753	65,258	292,616	592,557	1,317,893	39,291	179,352	45,936	109,003	173,188	546,772	52,629
	60–64	69.02	2,452,125	54,057	453,123	73,157	363,222	748,985	1,692,546	49,968	254,941	63,456	148,037	243,175	759,579	76,966
	65–69	67.73	3,540,973	62,655	686,603	90,510	503,632	1,054,791	2,398,195	64,850	388,566	92,563	220,271	376,526	1,142,778	130,610
	70–74	68.01	4,547,794	71,803	910,902	106,034	628,309	1,375,872	3,092,923	70,494	498,046	118,745	275,894	491,690	1,454,871	169,620
	75–79	66.45	3,041,986	40,751	593,437	62,518	390,954	933,873	2,021,535	51,973	349,589	92,040	179,277	347,571	1,020,451	168,490
	80–84	64.86	1,328,558	19,096	241,598	29,777	138,588	432,641	861,702	32,541	145,594	57,046	69,041	162,632	466,856	135,351
	85–89	62.46	330,175	6,006	44,471	14,291	18,573	122,874	206,218	13,181	27,334	24,862	13,401	45,177	123,957	93,070
	90–	63.60	23,119	0	424	425	0	13,855	14,704	1,280	507	1,899	1,151	3,576	8,415	56,905
	All	67.27	20,839,351	454,041 (3.24%)	3,687,273 (26.30%)	626,591 (4.47%)	2,888,244 (20.60%)	6,363,176 (45.39%)	14,019,328 (100.00%)	489,928 (7.18%)	2,290,284 (33.58%)	608,993 (8.93%)	1,251,912 (18.36%)	2,178,904 (31.95%)	6,820,023 (100.00%)	999,066
Men	0–4	1.76	29,480	0	0	0	520	0	520	3,317	18,832	0	3,302	3,508	28,960	483
	5–9	1.92	32,846	0	0	0	630	0	630	4,578	19,744	428	3,687	3,778	32,216	303
	10–14	1.18	41,655	0	0	0	491	0	491	7,643	22,297	1,284	5,371	4,566	41,164	365
	15–19	4.91	40,611	864	0	0	659	470	1,993	8,858	18,446	1,484	5,474	4,353	38,618	474
	20–24	10.82	33,304	1,604	0	0	679	1,320	3,603	6,311	10,957	2,809	5,150	4,473	29,701	701
	25–29	15.29	41,977	2,161	1,277	437	675	1,867	6,419	6,418	10,664	4,577	6,285	7,614	35,558	1,014
	30–34	23.17	50,283	1,685	4,595	0	1,160	4,211	11,652	6,140	9,801	5,998	6,802	9,888	38,631	1,653
	35–39	41.71	78,234	1,993	11,419	476	5,189	13,550	32,629	7,077	15,894	5,970	6,918	9,745	45,605	2,915
	40–44	53.05	154,022	3,148	28,820	1,893	14,002	33,840	81,705	14,545	24,338	7,044	8,949	17,440	72,317	5,458
	45–49	61.06	326,235	6,047	69,567	4,247	36,747	82,577	199,187	13,303	49,726	10,697	17,586	35,735	127,048	9,647
	50–54	66.05	514,361	8,436	122,962	6,168	66,209	135,954	339,732	14,636	72,286	12,117	24,975	50,613	174,629	15,388
	55–59	65.97	822,485	12,163	195,004	10,223	108,803	216,382	542,576	19,085	113,748	20,496	42,515	84,063	279,909	25,924

	60–64	65.10	1,269,068	15,422	290,666	19,259	165,494	335,262	826,105	26,174	169,104	33,748	74,426	139,510	442,963	44,918
	65–69	64.48	2,035,442	20,739	447,765	35,296	266,945	541,621	1,312,368	35,034	270,273	56,314	123,524	237,926	723,074	82,845
	70–74	65.12	2,746,699	29,449	592,875	48,620	361,745	756,043	1,788,735	39,307	350,019	74,951	169,844	323,841	957,964	110,569
	75–79	64.06	1,849,170	19,696	371,764	34,945	233,463	524,772	1,184,643	29,049	238,394	59,887	111,564	225,631	664,527	108,710
	80–84	63.16	793,506	11,132	148,369	20,692	86,040	234,937	501,172	17,994	92,005	36,708	43,935	101,689	292,334	81,995
	85–89	58.96	186,142	3,734	25,177	10,445	11,812	58,577	109,746	7,076	18,012	16,371	6,886	28,048	76,396	50,163
	90–	42.52	9,655	0	424	425	0	3,257	4,106	724	507	1,432	652	2,233	5,549	22,935
	All	62.85	11,055,193	138,281	2,310,688	193,130	1,361,271	2,944,647	6,948,020	267,277	1,525,057	352,322	667,853	1,294,662	4,107,173	566,460
				(1.99%)	(33.26%)	(2.78%)	(19.59%)	(42.38%)	(100.00%)	(6.51%)	(37.13%)	(8.58%)	(16.26%)	(31.52%)	(100.00%)	
Women	0–4	2.14	20,843	0	0	0	446	0	446	2,618	13,153	0	2,796	1,828	20,397	443
	5–9	4.22	22,333	0	0	0	534	408	942	3,487	12,749	0	2,928	2,225	21,391	251
	10–14	2.17	21,204	0	0	0	461	0	461	4,053	11,392	475	3,364	1,457	20,743	272
	15–19	3.13	21,180	664	0	0	0	0	664	4,575	7,523	1,474	3,761	3,181	20,516	492
	20–24	14.41	18,297	1,151	411	533	540	0	2,636	3,930	5,336	1,105	3,014	2,275	15,661	920
	25–29	47.58	27,199	2,959	2,473	1,072	2,011	4,426	12,943	3,058	5,033	1,323	2,484	2,356	14,256	1,669
	30–34	63.86	78,934	6,158	6,779	6,963	10,484	20,021	50,406	5,326	8,175	3,878	4,927	6,219	28,528	3,637
	35–39	75.62	184,162	12,881	14,173	18,401	33,061	60,753	139,270	6,816	12,859	5,171	8,451	11,593	44,892	7,149
	40–44	78.44	375,620	23,851	29,130	33,825	70,911	136,903	294,624	8,860	18,377	8,802	18,494	26,461	80,996	14,057
	45–49	77.90	711,772	38,870	59,847	55,224	139,215	261,341	554,499	14,124	35,150	17,336	37,472	53,190	157,273	23,446
	50–54	76.59	885,376	37,481	87,500	55,375	167,711	330,076	678,146	16,664	43,610	20,463	53,635	72,855	207,230	24,688
	55–59	74.39	1,042,180	37,545	122,749	55,034	183,813	376,174	775,317	20,205	65,604	25,440	66,487	89,124	266,863	26,705
	60–64	73.24	1,183,056	38,635	162,457	53,897	197,727	413,723	866,441	23,793	85,837	29,708	73,610	103,665	316,615	32,048
	65–69	72.12	1,505,529	41,915	238,838	55,214	236,687	513,170	1,085,826	29,815	118,292	36,248	96,747	138,599	419,703	47,765
	70–74	72.41	1,801,093	42,353	318,026	57,414	266,563	619,828	1,304,187	31,186	148,026	43,793	106,050	167,849	496,906	59,051
	75–79	70.16	1,192,816	21,054	221,673	27,573	157,490	409,101	836,892	22,923	111,194	32,152	67,713	121,940	355,924	59,780
	80–84	67.38	535,051	7,963	93,229	9,084	52,548	197,704	360,530	14,547	53,588	20,337	25,105	60,942	174,521	53,356
	85–89	66.98	144,032	2,272	19,294	3,846	6,761	64,297	96,472	6,104	9,321	8,490	6,514	17,129	47,560	42,907
	90–	78.71	13,462	0	0	0	0	10,597	10,597	556	0	467	499	1,343	2,865	33,970
	All	72.27	9,784,158	315,760	1,376,585	433,461	1,526,972	3,418,529	7,071,308	222,650	765,227	256,670	584,059	884,241	2,712,850	432,606
				(4.47%)	(19.47%)	(6.13%)	(21.59%)	(48.34%)	(100.00%)	(8.21%)	(28.21%)	(9.46%)	(21.53%)	(32.59%)	(100.00%)	

injectable anticancer drugs were used in hospitals for both men and women in their teenage years; however, outpatient use increased in patients starting their 20s. Among men, the percentage of outpatients exceeded 40% in the 35–39-year-old group, with the largest percentage (65.97%) in the 55–59-year-old group. Among women, outpatient usage exceeded 40% in the 25–29-year-old group, reaching a maximum of 78.44% in the 40–44-year-old group, and remained above 70% until the 75–79-year-old group.

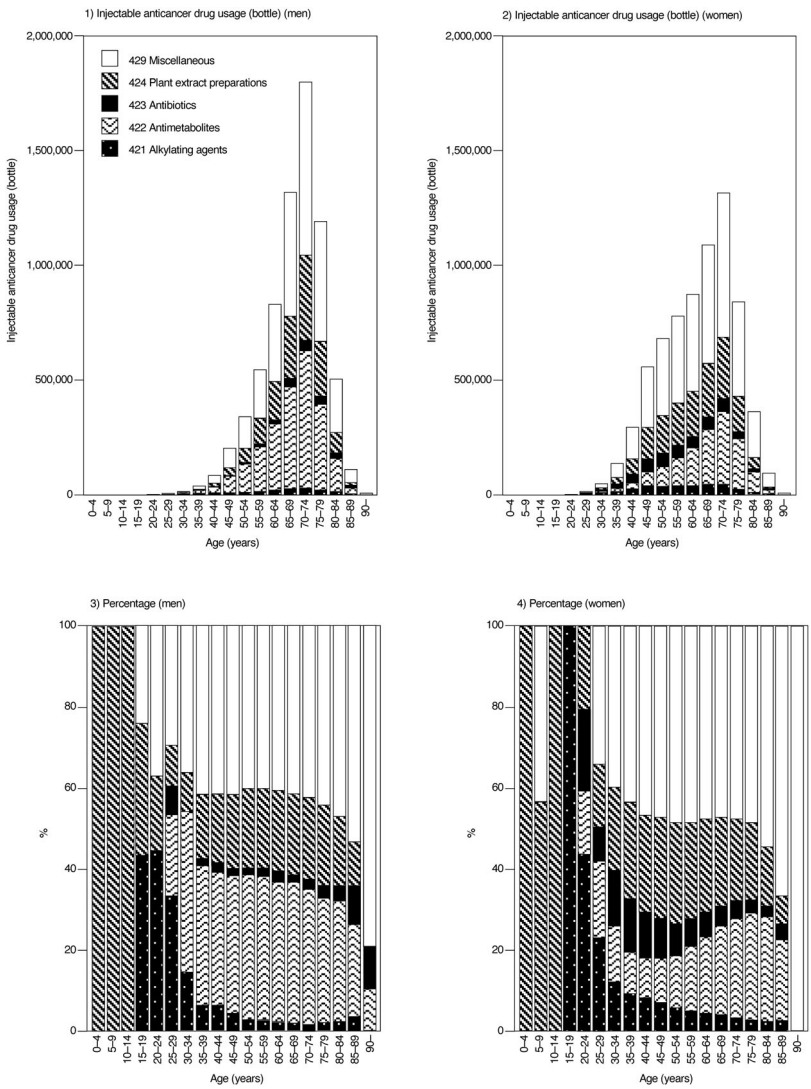

Figure 2. Injectable anticancer drug usage according to therapeutic category (outpatients and inpatients).

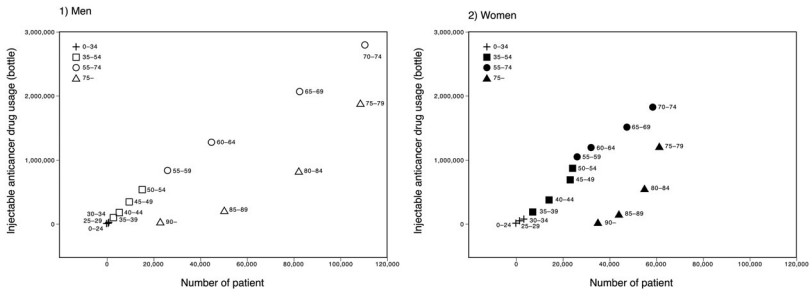

Figure 3. Number of patients and drug usage (outpatients).

Figure 2 presents an overview of the usage of each drug class according to 5-year age groups and sex. Regarding the drug class of injectable anticancer drugs used in the outpatient setting, 'miscellaneous (code: 429)' was frequently used, accounting for 42.38% and 48.34% usage in men and women, respectively. The use of antimetabolites (code: 422) was more common in men (33.26%) than in women (19.47%). Conversely, more women used alkylating agents (code: 421; 1.99% for men and 4.47% for women) and antitumor antibiotic preparations (code: 423; 2.78% for men and 6.13% for women) than men.

The relationship between the number of patients and injectable anticancer drugs used (total number of inpatients and outpatients) for all cancer sites (C00 – C96) is summarised in Figure 3. The number of patients with cancer and the use of injectable anticancer drugs increased with age in both men and women aged < 75 years, whereas the use of injectable anticancer drugs decreased relative to the number of patients with cancer aged ≥ 75 years compared to those aged < 75 years.

Table 2 summarises the number of claims for the AEC, ASD2, pharmacy admin fee, basic dispensing fee, and population. The total number of AEC claims was 332,480, of which 163,855 (49.28%) were for men and 168,625 (50.72%) were for women. The number of ASD2 claims was 17,938, of which 8,376 (46.69%) were for men and 9,562 (53.31%) were for women. The number of claims for the basic dispensing fee was 734,313,421, of which 321,335,654 (43.76%) were from men and 412,977,767 (56.24%) were from women. The ASD2-to-AEC ratio was 5.40% (5.11% in men and 5.67% in women).

A mosaic plot of the correlation between the population, the number of times the basic dispensing fee was claimed, the number of AEC and ASD2 claims, and age is shown in Figure 4. The population remained balanced, with approximately 50% men and 50% women, until the age of 60 years. However, the frequency of claiming the basic dispensing fee was 62.01% for women in the 25–29-year-old group. Women aged ≥ 90 years had the

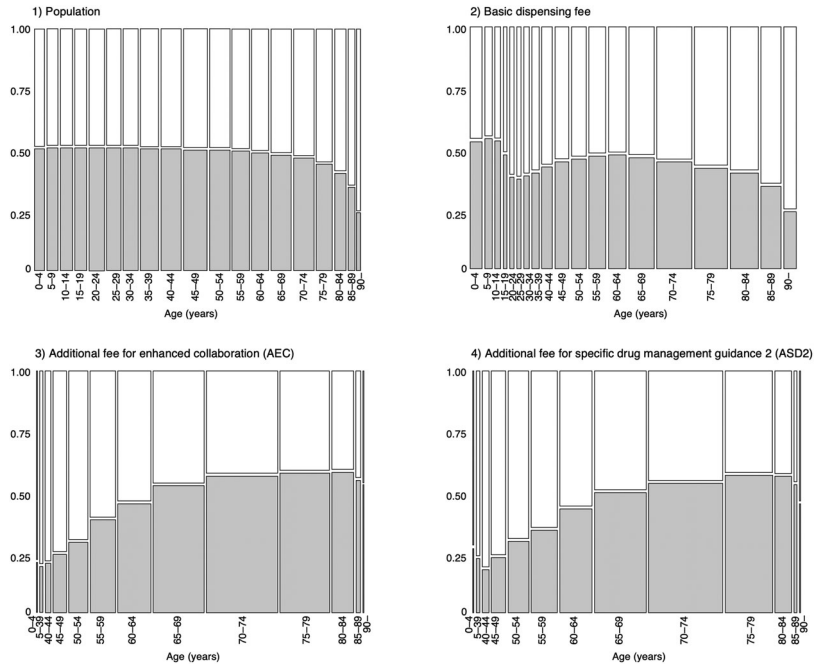

Figure 4. Mosaic plot of Population, Basic Dispensing Fee, AEC, and ASD2 (shaded: men; white: women).

largest difference, at 75.23%. The number of AEC claims was higher in women up to 64 years and higher in men over 65 years. The age group with the largest difference was the 35–39-year-old group, where 80.00% were women. Similar to the AEC, the number of ASD2 claims was higher among women up to 64 years and men over 65 years. The age group with the largest difference was the 40–44-year-old group, where 81.07% were women.

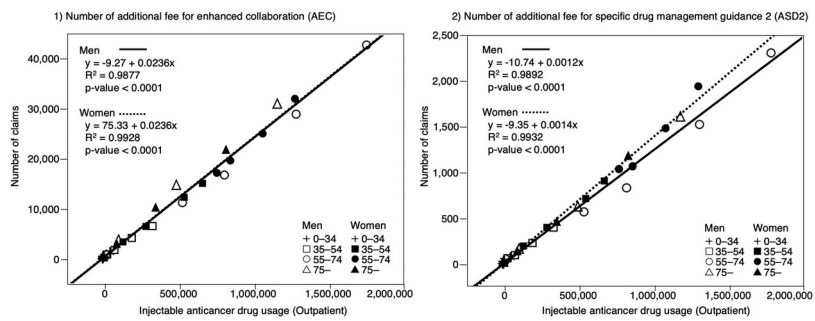

Figure 5. Correlation coefficients between injectable anticancer drugs and AEC and ASD2 claims.

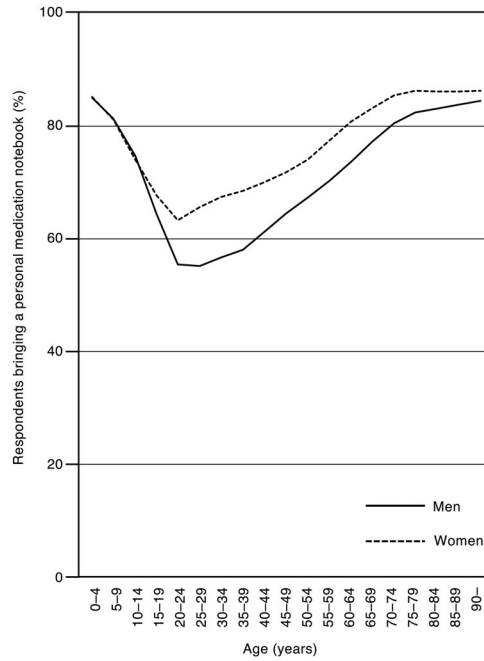

Figure 6. Percentage of respondents who brought a personal medication notebook.

The results of the linear regression analysis of the number of injectable anticancer drugs used in outpatients and the number of AEC and ASD2 claims are summarised in Figure 5. The coefficient of determination between the number of injectable drugs used and the number of AEC claims was $R^2 = 0.9877$, $p < 0.0001$, regression coefficient: 0.0236 for men and $R^2 = 0.9928$, $p < 0.0001$, regression coefficient: 0.0236 for women. The coefficient of determination between the number of injectable drugs used and the number of ASD2 claims was $R^2 = 0.9892$, $p < 0.0001$, regression coefficient: 0.0012 for men and $R^2 = 0.9932$, $p < 0.0001$, regression coefficient: 0.0014 for women.

Figure 6 shows the percentage of individuals who brought their personal medication notebooks according to the 5-year age groups. The percentage of men aged $\geq$ 15 years was lower than that of women across all age groups.

Discussion

According to the Cancer Statistics 2023 published by the Foundation for Cancer Research and Progress (Foundation for Promotion of Cancer Research, 2023), the distribution of the causal sites of cancer mortality varies by age group. Fig. S1 illustrates the number of affected persons according to cancer site, sex, and 5-year age group from the data obtained from the

NCR. In men, the number of cancer cases increased with age and was the highest among patients aged 70–74 years. Gastrointestinal cancers, such as stomach, esophagus, colon, liver, and pancreatic cancers, were more common among younger patients, whereas the prevalence of lung and prostate cancers increased with age. Among women, the number of cancer cases was the highest in the 75–79-year-old group. The distribution of cancer sites varied, with uterine cancers showing a higher percentage in the 50–54-year-olds and breast cancer being predominant in the 45–49 – and 70–74-year-olds. Uterine and breast cancers accounted for most cancer cases among women from younger age groups.

The National Comprehensive Cancer Network (NCCN) in the United States has listed Older Adult Oncology (Version: 1.2023) as a specific population in their guidelines (National Comprehensive Cancer Network, n.d.-a). These guidelines state that treatment decisions for elderly patients with cancer should be based on their overall life expectancy. In this study, the use of injectable anticancer drugs decreased relative to the number of patients with cancer aged $\geq$ 75 years compared to those aged < 75 years. Since the cancer site varies with age, the treatment may also differ. In addition, as indicated in the NCCN guidelines, treatment options for the elderly are likely to consider prognosis. Several reports indicate that older cancer patients receive treatment less frequently than younger patients (Craigs et al., 2018; Haase et al., 2023; Okuyama & Higashi, 2018; Sehgal et al., 2014). Injectable anticancer agents are likely to be used less frequently in the elderly than in younger patients due to differences in the sites affected and from the perspective of safety.

As Figure 4 shows, there is no difference between men and women in the younger age groups, but the proportion of women who were dispensed drugs was higher among those in their 20s to 40s; women also accounted for a higher number of AEC and ASD2 claims. This may be because cancers specific to women, such as breast and uterine cancer, are more common in the younger age groups.

The outpatient use of injectable anticancer drugs accounted for 67% of the total use of anticancer drugs (Table 1). These findings highlight the importance of supporting patients undergoing treatment in an outpatient setting to ensure the safe administration of chemotherapy.

There was a correlation between the number of AEC claims and the amount of injectable anticancer drugs used in both men and women, as well as between the number of ASD2 claims and the amount of injectable anticancer drugs used (Figure 5). The slope of the regression line between the number of AEC claims and the number of injectable anticancer drugs used did not differ between men and women. However, the slope of the regression line between the number of ASD2 claims and the number of injectable anticancer drugs used differed between men and women, with men having a smaller slope. To compensate for the lack of information

from the prescriptions, the AEC requires hospital pharmacists to communicate information to community pharmacists through the use of personal medication notebooks or other means. The ASD2 claim frequency may have been lower among men because they are less likely to provide a personal medication handbook (Figure 6). There were also gender differences in cancer site and type of injected anticancer drugs (Figure 2), which may be related to differences in the treatment regimens provided.

The number of times the community pharmacists claimed their ASD2 was approximately 5% of the number of times the hospital pharmacists claimed their AEC (Table 2). The following are possible reasons for the discrepancy between AEC and ASD2 claim counts. First, because some outpatient cancer chemotherapy regimens do not include oral anticancer agents or supportive care drugs, it is possible that some patients are treated with injectable anticancer agents but do not go to a community pharmacy. In other words, we speculate that some patients are eligible for AEC but not ASD2. Second, even if a patient receives a prescription dispensed at a community pharmacy, the community pharmacist may not have a reliable system to know that the patient is receiving anticancer drug treatment and is being instructed on AEC by the hospital pharmacist. In Japan, the disease name is not usually listed on the prescription, thereby preventing the community pharmacist from learning the name of the disease from the prescription. If no anticancer drugs are prescribed, the community pharmacist cannot know from the prescription that the patient is undergoing treatment for cancer. The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Antiemesis Version 2.2023–May 24, 2023® lists aprepitant as an antiemetic agent (National Comprehensive Cancer Network, n.d.-b). When prescribed, the community pharmacist knows from the information on the prescription that the patient is being treated with an injectable anticancer drug. However, for supportive care drugs, such as antidiarrheals, which are sometimes prescribed for noncancer conditions, it is difficult for the community pharmacist to determine the treatment being received at a hospital based solely on the information on the prescription. A third factor may be that information is communicated from the hospital pharmacist to the community pharmacist via the patient. However, the decision to use a medication notebook rests with the patient. If there is sufficient cooperation between hospital pharmacists and community pharmacists, the difference in the number of AEC and ASD2 calculations could be reduced. For patients undergoing outpatient cancer chemotherapy, a system for direct communication between the hospital and community pharmacists may be required.

Several reports have indicated that community pharmacists lack the necessary competence to ensure the safety of patient medication used in outpatient chemotherapy (Buhl et al., 2023; Mensah et al., 2019), suggesting that community pharmacists need to acquire more knowledge in dealing with

Table 2. The number of claims of AEC, ASD2, Pharmacy Admin Fee and Basic Dispensing Fee, and Population.

Sex	Age	Number of additional fee for enhanced collaboration (AEC)	Percentage by age group	Number of additional fee for specific drug management guidance 2 (ASD2)	Percentage by age group	Percentage of ASD2 to AEC (%)	Pharmacy admin fee (with a personal medication notebook) (1)	Pharmacy admin fee (without a personal medication notebook) (2)	Percentage of (1) to (2) (%)	Number of basic dispensing fee	Percentage by age group	Population	Percentage by age group
Total	0–4	0	–	0	–	0.00	19,658,250	3,240,040	85.85	33,592,151	–	4,783,530	–
	5–9	0	–	0	–	0.00	11,383,764	2,506,609	81.95	23,440,558	–	5,271,118	–
	10–14	0	–	0	–	0.00	6,680,911	2,223,720	75.03	16,697,471	–	5,473,614	–
	15–19	87	–	0	–	0.00	4,732,062	2,375,281	66.58	13,379,445	–	5,877,047	–
	20–24	213	–	0	–	0.00	4,429,534	2,872,011	60.67	13,917,126	–	6,410,149	–
	25–29	663	–	33	–	4.98	5,740,245	3,495,170	62.15	16,527,594	–	6,466,220	–
	30–34	1,672	–	97	–	5.80	7,316,622	4,177,697	63.65	19,440,819	–	6,950,524	–
	35–39	4,220	–	251	–	5.95	9,407,456	5,122,723	64.74	23,291,214	–	7,730,481	–
	40–44	8,222	–	486	–	5.91	12,678,144	6,340,590	66.66	28,506,899	–	8,798,415	–
	45–49	16,480	–	932	–	5.66	18,244,169	8,207,106	68.97	37,162,163	–	9,960,058	–
	50–54	21,674	–	1,292	–	5.96	21,031,042	8,412,029	71.43	39,371,080	–	8,666,374	–
	55–59	28,455	–	1,590	–	5.59	24,616,657	8,396,581	74.57	42,456,742	–	7,778,677	–
	60–64	36,414	–	1,881	–	5.17	29,291,324	8,280,751	77.96	46,806,654	–	7,484,949	–
	65–69	54,023	–	2,980	–	5.52	40,949,516	9,513,528	81.15	61,227,460	–	8,512,280	–
	70–74	74,881	–	4,215	–	5.63	59,407,533	11,348,051	83.96	84,562,373	–	8,760,156	–
	75–79	52,856	–	2,766	–	5.23	57,907,506	9,921,084	85.37	81,161,978	–	7,151,679	–
	80–84	25,052	–	1,077	–	4.30	48,304,392	8,103,035	85.63	69,770,239	–	5,261,420	–
	85–89	6,772	–	299	–	4.42	31,822,974	5,169,512	86.03	50,279,538	–	3,542,733	–
	90–	796	–	39	–	4.90	16,353,193	2,553,574	86.49	32,721,917	–	2,258,545	–
	All	332,480	–	17,938	–	5.40	429,955,294	112,259,092	79.30	734,313,421	–	127,137,969	–
Men	0–4	0	0.00	0	0.00	0.00	10,636,186	1,757,479	85.82	18,004,585	53.60	2,451,534	51.25
	5–9	0	0.00	0	0.00	0.00	6,385,477	1,396,669	82.05	12,800,279	54.61	2,703,139	51.28
	10–14	0	0.00	0	0.00	0.00	3,732,029	1,224,940	75.29	9,017,379	54.00	2,805,669	51.26
	15–19	28	32.18	0	0.00	0.00	2,289,127	1,236,634	64.93	6,459,874	48.28	3,012,009	51.25
	20–24	86	40.38	0	0.00	0.00	1,616,888	1,277,198	55.87	5,441,787	39.10	3,294,145	51.39

	25–29	262	39.52	0	0.00	0.00	1,952,327	1,557,022	55.63	6,279,139	37.99	3,332,499	51.54
	30–34	365	21.83	27	27.84	7.40	2,573,665	1,938,609	57.04	7,631,051	39.25	3,562,668	51.26
	35–39	844	20.00	59	23.51	6.99	3,475,546	2,468,531	58.47	9,467,116	40.65	3,938,861	50.95
	40–44	1,749	21.27	92	18.93	5.26	5,159,985	3,212,844	61.63	12,308,416	43.18	4,476,747	50.88
	45–49	4,163	25.26	225	24.14	5.40	8,022,764	4,306,594	65.07	16,851,546	45.35	5,052,054	50.72
	50–54	6,560	30.27	393	30.42	5.99	9,516,310	4,510,203	67.85	18,240,943	46.33	4,370,727	50.43
	55–59	11,246	39.52	563	35.41	5.01	11,422,762	4,689,867	70.89	20,292,348	47.80	3,893,633	50.06
	60–64	16,790	46.11	824	43.81	4.91	13,551,243	4,689,729	74.29	22,445,235	47.95	3,705,990	49.51
	65–69	28,963	53.61	1,511	50.70	5.22	18,626,120	5,264,586	77.96	28,812,488	47.06	4,136,887	48.60
	70–74	42,835	57.20	2,289	54.31	5.34	26,141,001	6,038,069	81.24	38,353,586	45.36	4,135,964	47.21
	75–79	31,018	58.68	1,595	57.66	5.14	24,312,500	4,925,862	83.15	34,829,183	42.91	3,190,582	44.61
	80–84	14,749	58.87	619	57.47	4.20	19,552,639	3,750,362	83.91	28,294,911	40.55	2,169,304	41.23
	85–89	3,766	55.61	161	53.85	4.28	11,662,561	2,137,874	84.51	17,701,555	35.21	1,246,148	35.17
	90–	431	54.15	18	46.15	4.18	4,660,983	804,002	85.29	8,104,233	24.77	557,450	24.68
	All	163,855	49.28	8,376	46.69	5.11	185,290,113	57,187,074	76.42	321,335,654	43.76	62,036,010	48.79
Women	0–4	0	0.00	0	0.00	0.00	9,022,064	1,482,561	85.89	15,587,566	46.40	2,331,996	48.75
	5–9	0	0.00	0	0.00	0.00	4,998,287	1,109,940	81.83	10,640,279	45.39	2,567,979	48.72
	10–14	0	0.00	0	0.00	0.00	2,948,882	998,780	74.70	7,680,092	46.00	2,667,945	48.74
	15–19	59	67.82	0	0.00	0.00	2,442,935	1,138,647	68.21	6,919,571	51.72	2,865,038	48.75
	20–24	127	59.62	0	0.00	0.00	2,812,646	1,594,813	63.82	8,475,339	60.90	3,116,004	48.61
	25–29	401	60.48	33	100.00	8.23	3,787,918	1,938,148	66.15	10,248,455	62.01	3,133,721	48.46
	30–34	1,307	78.17	70	72.16	5.36	4,742,957	2,239,088	67.93	11,809,768	60.75	3,387,856	48.74
	35–39	3,376	80.00	192	76.49	5.69	5,931,910	2,654,192	69.09	13,824,098	59.35	3,791,620	49.05
	40–44	6,473	78.73	394	81.07	6.09	7,518,159	3,127,746	70.62	16,198,483	56.82	4,321,668	49.12
	45–49	12,317	74.74	707	75.86	5.74	10,221,405	3,900,512	72.38	20,310,617	54.65	4,908,004	49.28
	50–54	15,114	69.73	899	69.58	5.95	11,514,732	3,901,826	74.69	21,130,137	53.67	4,295,647	49.57
	55–59	17,209	60.48	1,027	64.59	5.97	13,193,895	3,706,714	78.07	22,164,394	52.20	3,885,044	49.94
	60–64	19,624	53.89	1,057	56.19	5.39	15,740,081	3,591,022	81.42	24,361,419	52.05	3,778,959	50.49
	65–69	25,060	46.39	1,469	49.30	5.86	22,323,396	4,248,942	84.01	32,414,972	52.94	4,375,393	51.40
	70–74	32,046	42.80	1,926	45.69	6.01	33,266,532	5,309,982	86.24	46,208,787	54.64	4,624,192	52.79
	75–79	21,838	41.32	1,171	42.34	5.36	33,595,006	4,995,222	87.06	46,332,795	57.09	3,961,097	55.39
	80–84	10,303	41.13	458	42.53	4.45	28,751,753	4,352,673	86.85	41,475,328	59.45	3,092,116	58.77
	85–89	3,006	44.39	138	46.15	4.59	20,160,413	3,031,638	86.93	32,577,983	64.79	2,296,585	64.83
	90–	365	45.85	21	53.85	5.75	11,692,210	1,749,572	86.98	24,617,684	75.23	1,701,095	75.32
	All	168,625	50.72	9,562	53.31	5.67	244,665,181	55,072,018	81.63	412,977,767	56.24	65,101,959	51.21

outpatient cancer chemotherapy. Efforts should be made to improve the knowledge of pharmacists regarding cancer treatment to ensure the safe administration of outpatient chemotherapy. Cancer chemotherapy has many side effects (Ministry of Health, Labour and Welfare, 2009, 2019, 2021a, 2022a, 2023). The percentage of injectable anticancer drugs belonging to the miscellaneous category (code: 429), which includes novel anticancer agents, such as molecular-targeted agents, to the total was 45%. Hence, it is also crucial to pay attention to side effects that differ from those of conventional cytotoxic anticancer agents owing to their mechanism of action. To prevent the side effects of anticancer drugs, the Multinational Association for Supportive Care of Cancer and the NCCN have published guidelines (Multinational Association of Supportive Care in Cancer, n.d.; National Comprehensive Cancer Network, n.d.-c), and the European Society for Medical Oncology has published a position paper on supportive and palliative care (Jordan et al., 2018). Community pharmacists need to utilise these guidelines and contribute to administering safe cancer chemotherapy for their patients. Although the terms and conditions of the AEC stipulate that training should be held at least once a year for community pharmacists, it may be necessary to increase the number of training sessions to improve knowledge and collaboration.

With a universal health insurance system, all Japanese citizens are assumed to have access to the same level of medical care. However, a discrepancy exists between the AEC and ASD2 claims, which requires immediate resolution. A strong system must be developed in which patients, hospital pharmacists, and community pharmacists can collaborate to administer safe outpatient cancer chemotherapy. Regional medical information networks are currently being established in Japan (Ministry of Health, Labour and Welfare, n.d.-c). The urgent establishment of such a regional collaborative network system is desirable.

In France, to secure a path for patients to receive oral anticancer therapy, Rubira et al. reported the usefulness of a computerised tool for standardising information exchanged between ambulatory and hospital pharmacists. Conversely, insufficient communication between hospital and community pharmacies indicated that community pharmacists perceived problems in providing oral antineoplastic drugs (Cavallier et al., 2022). In the United States and the United Kingdom, an initiative called Collaborative Drug Therapy Management (CDTM) has been implemented with some success. In a CDTM, a physician and pharmacist enter into a contract for the treatment of a particular patient (contractual transfer of authority), and the pharmacist administers drug therapy independently according to an agreed-upon protocol. CTDM by pharmacists varies depending on the environment, such as outpatient pharmacist, and hospital pharmacist. On the contrary, in Japan, when pharmacists do not have the authority to prescribe prescriptions or order

tests, they provide drug treatment using their pharmacological knowledge and skills in collaboration with physicians and other technicians based on protocols developed and agreed upon in advance by the physician and pharmacist. Therefore, more importance is placed on feedback to the hospital by community pharmacists through monitoring and tracing reports of adverse drug reactions (Urakawa et al., 2021). There are differences in the administrative environment surrounding pharmacists in each country, it is important that community pharmacists and hospital pharmacists support patients by treating the side effects as they occur and by sharing information related to such events.

The present study had some limitations. The original data obtained from the NODJ dataset are primarily intended for insurance billing; therefore, there may be discrepancies with the actual practice. The requirements for insurance billing are strict and complex, and even if guidance is provided to patients, it may not be billed if it does not meet the requirements for insurance billing. Additionally, not all drugs used are listed, as the list in the NODJ is limited to the top 100 drugs used in each drug category. Patients with fewer than 10 AEC and ASD2 claims are not listed in the NODJ to protect their privacy. Given that the AEC and ASD2 used in this analysis are insurance points newly established in FY 2020, they were first listed in the 7th NODJ, indicating the need for continued surveys in the future.

Conclusion

This analysis examined the number of AEC and ASD2 claims, type of injectable anticancer drug, and cancer site according to age and sex. The use of injectable anticancer drugs decreased relative to the number of patients with cancer aged $\geq$ 75 years compared to those aged $<$ 75 years. The number of ASD2 claims by community pharmacists was approximately 5% of the number of AEC claims by hospital pharmacists. The percentage of ASD2 claims was lower in men than in women. Compared to the guidance provided by hospital pharmacists to patients with cancer, the guidance provided by community pharmacists was insufficient, suggesting a lack of sufficient cooperation between hospital and community pharmacists.

Abbreviations

AEC	Additional fee for enhanced collaboration
ASD2	Additional fee for specific drug management guidance 2
NDB	National Database of Health Insurance Claims and Specific Health Checkups of Japan
NODJ	NDB Open Data Japan
NCR	National Cancer Registry
MHLW	Ministry of Health, Labor and Welfare

WHO World Health Organization
DPC diagnosis procedure combination
NCCN National Comprehensive Cancer Network

Authors' contributions

MI, MM, and MN conceived the study, participated in its design and coordination, and drafted the manuscript. KM, SH, TS, SN, and HT conceived the study, participated in its design, helped with statistical analysis, and drafted the manuscript. NI and YN performed the statistical analyses. MM, HU, YN, and KI interpreted the data. All the authors have read and approved the final version of the manuscript.

Ethics approval and consent to participate

Ethical approval was not sought for this study, as this was an observational study with no research participants. All data obtained were fully anonymized prior to the authors' access and are openly available from the MHLW website. Our research does not fall within the purview of any of the following laws and guidelines: 'Clinical Trials Act (Act No. 16 of April 14, 2017)', 'Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Law number: Act No. 145 of 1960, Last Version: Amendment of Act No. 50 of 2015)', 'Guideline for good clinical practice E6 (R1), https://www.pmda.go.jp/int-activities/int-harmony/ich/0076.html', 'Ethical guidelines for human genome and gene analysis research, https://www.mhlw.go.jp/general/seido/kousei/i-kenkyu/genome/0504sisin.html', and 'Ethical Guidelines for Medical and Health Research Involving Human Subjects, https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/hokabunya/kenkyujigyou/i-kenkyu/index.html#HID1_mid1'.

Disclosure statement

MI is an employee of Kifune Pharmacy. The other authors declare no conflicts of interest.

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Availability of data and material

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

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