ASCO® Guidelines

Patient-Centered Standards for Medically Integrated Dispensing: ASCO/NCODA Standards

Supplement

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Table 1

Population: Patients receiving oral anti-cancer drugs (Escudera-Vilaplana et al 2017) [1]

Setting: Hospital outpatient pharmacy in Madrid, Spain

Intervention: Prospectively studied pharmaceutic follow up program (interviews with patients and education at treatment initiation, 1 month, and 6 months) (Jan-Dec 2013). Description of intervention: "The pharmacotherapy follow-up programme was performed during 2012 by a group of clinical pharmacists specialized in onco-haematology, oncologists, haematologists and nurses. It was designed according to safety standards, specific drug indication, dosing regimen, route of administration, laboratory tests, interactions with other current medications and AE (Goodin et al. 2011). Pharmaceutical care was structured into three clinical interviews. The first was at the onset of treatment and aimed to inform patients about their therapy, prevention and management of AE, interactions and dietary restrictions. Patient attitudes, knowledge and habits were also explored. The second interview was conducted after the first month of treatment in order to identify and manage AE, to revise dose adjustments and to reinforce health education. The third interview was held after 6 months of treatment to detect long-term AE. In addition to this programme, all patients were able to consult pharmacists by telephone to clarify doubts about treatment. Finally, high-risk patients were prioritised based on the safety outcomes obtained. High-risk patients were those who were prone to a greater number or severe AE or more interactions owing to their clinical characteristics or pharmaceutical regimen (p.2)."

Comparator: Pre-intervention historical control group (usual care) (Jan-Dec 2011)

Outcome Timeframe	**Study results and measurements**	**Absolute effect estimates** usual care or other intervention	Pharmacotherapy follow up	**Certainty of the Evidence** (Quality of evidence)	**Plain text summary**
Adverse events at one month 1 month	Odds Ratio: 0.67 (CI 95% 0.33 - 1.36) Based on data from 249 patients in 1 study Follow up 1 month	**865** per 1000	**811** per 1000 Difference: **54 fewer per 1000** (CI 95% 186 fewer - 32 more)	**Low**	Pharmacotherapy follow up may improve adverse events at one month slightly
Adverse events 2-6 months 6 months	Odds Ratio: 0.96 (CI 95% 0.52 - 1.76)	**790** per 1000	**783** per 1000 Difference: **7 fewer per 1000**	**Low**	Pharmacotherapy follow up may improve adverse events 2-6 months slightly

	Based on data from 249 patients in 1 study Follow up 2-6 months	(CI 95% 128 fewer - 79 more)		
Drug interactions 6 months	Odds Ratio: 1.25 (CI 95% 0.76 - 2.08) Based on data from 1 patients in 249 studies Follow up 6 months	**455** per 1000 **511** per 1000 Difference: **56 more per 1000** (CI 95% 67 fewer - 180 more)	**Low**	Pharmacotherapy follow up may improve detection of drug interactions.
Food interactions[2] at initiation of treatment	Based on data from 249 patients in 1 study Follow up 6 months		**Very Low** No comparison group - very low quality	No comparison group data were available for this outcome. "The most frequent recommendation was to correct the fasting period. Interventions were performed at the beginning of treatment in 58.5% of cases, at the second interview (1 month) in 19.4%, and at the third interview (6 months) in 22.1%. The rate of acceptance of the recommendations concerning the dietary restrictions was 94.4%."

Table 2

Population: Patients with metastatic castrate-resistant prostate cancer (Patel et al 2016) [2]

Setting: Single institution

Intervention: Before pharmacist-led oral chemotherapy monitoring program. Description of intervention: "oral chemotherapy education, medication therapy management (MTM), adherence monitoring, toxicity monitoring, toxicity management, and management of related-supportive care issues. Resources such as the comprehensive review of oral chemotherapy drug–drug and drug–food interactions recently published by Segal et al [3] was used to facilitate identification of these interactions. Patients were followed either collaboratively with the medical oncologist during scheduled clinic visits, through clinic visits with the oncology pharmacist alone, by telephone contact or by email contact (p.778)."

Comparator: After pharmacist-led oral chemotherapy monitoring program

Outcome Timeframe	**Study results and measurements**	**Absolute effect estimates**		**Certainty of the Evidence** (Quality of evidence)	**Plain text summary**
		usual care	pharmacist-led oral chemotherapy monitoring		
Adherence to lab parameter monitoring	Odds Ratio: 4.95 (CI 95% 1.03 - 29.44) Based on data from 31 patients in 1 study Follow up to 24 months	**786** per 1000	**948** per 1000 Difference: **162 more per 1000** (CI 95% 5 more - 205 more)	**Low**	Significantly higher adherence to laboratory monitoring in the intervention group. Lab monitoring is important for early identification and management of side-effects.
Mean number of interventions per patient	Measured by: Scale: - High better Based on data from 31 patients in 1 study Follow up 21-24 months	**6.2** Mean	**13.5** Mean Difference: **MD 7.3 fewer**	**Low** Differences between the population of interest and those studied - specific population of metastatic castrate resistant cancer	There was a significantly higher mean number of interventions per patients in the group managed by oncology pharmacists (p=0.002). Interventions addressed adherence, drug interactions, alterations to therapy,

			patients may not be representative.	cost issues, management of AEs, provision of drug information.

Table 3

Population: Patients initiating new oral oncolytic agents (Sikorskii et al 2018) [4]

Setting: Six comprehensive cancer centers in Pennsylvania, Connecticut, Indiana and Michigan

Intervention: Automated intervention: "Patients randomized to the intervention arm received daily adherence reminder calls and weekly symptom assessment and management calls delivered by an IVR system (p.729)."

Comparator: weekly standard care and symptom assessment calls by IVR

Outcome Timeframe	**Study results and measurements**	**Absolute effect estimates**		**Certainty of the Evidence** (Quality of evidence)	**Plain text summary**
		standard care (symptom assessment only)	Telephone adherence and symptom management intervention		
Relative dose intensity (RDI) (ratio of dose consumed by patient to dose prescribed by oncologist)	Measured by: Relative dose intensity score Scale: - High better Based on data from 272 patients in 1 study Follow up baseline to week 4	**0.95** RDI Mean	**0.94** RDI Mean Difference: **MD 0.01 lower** (CI 95% 0.04 lower - 0.02 higher)	**Moderate**	Telephone adherence and symptom management intervention may have little or no difference on RDI
RDI (5-8 weeks)	Measured by: Relative dose intensity score Scale: - High better Based on data from 272 patients in 1 study Follow up 5-8 weeks	**0.97** RDI Mean	**0.95** RDI Mean Difference: **Range 0.02 lower** (CI 95% 0.04 lower - 0.02 higher)	**Moderate**	Telephone adherence and symptom management intervention probably has little or no difference on RDI (5-8 weeks)
RDI (9-12 weeks)	Measured by: Relative dose intensity score Scale: - High better	**0.92** RDI Mean	**0.90** RDI Mean	**Moderate**	Telephone adherence and symptom management intervention probably

	Based on data from 272 patients in 1 study Follow up 9-12 weeks	Difference: **Range 0.02 lower** (CI 95% 0.07 lower - 0.03 higher)		has little or no difference on RDI (9-12 weeks)
Adjusted mean number of symptoms above severity threshold at 4 weeks 4 weeks after start of treatment (midintervention)	Measured by: Scale: - Lower better Follow up 4 weeks	**2.84** number of symptomsMean Difference: **MD 0.38 fewer** (CI 95% 0.97 fewer - 0.21 more)	**2.46** number of symptomsMean	**Moderate**	Telephone adherence and symptom management intervention probably has little or no difference on adjusted mean number of symptoms above severity threshold at 4 weeks
Adjusted mean number of symptoms above severity threshold at 8 weeks 8 weeks after start of treatment (postintervention)	Measured by: Scale: - Lower better [1] Follow up 8 weeks	**1.91** number of symptoms (Mean) Difference: **MD 0.81 fewer** (CI 95% 1.41 fewer - 0.19 fewer)	**2.72** number of symptoms (Mean)	**Moderate**	Telephone adherence and symptom management intervention probably improves adjusted mean number of symptoms above severity threshold at 8 weeks
Adjusted mean number of symptoms above severity threshold at 12 weeks	Measured by: Scale: - Lower better [2] Follow up 12 weeks	**1.94** number of symptoms (Mean)	**2.35** number of symptoms (Mean)	**Moderate**	Telephone adherence and symptom management intervention probably has little or no difference on adjusted mean number of symptoms above severity threshold at 12 weeks

12 weeks after start of treatment (follow up)		Difference: **MD 0.41 fewer** (CI 95% 1.02 fewer - 0.21 more)		

Table 4

Population: Patients receiving oral chemotherapy (McNamara et al 2016) [5]

Setting: Michigan Oncology Quality Consortium (MOQC) Oral Oncolytics Collaborative at a practice with three physicians in Owosso, MI

Intervention: After workflow modification, including assessment with the Edmonton Symptom Assessment Scale, an adherence questionnaire, improved patient monitoring and management of symptoms.

Comparator: Before workflow modification

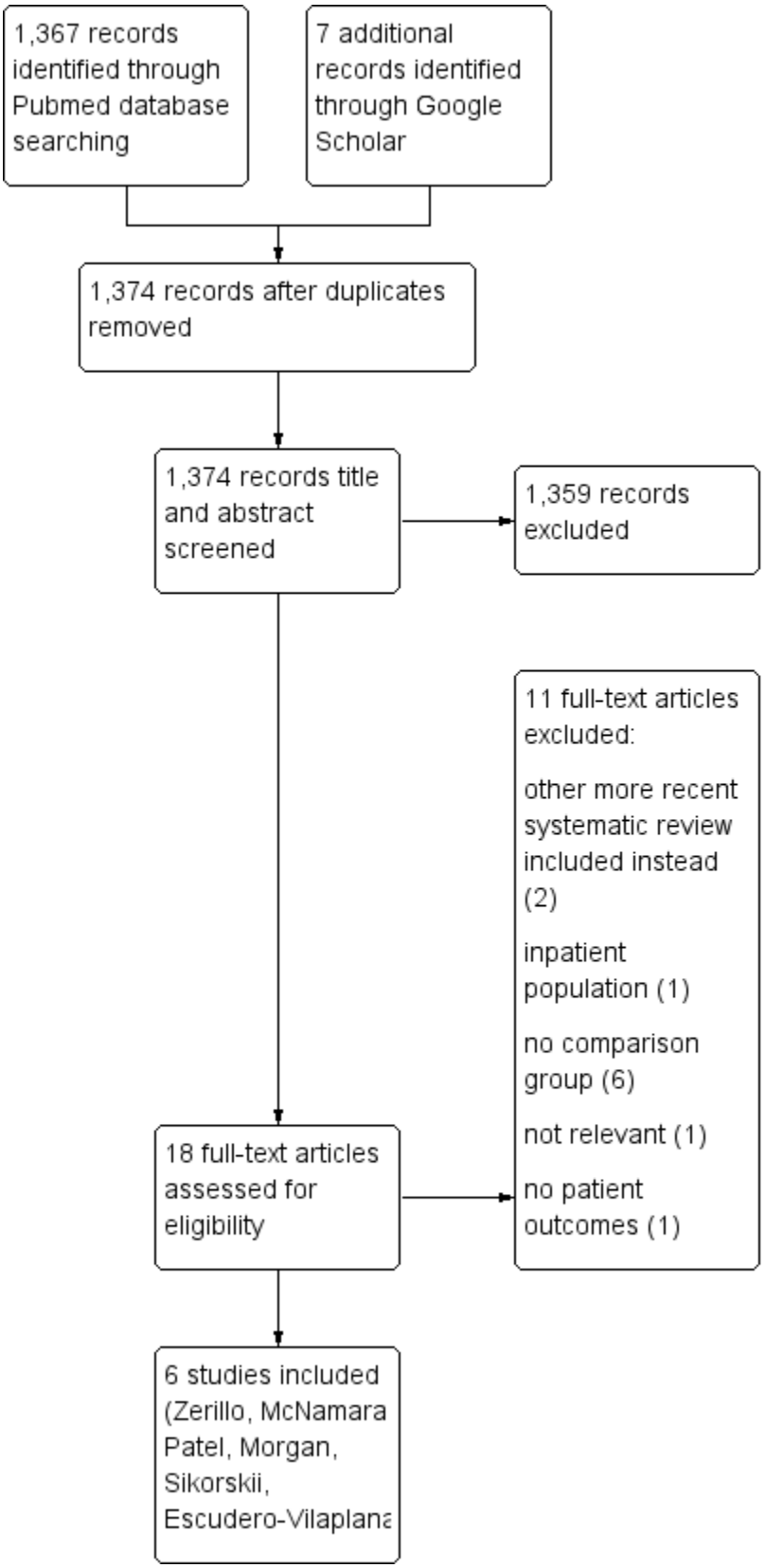
Outcome Timeframe	**Study results and measurements**	**Absolute effect estimates** usual care	workflow modification	**Certainty of the Evidence** (Quality of evidence)	**Plain text summary**
start of drug within one week after prescription	Relative risk: 1.74 (CI 95% 1.11 - 2.71) Based on data from 49 patients in 1 studies	**480** per 1000	**835** per 1000 Difference: **355 more per 1000** (CI 95% 53 more - 821 more)	**Low**	Workflow modification may improve start of drug within one week after prescription
drug discontinuation without notifying physician	Relative risk: 0.04 (CI 95% 0.0 - 0.68) Based on data from 49 patients in 1 studies	**480** per 1000	**19** per 1000 Difference: **461 fewer per 1000** (CI 95% 480 fewer - 154 fewer)	**Low**	Zero patients discontinued drug after intervention.

Table 5
Population: Patients prescribed oral chemotherapy (Morgan et al 2018) [6]
Setting: Institutional specialty pharmacy and
Intervention: Prospective quality intervention including the launch of an integrated oral chemotherapy program that included assistance with medication access, initial and continued education and counseling, side effect monitoring and management, frequent phone calls to ensure timely refills, and troubleshooting problems associated with non-compliance.
Comparator: Historical pre-intervention control group

Outcome Timeframe	**Study results and measurements**	**Absolute effect estimates** pre-intervention	Prospective quality improvement intervention	**Certainty of the Evidence** (Quality of evidence)	**Plain text summary**
interruption of chemotherapy without informing a physician	Odds Ratio: 0.21 (CI 95% 0.01 - 1.71) Based on data from 30 patients in 1 studies[1]	**380** per 1000	**114** per 1000 Difference: **266 fewer per 1000** (CI 95% 374 fewer - 132 more)	**Low**	Quality improvement intervention may improve interruption of chemotherapy without informing a physician, however it is difficult to draw conclusions with the small sample size.
Medication possession ratio	Based on data from 30 patients in 1 studies			**Low**	The medication possession ratio was 0.92 (sd = 0.1) in the intervention group (no data was presented for MPR for historical controls).

1. Primary study. **Baseline/comparator:** Control arm of reference used for intervention . Supporting references [6]

Figure 1. Flow diagram of included studies.



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2. Patel JM, Holle LM, Clement JM, et al: Impact of a pharmacist-led oral chemotherapy-monitoring program in patients with metastatic castrate-resistant prostate cancer. J Oncol Pharm Pract 22:777-783, 2016

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