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ORIGINAL RESEARCH ARTICLE

Staff Time and Motion Assessment for Administration of Erythropoiesis-Stimulating Agents: A Two-Phase Pilot Study in Clinical Oncology Practices

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Abstract

Background Erythropoiesis-stimulating agents (ESAs) are used for the management of anaemia in patients with non-myeloid malignancies where anaemia is due to the effect of concomitant myelosuppressive chemotherapy. Assessing the impact of different ESA dosing regimens on office staff time and projected labour costs is an important component of understanding the potential for optimization of oncology practice efficiencies.

Objectives A two-phase study was conducted to evaluate staff time and labour costs directly associated with ESA administration in real-world oncology practice settings among cancer patients undergoing chemotherapy. The objective of Phase 1 was to determine the mean staff time required for the process of ESA administration in patients with anaemia due to concomitantly administered chemotherapy. The objective of Phase 2 was to quantify and compare the mean staff time and mean labour costs of ESA administered once weekly (qw) with ESA once every 3 weeks (q3w) over an entire course of chemotherapy.

Methods Phase 1 was a prospective, cross-sectional time and motion study conducted in six private oncology practices in the US based on nine steps associated with ESA administration. Using findings from Phase 1, Phase 2 was conducted as a retrospective chart review to collect data on the number and types of visits in two private oncology practices for patients receiving a complete course of myelosuppressive chemotherapy.

Results In Phase 1, the mean total time that clinic staff spent on ESA administration was 23.2 min for patient visits that included chemotherapy administration ($n_{chemo} = 37$) and 21.5 min when only ESA was administered ($n_{ESAonly} = 36$). In Phase 2, the mean duration of treatment was significantly longer for q3w than qw (53.84 days for qw vs. 113.38 for q3w, $p < 0.0001$); thus, analyses were adjusted using analysis of covariance (ANCOVA) for episode duration for between-group comparisons. Following adjustment by ANCOVA, qw darbepoetin alfa (DA) patients ($n_{qw} = 83$) required more staff time for ESA + chemotherapy visits and ESA-only visits than q3w patients ($n_{q3w} = 118$) over a course of chemotherapy. Overall, mean total staff time expended per chemotherapy course was greater for patients receiving qw versus q3w DA. Weekly DA dosing was associated with greater projected mean labour costs ($US38.16 vs. $US31.20 [average for 2007–2010]).

Conclusions The results from this real-world study demonstrate that oncology practices can attain staff time and labour costs savings through the use of q3w ESA. The degree of savings depends on the individual oncology practice's staffing model and ESA administration processes, including those that allow for optimized synchronization of patient visits for ESA and chemotherapy administration. These findings indicate that additional research using standard ESA administration protocols for longer periods of time with a larger number of oncology practices and patients should be conducted to confirm these findings.

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1 Background

While chemotherapeutic approaches to the treatment of cancer are evolving, anaemia, characterized by reduced levels of red blood cells, lower-than-normal levels of haemoglobin in red blood cells, or both, continues to be a common adverse effect of these regimens. Anaemia affects an estimated 1.3 million cancer patients in the US [1]. Erythropoiesis-stimulating agents (ESAs) increase haemoglobin levels and reduce the need for red blood cell transfusions [2]. However, to gain these ESA treatment benefits may require additional patient clinic visits, which may consume additional staff time and clinic resources, in addition to imposing time burdens on the patients and their caregivers [3].

Long-acting ESAs have the potential to improve practice efficiency by allowing longer time intervals between doses, reducing the overall number of doses needed over the course of the chemotherapy regimen and staff time requirements [4, 5]. Darbepoetin alfa (DA) is a long-acting ESA that may be administered either every week (qw) or every 3 weeks (q3w) [6]. Studies suggest that the use of long-acting agents lessens patient and staff time requirements [4, 7–14]. Questions remain on how dosing flexibility of ESAs in clinical practice impacts on oncology practice staff time, especially regarding completion of activities associated with the administration of ESAs. While there have been previous studies quantifying ESA administration time, not all events and times were included in those studies [3–5, 15]. To better define and evaluate the efficiencies of ESA dosing in the oncology practice setting, a study comprised of two separate phases was conducted. The first phase was a prospective, cross-sectional time and motion study designed to determine the mean time required to complete the process of ESA administration in the US. The primary outcome measure was the observed and recorded time required to complete each of the nine tasks involved in ESA administration, with and without concomitant chemotherapy administration. Phase 2 was conducted as a retrospective chart review pilot designed to collect the frequency of visits where ESA administration, haemoglobin determinations and chemotherapy administration occurred together or separately. Results from the two phases were then combined to compare time and labour cost in actual clinical care in two private oncology practices for patients receiving a complete course of myelosuppressive chemotherapy.

2 Methods

2.1 Phase 1 Prospective, Cross-Sectional, Observational Time and Motion Study

Phase 1 included a prospective time and motion study designed to determine the mean time required to complete each of nine identified distinct steps in the process of ESA administration. This phase was conducted in six private oncology practices throughout the US (two sites in the mid-Atlantic, and one site each in the southeast-Atlantic, south, mid-west and west). Study data were collected between February and April of 2010. To be eligible for inclusion in the study, sites had to provide at least 12 patients for observation of time and motion procedures. In addition, the practice was required to demonstrate sufficient patient volume (i.e. at least 15 unique patient visits for anaemia due to concomitantly administered chemotherapy-related ESA administration between 1 August 2009 and 1 November 2009, including more than six ESA-only visits and more than six visits for concomitant ESA and chemotherapy administration).

Adult patients receiving myelosuppressive chemotherapy for the treatment of solid tumour malignancies, including but not limited to breast, lung, gastrointestinal, uterine, cervical, ovarian and lymphoma, were eligible for inclusion. Patients under the age of 18 years or with a history of myelodysplastic syndrome or renal disease were excluded from analysis. In addition, duplicate patient visits and visits in which patients did not undergo all of the nine required components of ESA administration were excluded from the study. The study was Institutional Review Board (IRB)-approved and each patient participant provided written informed consent.

A total of 12 patient visits were selected per site; of these, six assessments evaluated ESA-only visits, while the remaining six evaluations included visits in which patients received an ESA in combination with chemotherapy. Independent study data monitors collected and recorded all data, and a stopwatch was used to record start and stop points for each of the nine events related to ESA administration. Patient visits with and without concomitant chemotherapy were analysed separately.

2.1.1 Data Points

The outcome data were the time required to complete each of the following nine standard tasks involved in ESA administration, with and without concomitant chemotherapy administration [4, 15]:

1. patient registration/check-in
2. phlebotomy
3. laboratory
4. chart retrieval
5. patient counselling/preparation/vital signs
6. ESA preparation
7. ESA administration and documentation
8. patient billing
9. patient appointment scheduling

At each site, a trained observer recorded the time for each step, in minutes and seconds, using a stopwatch. The start and stop times were recorded on the case report form.

The time needed to fulfil ESA Risk Evaluation and Mitigation Strategies requirements was not included in the observation, as this is a prescriber activity, as opposed to one that is performed by clinic staff.

2.1.2 Statistical Analysis

Mean times to complete individual tasks and all tasks and corresponding 95 % confidence intervals were estimated using linear mixed-effect models with site as a random effect to account for the clustering effect within each site.

2.2 Phase 2 Retrospective Chart Review

Phase 2 was conducted as a retrospective chart review collecting information about ESA administration, haemoglobin determinations and chemotherapy administration for adult patients initiating chemotherapy between 1 August 2007 and 31 December 2010. Patients were included if they were treated for solid tumour malignancies, including lung, colorectal, prostate, ovary, lymphoma, metastatic breast and metastatic head/neck. All subjects had to have received DA therapy on a qw or q3w regimen, and have all treatment records (i.e. chemotherapy, DA administration, haemoglobin values) available for review. Patients under the age of 18 years, with other types of tumours, who received any portion of their chemotherapy regimen outside of the specified time frame, who received an ESA other than DA or who initiated DA on an alternative schedule were excluded from this analysis.

Eligible records were identified via electronic query of the electronic medical record/billing databases of the two private oncology practices that employ qw or q3w DA administration as a standard practice. Following electronic identification, a manual chart review was conducted to eliminate records based on inclusion/exclusion criteria, and to gather study data from acceptable records. Records were searched until all available records were exhausted. This phase was IRB-approved and Health Insurance Portability and Accountability Act (HIPPA) compliant.

2.2.1 Data Points

Data points for the retrospective chart review were the mean number of clinic visits over a complete course of chemotherapy, classified as:

- ESA-only visits
- ESA + chemotherapy visits
- haemoglobin check-only visits

2.2.2 Combining Results of Phases 1 and 2

Results of the two phases were then combined to compare time and labour cost in actual clinical care in two private oncology practices for patients receiving a complete course of myelosuppressive chemotherapy. By multiplying the time for a visit by the number of visits, the total time could be determined over an entire course of chemotherapy.

Staff resource costs were based on the U.S. Bureau of Labor Statistics national average for the study years (2007–2010) relative to hourly wage rates for various personnel involved in the ESA administration process (e.g. nurses, receptionists, medical technologists, phlebotomists, laboratory technicians); wage rates were multiplied by the actual mean time expended by clinic staff for each component of DA administration. The resultant mean were then multiplied by the mean number of clinic visits, in order to determine the mean total labour cost for each visit type. Total labour cost data was then obtained and compared for each DA administration regimen.

Secondary study outcomes included:

- total number of DA-related patient visits; and
- percentage of planned DA doses not administered (i.e. missed planned doses).

An ESA dose was considered "administered as planned" if it was given as scheduled, within a window of ± 2 days. Patients on a qw regimen were expected to receive the ESA between 5 and 9 days following their previous dose, while those on a q3w regimen were expected to receive the ESA between 19 and 23 days after their previous dose; planned ESA doses that were not administered before or within this timeframe, due to haemoglobin higher than 10 g/dL, were considered "missed planned doses." Analyses were conducted to identify the impact of DA administration frequency on these secondary outcome measures.

2.2.3 Statistical Analysis

A sample size of 78 patients per group was deemed sufficient to test for differences between groups, with an anticipated moderate effect size of 0.4 at an alpha level of 0.05, with a desired statistical power of 0.8. Summary statistics (i.e. mean, median, standard deviation) were calculated for all outcome measures. The one-tailed *t*-test was used to compare the means of key variables (i.e. staff time expended, staff resource cost, number of DA-related patient visits, percentage of planned DA doses not administered), and the chi-square test was applied to compare proportions. Furthermore, cost data were log-transformed and analysed with the one-tailed *t*-test.

Table 1 Mean observed times to complete the nine-step erythropoiesis-stimulating agent administration process with or without chemotherapy included in the patient visit

Task	ESA + chemotherapy ($n = 37$)	ESA-only ($n = 36$)	Haemoglobin check-only
Patient registration/check-in	3.0 (0.0–8.3)	2.2 (1.1–3.4)	2.2
Phlebotomy	3.7 (2.0–5.5)	3.6 (2.3–4.8)	3.6
Laboratory	7.0 (3.0–10.9)	6.7 (4.4–9.1)	6.7
Chart retrieval	0.3 (0.1–0.5)	0.3 (0.2–0.4)	0.3
Patient counselling, preparation and evaluation of vital signs	2.3 (1.7–2.9)	2.3 (1.9–2.7)	
ESA preparation	1.1 (–3.2 to –5.5)	1.4 (0.8–1.9)	
ESA administration and documentation	1.4 (0.3–2.5)	1.3 (0.9–1.8)	
Patient billing	1.7 (0.4–3.0)	1.7 (0.5–2.9)	1.7
Patient appointment scheduling	2.7 (0.7–4.8)	2.0 (0.3–3.6)	2.0
Total time to complete all tasks	23.2 (16.8–29.6)	21.5 (14.4–28.8)	16.5

Data are given as the mean number of minutes observed to complete the task (95 % CI)

ESA erythropoiesis-stimulating agent

Analysis of covariance (ANCOVA) was used to adjust for the difference in treatment duration for the two groups.

3 Results

3.1 Phase 1 Prospective, Cross-Sectional, Observational Time and Motion Study

Seventy-three patient visits were included in the staff time and motion study (patient visits when only ESA was administered [$n_{\text{ESA only}}$] = 36, patient visits that included chemotherapy administration [n_{chemo}] = 37). As shown in Table 1, the mean total time that oncology practice staff spent to complete all of the nine tasks of ESA administration was 23.2 min for patient visits that included chemotherapy administration. The most time-consuming individual steps were laboratory and phlebotomy, with mean times of 7.0 (95 % CI 3.1–10.9) and 3.7 (95 % CI 2.0–5.5) min, respectively. For patient visits that did not include chemotherapy administration, the mean total time spent to complete all nine tasks was 21.5 min. The most time-consuming individual steps were laboratory and phlebotomy, requiring 6.7 (95 % CI 4.4–9.1) and 3.6 (95 % CI 2.3–4.8) min, respectively. A haemoglobin check-only visit was estimated at a mean time of 16.5 min.

3.2 Phase 2 Retrospective Chart Review

A total of 195 patients were included in the phase pilot (qw DA patients [n_{qw}] = 83; q3w DA patients [n_{q3w}] = 112). The majority of study subjects were female and there were no significant differences in age or ethnicity between the groups (Table 2). Predominant cancer types included lung, ovarian, colorectal, lymphoma and metastatic breast. Ovarian cancer patients were more likely to receive q3w than qw DA, while colorectal and metastatic head/neck patients more often received qw than q3w DA. The mean duration of treatment was significantly longer for q3w than qw (53.84 days for qw vs. 113.38 days for q3w, $p < 0.0001$); thus, analyses were adjusted using ANCOVA for episode duration for between-group comparisons.

3.3 Results Adjusted by ANCOVA

Patients receiving qw DA required more staff time for ESA + chemotherapy visits than those receiving q3w (67.51 vs. 60.09 min [Table 3]). Overall, the mean total staff resource time expended per chemotherapy course was greater for patients receiving weekly versus q3w DA (120.69 vs. 112.45 min). Weekly DA dosing was associated with greater mean labour costs for ESA + chemotherapy visits and ESA-only visits than q3w dosing ($US21.18 vs. $US18.82 and $US12.75 vs. $US3.85; average for 2007–2010 [Table 4]). Q3w dosing resulted in greater mean labour costs for haemoglobin check-only visits than qw DA administration ($US13.53 vs. $US4.93). Overall, patients receiving qw versus q3w DA therapy imposed higher mean total labour costs per patient related to DA administration and haemoglobin monitoring throughout the entire course of chemotherapy ($US38.16 vs. $US31.20).

The mean number of total patient visits related to DA administration was 4.90 visits for the qw group compared with 6.08 for the q3w group. Following adjustment for inter-group variance, there was no difference in total patient visits between groups (5.56 for qw therapy vs. 5.59 for q3w therapy).

Table 2 Demographic data: once weekly versus once every 3 weeks darbepoetin alfa administration

Demographic	qw ESA administration group	q3w ESA administration group	*P* value
Number of patients	83	112[a]	
Age, years (SD)	59.5 (9.8)	62.3 (13.3)	NS
Gender			
Male	20 (24.1)	18 (16.1)	NS
Female	63 (75.9)	94 (83.9)	NS
Ethnicity			
Unknown	1 (1.2)	5 (4.5)	NS
Hispanic or Latino	3 (3.6)	0	NS
Not Hispanic or Latino	79 (95.2)	107 (95.5)	NS
Cancer type			
Lung	27 (32.5)	23 (20.5)	NS
Ovarian	12 (14.5)	36 (32.1)	0.0056
Colorectal	13 (15.7)	6 (5.4)	0.0216
Prostate	2 (2.4)	3 (2.7)	NS
Lymphoma	6 (7.2)	11 (9.8)	NS
Metastatic breast	15 (18.1)	25 (22.3)	NS
Metastatic head/neck	7 (8.4)	2 (1.8)	0.0466
Lung, metastatic breast	0	1 (0.9)	NS
Lung, metastatic head/neck	1 (1.2)	1 (0.9)	NS
Ovarian, lymphoma	0	4 (3.6)	NS
Duration of ESA therapy in days [mean (SD)]	53.84 (55.46)	113.38 (83.81)	<0.0001

Values are presented as *n* (%) unless specified otherwise

ESA erythropoiesis-stimulating agent, *NS* non-significant, *q3w* once every 3 weeks, *qw* once weekly

[a] Site 1 subject 50 was excluded due to excessive visitation frequency (257 visits)

4 Discussion

The current study provides unique insights into clinical oncology practices utilizing different ESA dosing regimens. The time and motion assessment, using the nine-step standardized process of ESA administration, found a total mean time of 23.2 min for patient visits that included chemotherapy administration and 21.5 min for visits that involved ESA administration alone. This evaluation demonstrated that the measured time for the process of ESA administration was similar regardless of whether chemotherapy administration was included in the visit or not.

In the second phase, there was significantly longer duration of ESA treatment for the q3w regimen than for the qw regimen. Following ANCOVA adjustment for intergroup variance, patients receiving qw versus q3w DA therapy imposed higher mean total labour costs per patient related to DA administration and haemoglobin monitoring throughout the entire course of chemotherapy ($US38.16 vs. $US31.20).

Cross-sectional studies such as this one give practices the ability to examine their office systems for areas that may be streamlined, and to identify potential differences between ESA regimens in terms of time requirements. The opportunity cost of such time differences may be significant and should be taken into account when selecting anaemia management options. Specifically, clinics may optimize the practice efficiency of ESA therapy by offering anaemia management strategies that require less frequent administration, thereby reducing the time burden for staff [5, 16]. Clinics utilizing q3w ESA administration may synchronize ESA therapy with current chemotherapy regimens, thereby eliminating the need for ESA-only visits. This may offer an opportunity for efficiency, as study findings indicate that the additional time to administer an ESA during a chemotherapy visit is negligible. Freeing up time may allow clinics flexibility in staff scheduling, performance of other clinical activities, scheduling of new patients, and could shorten the time of referral to the oncology clinic.

The prospective time and motion phase has several potential limitations. First, the site selection criteria were based on sites with significant ESA patient volume. The non-random selection of sites limits the generalizability of these findings beyond similar practices within similar geographic locations. However, this study included a more complete assessment of the total events associated with ESA administration than have been previously examined.

Second, this study assumes that the time spent on ESA-related tasks during the visits was the same regardless of dose regimen (q3w vs. qw). In real-world practice, there might be a difference in time burden to the office staff in administering one regimen versus the other; however, since the process of ESA administration within a visit was standardized, any difference is unlikely to be substantive.

Measurement error could have occurred due to variation in trained observer start and stop points. To minimize measurement error, data collectors were trained before the study was initiated and the tasks had clearly defined starting and stopping events to reduce the possibility for differences in interpreting the start and stop of a task.

Lastly, if a patient had prior experience and knowledge with receiving ESAs, this could impact the amount of time a site staff member needed to spend counselling the patient and monitoring the patient after ESA administration. The quantity of paperwork and preliminary diagnostics could also have varied between new patients to the clinic and returning patients.

Table 3 Mean staff time expended by visit type (adjusted by ANCOVA)

Visit type	qw ESA administration group			q3w ESA administration group		
	Mean no. of visits	Mean time (min)	Total time (min)	Mean no. of visits	Mean time (min)	Total time (min)
ESA-only visits	1.89	21.5	40.64	0.57	21.5	12.26
ESA + chemotherapy visits	2.91	23.2	67.51	2.59	23.2	60.09
Haemoglobin check-only visits	0.76	16.5	12.54	2.43	16.5	40.10
Total	5.56		120.69	5.59		112.45
Total for ESA-related visits only	4.8		108.15	3.16		72.35

ANCOVA analysis of covariance, *ESA* erythropoiesis-stimulating agent, *q3w* once every 3 weeks, *qw* once weekly

Table 4 Mean staff cost by visit type (adjusted by ANCOVA)

Visit type	qw ESA administration group			q3w ESA administration group		
	Mean no. of visits	Mean cost ($US)	Total cost ($US)	Mean no. of visits	Mean cost ($US)	Total cost ($US)
ESA-only visits	1.89	6.75	12.75	0.57	6.75	3.85
ESA + chemotherapy visits	2.91	7.28	21.18	2.59	7.28	18.82
Haemoglobin check-only visits	0.76	5.57	4.93	2.43	5.57	13.53
Total	5.56		38.16	5.59		31.20
Total for ESA-related visits only	4.80		33.93	5.59		22.67

ANCOVA analysis of covariance, *ESA* erythropoiesis-stimulating agent, *q3w* once every 3 weeks, *qw* once weekly

In the retrospective chart evaluation phase, examination of staff resources and costs associated with administration of supportive care, such as ESA therapy, in relation to chemotherapy represents an important approach to improving the overall quality and efficiency of an outpatient oncology practice. As shown by the results of our current study, patients receiving qw DA required more staff time for ESA + chemotherapy visits and ESA-only visits than those receiving q3w DA, while patients receiving q3w DA required more staff time for haemoglobin check-only visits than those receiving weekly therapy. Overall, mean total staff resource time expended per chemotherapy course was greater for patients receiving qw versus q3w DA. In addition, qw DA dosing was associated with greater mean labour costs for ESA + chemotherapy visits and ESA-only visits than q3w DA. When the patient groups were adjusted using ANCOVA, q3w DA dosing resulted in greater mean labour costs for haemoglobin check-only visits than qw DA administration.

The study presented here is the collection of data from actual clinical practice, utilizing two different methodologies, which served to both validate previously conducted studies as well as enable a real-world, real-time time and motion and economic assessment. The findings reported here provide very detailed data into the actual the cost impact of qw vs. q3w ESA administration using different assessment methodologies and together provided valuable insights into maximizing the cost benefits of ESA use in real-world patient care settings.

5 Conclusion

The findings from this study demonstrate that implementation of a q3w dosing schedule with a long-acting ESA for treatment of anaemia due to concomitantly administered chemotherapy which more closely coincides with many patients' chemotherapy schedules, can minimize ESA-only visits, reducing staff time, staff resources and total labour costs. The methodology used in this study can be implemented in the real-world oncology setting and represents a potential opportunity for increased operational efficiency for oncology practices.

In summary, the introduction of ESAs into clinical oncology practice has been an advance in the management of patients with anaemia undergoing chemotherapy. The results from the study presented here detail how the implementation of a q3w dosing schedule with a long-acting ESA, which often more closely coincides with patients' chemotherapy schedules, may minimize ESA-only visits, reducing staff time and total labour costs in settings that represent real-world practice.

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