Objective: To compare the quality of two pharmaceutical care models (with and without pharmacist participation in the clinical team), in hospitalised onco-haematological patients.

Method: A prospective cohort study in the oncology and haematology departments of a university hospital over a 26-month period. A centralised model (model C) was used over 16 months and a decentralised integration model (model D) was used during the remaining 10 months. The laser® methodology was used to identify candidates for improved drug treatment and for the follow up of patients with drug-related problems (DRP). The results obtained were compared using a series of pharmaceutical care quality indicators.

Results: The rate of patients identified with DRP increased significantly (RR = 2.3; CI 95%: 1.8-2.8), as did the frequency of DRP (RR = 3.4; CI 95%: 2.8-4.0), especially the of PRM preventibles (RR = 3.8; CI 95%: 2.5-4.2). The identification of the type of DRP of indication increased significantly (RR = 4.5; CI 95%: 3.4-5.8), followed by DRP relating to efficacy and safety. The acceptance of pharmaceutical care interventions did not improve proportionally (RR = 1.0; CI 95%: 0.9-1.1), although there was a significant increase in practices with clinical importance (RR = 4.1; CI 95%: 3.3-5.0), that showed an objective or subjective decrease in the risk of drug-related morbidity in patients (RR = 4.1; CI 95%: 3.1-5.4).

Conclusions: Pharmacist participation in the interprofessional team improved the quality of pharmaceutical care, in particular with respect to the increased identification of possibilities to improve drug treatment and clinically significant pharmaceutical practices. As a result, the risk of drug-related morbidity can be reduced in patients.


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Quality assessment of two pharmaceutical care models for onco-haematological patients

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Resumen

Objetivo: Comparar la calidad de dos modelos de atención farmacéutica, con y sin integración del farmacéutico en el equipo clínico, en pacientes onco-hematológicos hospitalizados.

Método: Estudio de cohortes prospectivo en un hospital universitario, en los servicios de oncología y hematoLOGIA, durante 26 meses. El modelo centralizado (modelo C) se aplicó durante 16 meses y el modelo con integración o descentralizado (modelo D) durante los 10 meses restantes. Se utilizó el método laser® para la identificación de pacientes con oportunidades de mejora en su farmacoterapia y para el seguimiento de los pacientes con problemas relacionados con la medicación (PRM). La comparación de los resultados obtenidos se realizó a través de indicadores de calidad de atención farmacéutica.

Resultados: La tasa de pacientes identificados con PRM se incrementó significativamente (RR = 2,3; IC 95%: 1,8-2,8), así como la frecuencia de PRM (RR = 3,4; IC 95%: 2,8-4,0), especialmente la de PRM preventibles (RR = 3,8; IC 95%: 2,5-4,2). La identificación del tipo de PRM de indicación aumentó significativamente (RR = 4,5; IC 95%: 3,4-5,8), seguidos de los de efectividad y los de seguridad. No se mejoró proporcionalmente la aceptación de las actuaciones farmacéuticas (RR = 1,0; IC 95%: 0,9-1,1), aunque se incrementaron significativamente las actuaciones con significación clínica (RR = 4,1; IC 95%: 3,3-5,0), y que permitieron documentar, de forma objetiva o subjetiva, una reducción de riesgo de morbilidad farmacoterapéutica en los pacientes (RR = 4,1; IC 95%: 3,1-5,4).

Conclusiones: La integración del farmacéutico en el equipo interprofesional mejora la calidad de la atención farmacéutica, especialmente a través del aumento de identificación de oportunidades de mejora de la farmacoterapia y de actuaciones farmacéuticas con significación clínica, que permiten documentar la reducción del riesgo de morbilidad farmacoterapéutica en los pacientes.


Summary

Objective: To compare the quality of two pharmaceutical care models (with and without pharmacist participation in the clinical team), in hospitalised onco-haematological patients.

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Conclusions: Pharmacist participation in the interprofessional team improved the quality of pharmaceutical care, in particular with respect to the increased identification of possibilities to improve drug treatment and clinically significant pharmaceutical practices. As a result, the risk of drug-related morbidity can be reduced in patients.


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INTRODUCTION

Various studies\(^2\) have shown that during the drug treatment process, drug-related problems (DRP) can appear, which interfere with the outcome or lengthen the time needed to obtain optimum results from drug treatment. These problems may lead to drug-related morbidity (DRM) in patients with a subsequent detrimental effect on quality of life and increased healthcare costs. DRM has been recognised as a very serious problem, both in terms of its social and human repercussions and the corresponding financial implications\(^3\). It has been estimated that between 2.5 and 30% of hospitalised patients present drug-related problems (a rate of DRM of 1.1-6.0 per 100 hospitalisations)\(^4\). In addition, prescriptions are associated with DRP percentages of over 50%\(^5\), capable of causing adverse drug events which are mostly preventable\(^6\). This, added to the intrinsic characteristics of onco-haematological patients, the complexity of the treatments, the narrow therapeutic margin of the drugs used, the need for individualised posology and the serious possibility of medication errors (ME), strengthens the need to form an interdisciplinary team to improve the safety and quality of the drug treatment received by the patient, despite the fact that few studies have been published on Pharmaceutical Care (PC) for these patients and these studies centre on the prevention and detection of ME in antineoplasial treatment\(^1\).\(^7\)\(^8\).

Putting the PC programmes into practice involves introducing models that present opportunities to improve the quality of drug treatment and patient safety. Traditionally, these models have been based on monitoring the patients centrally in the Pharmacy Department\(^9\)\(^1\) and prioritising patients based on their risk of suffering DRM and efficacy criteria. The added value of this centralised model has been documented by several authors, fundamentally highlighting the clinical benefits to the patient, the prevention of drug-related morbidity and healthcare costs\(^1\)\(^0\)\(^1\)\(^1\).

However, the co-responsibility and participation of the pharmacist in caring for the patient must be incorporated in order to collaborate in the initial design of the drug treatment to be received by the patient, as well as in the follow up. Consequently, this initiative requires a decentralised, personalised PC model to be created, fostering identification, prevention and resolution of DRP before they arise and, especially, those affecting the patient\(^1\).

The comparison of both models requires PC quality indicators to be defined, which quantify the most relevant aspects of the process and their results on the patients. This analysis must allow opportunities for improvements to be identified and for the management of drug treatment in general, since identifying patients with DRP, in accordance with the methodology used\(^1\)\(^2\), requires an analysis of the possible causes of DRP and the failure of the systems involved in these, in order to propose strategies for making improvements.

Consequently, the objective of this study is to compare the quality of the two PC models—a centralised model (C) involving drug treatment monitoring by the pharmacy department using the Integrated Personalised Drug Dispensing System (IPDDS) and a decentralised model (D), with pharmacist participation in the interdisciplinary clinical team, to identify opportunities for improving drug treatment and carry out clinically significant pharmaceutical interventions that reduce the risk of DRM in onco-haematological patients.

METHOD

A prospective cohort study carried out at the general university hospital between January 2003 and February 2005. The period studied with the PC centralised model (model C) had a duration of 16 months, and the PC decentralised model (model D) had a duration of 10 months. The study included adult patients admitted to the oncology department (20 beds) and haematology department (6 beds) during both periods of time. In model D, four resident pharmacists in their fourth years were successively integrated into the clinical teams of these departments, their activity being closely supervised by the hospital pharmacist responsible for providing PC to onco-haematological patients during the period corresponding to model C.

The PC procedure applied to both models is based on Iaser\(^1\) methodology and the activities involved in the phases that define this methodology (identifying the patients, drug treatment actions, drug treatment follow up, assessing individual results, analysing and publicising the results in the population) are shown in figure 1.

The variables recorded are shown in table I. The classification into ME and DRP, the potential seriousness of these, the suitability of the pharmaceutical intervention (PI) and the results on the patient were recorded in accordance with previously defined and validated methodology\(^1\)\(^3\)\(^1\)\(^4\). The comparison of both models was carried out by calculating the indicators described in table II. The pharmaceutical interventions were recorded and documented in the Atefarm\(^1\) v2005.0.0.18 application (IMF S.L. Valencia 2005). The statistical analysis was carried out using the SPSS\(^1\) v12.0 computer programme and Microsoft Excel 2000\(^9\). The median was calculated from the quantitative variables (range) for abnormal distributions and the average (CI 95%) was calculated for normal distributions. The Kolmogorov-Smirnov normality test was used.

The comparison between quantitative variables was made using the Mann-Whitney U test for abnormal distributions and the t-test for the normal distributions. The comparison between two proportions observed was made using the Pearson \(\chi^2\) test. The rates obtained were standardised per 1,000 patients/day. The indicators were compared by calculating the association measures (relative risk or odds ratio), together with the confidence interval of 95% (CI 95%). Values of \(p < 0.05\) were considered as statistically significant.

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A total population of 1,939 patients was studied, corresponding to a total of 18,443 patients/day of follow-up, who were distributed into 81.4% (14,696 patients/day) in the PC model C and 18.6% (3,747 patients/day) in the PC model D. The average age of the population corresponding to model C was 63 years old (16-89) and in model D, 64 years old (15-94). The gender distribution of the population in model C was 60.6% men (CI 95% 58.1-63.0) and 39.3% women (CI 95% 36.9-41.9) and in model D it was 53.1% men (CI 95% 47.7-58.3) and 46.9% women (CI 95% 41.7-52.2). Neither population presented statistically significant differences regarding age or gender distribution.

The total number of DRP in models C and D was 258 and 221, respectively. The results obtained for the indicators defined for models C and D are shown in Table III. The rate of patients in which DRP were identified increased significantly with the decentralisation of the PC, (RR = 2.3 CI 95%: 1.8-2.8), and the rate of identified DRP was even higher (RR = 3.4 CI 95% 2.8-4.0). The study of the origins of the DRP shows that the rate of preventable DRP identified increased significantly (RR = 3.8 CI 95% 2.5-4.2) with the decentralised model. Simi-

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### Results

A total population of 1,939 patients was studied, corresponding to a total of 18,443 patients/day of follow-up, who were distributed into 81.4% (14,696 patients/day) in the PC model C and 18.6% (3,747 patients/day) in the PC model D. The average age of the population corresponding to model C was 63 years old (16-89) and in model D, 64 years old (15-94). The gender distribution of the population in model C was 60.6% men (CI 95% 58.1-63.0) and 39.3% women (CI 95% 36.9-41.9) and in model D it was 53.1% men (CI 95% 47.7-58.3) and 46.9% women (CI 95% 41.7-52.2). Neither population presented statistically significant differences regarding age or gender distribution.

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**Fig. 1. Description of the phases and interventions of the laser® Methodology for Pharmaceutical Care centralised models (C) and decentralised models (D).**

PD: pharmacy department; IU: internation unit; DRP: drug-related problem.

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**Table III.**

<table>
<thead>
<tr>
<th>Phase</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>1&lt;sup&gt;st&lt;/sup&gt;</td>
<td>Drug treatment monitoring:</td>
</tr>
<tr>
<td></td>
<td>- Reviewing the list of drug treatment events (PD)</td>
</tr>
<tr>
<td></td>
<td>- Reviewing the drug treatment history and the patient's analytical data (biochemical and haematology) (PD)</td>
</tr>
<tr>
<td>2&lt;sup&gt;nd&lt;/sup&gt;</td>
<td>Clinical history review (IU):</td>
</tr>
<tr>
<td></td>
<td>- Administrative data</td>
</tr>
<tr>
<td></td>
<td>- Biometric data</td>
</tr>
<tr>
<td></td>
<td>- Clinical situation</td>
</tr>
<tr>
<td></td>
<td>- Drug treatment data</td>
</tr>
<tr>
<td>3&lt;sup&gt;rd&lt;/sup&gt;</td>
<td>Not applicable</td>
</tr>
<tr>
<td>4&lt;sup&gt;th&lt;/sup&gt;</td>
<td>DRP analysis using SOAP methodology for preventing/resolving (PD)</td>
</tr>
<tr>
<td>5&lt;sup&gt;th&lt;/sup&gt;</td>
<td>Introducing and developing the pharmaceutical intervention plan (PD)</td>
</tr>
<tr>
<td>6&lt;sup&gt;th&lt;/sup&gt;</td>
<td>Communicating the drug treatment recommendation verbally or in writing on forms (ad hoc) and/or in the clinical history (IU or PD)</td>
</tr>
<tr>
<td>7&lt;sup&gt;th&lt;/sup&gt;</td>
<td>Registering acceptance of the drug treatment recommendation carried out for preventing and resolving the DRP (IU or PD)</td>
</tr>
<tr>
<td>8&lt;sup&gt;th&lt;/sup&gt;</td>
<td>Monitoring the drug treatment indicators selected with the frequency and duration established based on the patient and their DRP (IU or PD)</td>
</tr>
<tr>
<td>9&lt;sup&gt;th&lt;/sup&gt;</td>
<td>Identifying or preventing new DRP based the patient's evolution</td>
</tr>
<tr>
<td>10&lt;sup&gt;th&lt;/sup&gt;</td>
<td>Recording (IU or PD):</td>
</tr>
<tr>
<td></td>
<td>- Suitability of pharmaceutical intervention</td>
</tr>
<tr>
<td></td>
<td>- Drug treatment and/or clinical results</td>
</tr>
<tr>
<td></td>
<td>- Impact of the pharmaceutical intervention</td>
</tr>
<tr>
<td></td>
<td>- Pharmacoeconomic and humanistic outcomes</td>
</tr>
<tr>
<td>11&lt;sup&gt;th&lt;/sup&gt;</td>
<td>Analysis and interpretation of the individual population results previously taken from the registers (PD)</td>
</tr>
</tbody>
</table>
larly, the average number of DRP increased significantly per patient, to 1.2 (CI 95%: 1.0-1.3) and 1.7 (CI 95%: 1.5-1.9), for models C and D respectively.

The relationship between potential and actual DRP was reversed in a statistically significant way between the two periods (Table III), due to the larger proportion of potential DRP identified in the decentralised model.

The average potential seriousness of the DRP identified in patients was similar in both models (2.20, CI 95%: 2.11-2.29 versus 2.08, CI 95%: 1.00-2.18, for model C and D, respectively), without statistically significant differences.

The rate of MEs intercepted, i.e., those that were resolved before reaching the patient, increased significantly (RR = 2.2 CI 95%: 1.5-3.3), as well as the actual and potential ME ratio, between the two periods (OR = 4.1 CI 95%: 1.9-8.8), supporting proactivity in pharmaceutical interventions.

The percentage of actual preventable DRM identified as a result of possible MEs, quantified by the preventability of the DRM, increased, although with no statistically significant differences (RR = 2.1 CI 95%: 0.7-5.9). In addition, an increase of 20% was seen in the potential/actual DRM rate, although this was not statistically significant.

In the decentralised model, a total of 221 PI with respect to drug treatment optimisation recommendations were recorded, while during the centralised period a total of 251 were recorded. The difference between the average number of PI per patient was statistically significant: 1.2 (CI 95%: 0.8-1.5) in model C and 1.8 (CI 95%: 1.7-1.9) in model D. The percentage of PI acceptance was greater (95.7%, CI 95%: 92.4-98.1) when the pharmacist participated in the clinical team, although there was no statistical significance compared with the centralised model.

The analysis of drug treatment suitability or clinical significance of the PI, showed a significant increase of 75% (RR = 4.1 CI 95%: 3.3-5.0) in the rate of significant or very significant pharmaceutical interventions, i.e. scoring three or above on a scale ranging from one to five*. With regard to the clinical and/or drug treatment results in patients, a significant increase in PI was obtained, meaning a reduction in the risk of subjective or objective documented DRM, with a rate of 6.5 in model C and 26.4 in model D (RR = 4.1 CI 95%: 3.1-5.4).

### Table I. Description of the variables studied to assess the quality of the two pharmaceutical care models

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>Age, sex, number of patients seen, number of patients with ME, number of patients with DRM</td>
</tr>
<tr>
<td>DRP</td>
<td>Classification of ME and stage, classification and category of DRP, severity (scale 1-5), type of medication involved</td>
</tr>
<tr>
<td>DRM</td>
<td>Number and classification of DRM</td>
</tr>
<tr>
<td>Pharmaceutical intervention</td>
<td>Number, classification, acceptance, suitability (scale 1-5), results (scale 1-5) of the patient</td>
</tr>
</tbody>
</table>

ME: medication error; DRP: drug-related problem; DRM: drug-related morbidity.

### Table II. Indicators of the quality of pharmaceutical care

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Formula</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate of patients with DRP</td>
<td>Number of patients with DRP/patients per day x 1,000</td>
</tr>
<tr>
<td>DRP Rate</td>
<td>Number of drug-related problems/patients per day x 1,000</td>
</tr>
<tr>
<td>Preventable DRP rate</td>
<td>Number of DRP originating from ME/patients per day x 1,000</td>
</tr>
<tr>
<td>Potential/actual DRP ratio</td>
<td>Number of potential DRP/number of actual DRP</td>
</tr>
<tr>
<td>Rate of ME intercepted</td>
<td>Number of ME not reaching the patient/patients per day x 1,000</td>
</tr>
<tr>
<td>Potential/actual ME ratio</td>
<td>Number of potential ME/number of actual ME</td>
</tr>
<tr>
<td>Potential/actual DRM ratio</td>
<td>Number of DRP with potential DRM/number of DRP with actual DRM</td>
</tr>
<tr>
<td>Percentage of preventability of actual DRM</td>
<td>Number of DRP with actual DRM and origin of ME/total number of DRP with actual DRM x 100</td>
</tr>
<tr>
<td>Percentage of acceptance of PI</td>
<td>Number of PI accepted/patients per day x 100</td>
</tr>
<tr>
<td>Rate of clinically significant PI*</td>
<td>Number of DRP with suitability for the PI ≥ 3/patients per day x 1,000</td>
</tr>
<tr>
<td>Rate of PI with document risk reductions of DRM* with objective and/or subjective data</td>
<td>Number of DRP with suitability for the PI ≥ 3/patients per day x 1,000</td>
</tr>
</tbody>
</table>

DRP: drug-related problems; ME: medication errors; DRM: drug-related morbidity; PI: pharmaceutical interventions. *: value equal to or above 3 on the suitability scale 1-5 defined; **: values 4 and 5 on the scale of results in patients 1-5 defined.
The profile of the DRP identified by category is described in Table IV. The decentralised model led to a greater number of DRP being identified in the three major categories. However, the degree of identification of the DRP relating to indication increased proportionally (RR = 4.5 CI 95%: 3.4-5.8), after DRP related to efficacy (RR = 2.7 CI 95%: 1.8-3.9) and, finally, to safety (RR = 2.4 CI 95%: 1.8-3.2).

The number of different medications involved in the DRP identified was greater in the traditional centralised model (79 vs. 69). Its standardisation per 1,000 patients/day, according to classification by treatment group and PC model gave the results shown in Table V. The three main groups implied in the DRP in both models were, in this order, systemic anti-infectious agents (group J), alimentary tract and metabolism (group A), blood and haematopoietic organs (group B). However, the three groups with the greatest increases in the rate of identified DRP were group V (miscellaneous), C (cardiovascular system) and M (musculoskeletal system).

**DISCUSSION**

Various authors, in different care environments, have shown that the risks involved in handling drugs can lead to DRM in patients and that decentralising the processes in PC can improve the pharmacist’s contribution to significantly reducing these adverse drug events and preventing ME compared to centralised PC in the pharmacy department.

This study analyses and assesses pharmacist participation in improving the quality of drug treatment and the safety of onco-haematological patients, structured by the ability to be proactive, by preventing and resolving the DRP and ME that these patients can present. To this end, indicators have been selected to assess the quality of the two PC models (centralised and decentralised), and the results obtained during the two periods have been compared. However, comparison with other studies is difficult mainly due to the heterogeneous nature of the methods used to measure the procedures and results of PC. In this respect, we consider that the proposed indicators could contribute to standardising measurement of care practices and facilitate future comparisons between centres and different services.

During the period that the pharmacist was integrated into the team, a greater ability to identify opportunities for improving the drug treatment was observed, with a significant increase in the overall rate of DRP and, to a greater degree, the rate of preventable DRP identified. This was due not only to the increased number of patients with DRP but also to the fact that significantly more DRP were identified per patient. These results suggest that the DRP omitted in a centralised model become visible. In addition, the decentralised model doubled the rate of ME intercepted before reaching the patient. The indicator showing the greatest variation between the two models is the potential and actual ME ratio, since during the centralised period eight situations were identified as having potential to produce an ME per 100 actual MEs, and in the decentralised period 34 potential MEs were identified for every 100 actual MEs. Thus, the physical presence of the pharmacist in the hospitalisation unit quadrupled the ability to identify situations which could potentially cause an ME. The reversal of the potential/actual DRP ratio confirms the greater proactivity of PI carried out in model D, as action is taken prior to the appearance of DRM in patients.

One significant finding was the modification in the profile of identified DRP. Basically, the identification of DRP related to indication is improved and, to a lesser degree, the efficacy and safety of the treatments (Table IV), whilst, traditional PC programmes tend to prioritise safety. Some authors have obtained similar results, with respect to the higher rate of identifying DRP relating to drug indications by integrating the pharmacist into the clinical teams. Incorporating new sources of identification of DRP (reviewing the clinical history and interviewing the patient or the healthcare personnel), are suggested as explanatory causes, in part, of the results obtained.

The classification of medications involved in the DRP shows a greater increase in three groups which are not usually majority groups (Table V). This appears to suggest an integral understanding of the patients’ drug treatment needs and problems in the decentralised PC model. In addition, the low involvement of the group of antineoplastic drugs is due to the fact that most of these treatments are administered in the out-patient unit of the hospital.

Acceptance of pharmaceutical recommendations as an indicator of the credibility of the figure of the pharmacist coincides with the results obtained by other authors with similar models. However, the fact that no statistically significant differences have been detected between the two models may be explained by the fact that since the year 2000, the centralised PC model has been introduced and consolidated, with a higher level of PC acceptance (approximately 90-94% %).

In addition, in the D model there is a significant increase in the PI rate assessed with clinically significant
potential, in accordance with the methodology used and, in a parallel manner, there is an increase in the rate of PI, recording results with both subjective and/or objective data in the patient. This may be due to a greater knowledge of patients and their clinical evolution by the pharmacist when he or she is included in the team, continuously participating in the patients' follow-ups.

Finally, in the decentralised model, a greater percentage of actual, preventable DRM has been observed, obtaining that this is twice that found in the centralised model, although the variability in estimating the indicator is high, due to the few cases of patients with actual DRP and DRM identified in both models. However, this indicator allows us to pinpoint opportunities to improve the PC model and set future objectives for reducing this indicator.

The main limitation presented by this study is the difficulty involved in establishing if the differences seen are due to the different PC models, since the influence of possible factors such as the number of drugs prescribed, the diagnosis and length of hospital stay, or the individual pharmacist who participated in each of the models studied, have not been analysed. In addition, it is also difficult to establish the actual contribution of PI to drug treatment and/or clinical results in the patient, as no randomised clinical study has been carried out due to ethical problems and difficulties arising in clinical practice. Ideally, the impact or added value of the PC should be measured in terms of the actual results in patients. This would be highly valid but with practical limitations, particularly if the ME and/or DRP are intercepted before they reach the patient, as is most frequent and desirable case, since in these cases evaluating the results is not so reliable. In this respect, the availability of a scale outlining severity, based on the potential consequences or DRM of the patient would have the advantage of not requiring any actual results, but would also have the disadvantage of being more subjective, reducing its validity and, in particular, possibly giving rise to a low rate of agreement between different assessors. This aspect that has not been covered in this study, as the methodology applied has been valued at an earlier stage.

To conclude, integrating the pharmacist into the clinical team improves the quality of pharmaceutical care provided to onco-haematological patients, as it offers a better opportunity to identify DRP in patients, especially preventable DRP and those related to the indication of the drug treatment, as well as intercepting ME before they cause DRP for patients. In addition, the rate of clinically significant pharmaceutical interventions increased, as did the pharmacists' ability to document reductions in the risk of DRM relative to his or her participation in the care of onco-haematological patients.

References

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