Multivariate regression analysis was performed to evaluate the impact of the establishment of the Japanese regulatory agency Pharmaceuticals and Medical Devices Agency (PMDA) in 2004 with respect to the contents of guidance for proper usage.
Results: From 91 approved oncology pharmaceuticals, we obtained 59 guidance for proper usage for 50 approved oncology pharmaceuticals. The median total number of pages in the guidance for proper usage was 48 (range, 11−98 pages). The proportions of pages in the guidance that discussed toxicity, drug information, and the results of registration trials were 30%, 26%, and 11%, respectively. After the PMDA was established, the total number of pages and the proportion of pages discussing the results of registration trials significantly increased ($p = 0.007$ and $p = 0.002$, respectively). On analyzing guidance published for different types of drugs, we observed that the total number of pages and the proportion of pages discussing toxicity in the case of molecular-targeted drugs was significantly greater ($p < 0.001$ and $p = 0.008$, respectively) than that for the other types of drugs, whereas the proportion of pages discussing indications was significantly lower ($p = 0.001$) than that for the other types.
Conclusion: The guidance for proper usage distributed to medical oncologists in Japan include drug information that is not provided in package inserts. The establishment of the PMDA and the type of drugs for which the guidance for proper usage were distributed may have influenced the contents of and trends with regard to the guidance for proper usage.

1316 POSTER

Oral Chemotherapy Administration Practices in Ireland

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Background: The use of oral chemotherapy (OC) and biologic therapy (BT) is increasing due to ease of administration compared with intravenous therapy, pressure on hospital resources and expanding indications for use. In Ireland, OC is prescribed by medical oncologists and dispensed by community pharmacies. The objective of this study was to assess procedures for OC and BT prescription, as well as patient monitoring and patient education practices for these agents in Ireland.
Materials and Methods: A cross-sectional survey was administered to all medical oncology specialist registrars and consultants in Ireland to assess OC and BT prescribing practices and efforts made to educate and monitor patients receiving these agents.
Results: Forty-one physicians were surveyed. Responses were received from physicians representing 7 of the 8 Irish cancer centres. Factors positively influencing prescription of OC or BT included ease of administration (76%) and patient travel considerations (71%). All respondents believed that BT should be prescribed only by medical oncologists and that it should be prescribed and supplied using the same procedures as OC. Baseline laboratory investigations were required by all centres prior to prescription of OC or BT. The majority of centres used hand-written prescriptions, included body surface area calculation on prescriptions and a record of the prescription in the patient's chart. Only one centre required that a second clinician check was performed.
All physicians reported questioning patients about compliance, while 24% of physicians reviewed patient diaries and 6% carried out a pill count. Errors related to OC use were reported most frequently at prescription (14%) and monitoring stages (14%).
Physicians listed company-based nurses and hospital-based specialist nurses as the most important resource for patients. Information about potential interactions and hospital-based specialist nurses were listed as the most important resources for doctors. Two centres held OC clinics, with all respondents believing these improved practice. Consultation with an oncology pharmacist was offered in one centre. Communication with community pharmacies was rated as fair by 65% and poor by 24% respondents.
Conclusions: Despite increasing use of OC, prescription and monitoring is not standardised within Ireland. The availability of specialist nurses and OC clinics were suggested as potential interventions to reduce errors and improve patient education. Improved communication with pharmacies is required. This study gives an insight into oral chemotherapy and biologic therapy prescribing and monitoring in Ireland.

1317 POSTER

Is It Possible to Contaminate Monoclonal Antibodies by Cytotoxic Drugs in Centralized Preparation Units? − a Consensus Conference From the French Society of Oncology Pharmacy

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Background: Pharmacy-centralized handling of anticancer drugs is mandatory in many countries, especially in the EU. The use of monoclonal antibodies (mAbs) in oncology is growing, mainly associated with cytotoxic drugs. Despite mAbs are not considered as hazardeous, they are anticancer drugs and often handled in the same isolators or laminar-flow hoods (LAF) as cytotoxic drugs. Nevertheless, there are no generally accepted guidelines and some national health authorities consider that mAbs should be handled in separate safety cabinets to avoid cross-contamination with cytotoxic drugs. However, this position is not scientifically based and should induce high additional costs and logistic problems for hospitals.
Method: French Society of Oncology Pharmacy (SFPO) performed a consensus conference to analyze available data and to propose guidelines. Handled drugs were classified in 4 groups: group I: cytotoxics (as listed by international safety agencies); group II: mAbs used for cancer patients also receiving cytotoxics; group III: mAbs in monotherapy used in patients for cancer or another diseases (i.e. auto-immune disorders) and group IV: others.
Results: According to the current practices, the group considered that low-level external contaminations cannot be excluded for gloves, drug containers and preparation area. Since environmental risks induced by mAbs were considered as low, the safety concern is mainly due to external cross-contamination of mAbs-containing bags by cytotoxics. No published data is available on internal cross-contamination during simultaneous preparation of drugs in the same flow LAF or isolator. Moreover, a recent experimental study from a Swiss group showed that no internal contamination occurred even if external contamination of working area and containers was present. However, the consequences of an accidental contamination of mAbs by a cytotoxic such as the use of the same needle to withdrawn both products, remain questionable and experimental works should be initiated to clarify this point. Although the risk appears of very low, a possible consequence could be the induction of mAb aggregation, leading to immunological side-effects.
Conclusion: SFPO considers there is no objective risk of internal cross contamination during simultaneous handling of different drugs in centralized units if accepted procedures for sterile preparations are respected. Therefore, there is no reason to prepare cytotoxic drugs and mAbs in separate safety equipments.

1318 POSTER

Physicochemical Stability of Diluted Azacytidine Suspensions Stored at 4ºC and −20ºC: Preliminary Results

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Background: The recommended regimen of azacytidine (AZC) in hematological diseases is a 7-days subcutaneous administration of 25 mg/ml extemporaneously prepared suspensions, noticed by the manufacturer as stable for 8 hours at 4ºC. Thus, syringes cannot be prepared in advance by hospital pharmacies, inducing non-availability during non-working days and violation of the regimen. We studied the physicochemical stability of AZC suspensions reconstituted by iced or 25ºC water and after freezing.
Materials and Methods: To test the role of iced water on the degradation kinetics, vials of lyophilizate were reconstituted with water at 4º or 25ºC (25 mg/ml). Under stirring, 100 µl samples were taken, immediately diluted at 20 ml by iced water and aliquots were analyzed by HPLC using the method of Argeni *et al*. The degradation kinetics was followed during