medical adverse events by the side effects, overdoses and extravasation of anticancer drugs.

**Aims and Methods:** Our method of outpatient cancer chemotherapy is presented as follows.

1. We must entry every kind of cancer chemotherapy regimen. Every regimen is under dept. of pharmacy control.
2. We make an application to dept. of pharmacy about patient's name and regimens with another doctor's reconfirmation of species, dosages and processes.
3. Then special doctors, pharmacists, nurses have a proper understanding of detailed treatment for cancer patients.
4. Every regimen is performed according to clinical pathway.
5. Further information of side effects of cancer drugs for the patients is provided by special pharmacists.
6. Patients are carefully observed during the administration of cancer drugs by the well trained full-time nurses and pharmacists.
7. Outpatient's private room for chemotherapies is in full-time nurse's attendance. The room is furnished with TV, CD-player and refrigerator. They have a good quality of life.
8. Cancer drugs were injected only by special doctors.

**Results:** To my great relief, since our safety management committee adopted this method of outpatient cancer chemotherapy, medical adverse events decreased remarkably (Table 1) and then patients have been comfortable and safe without even trifling incidents. This outpatient chemotherapy fee with full-time pharmacists and nurses is 30 dollars a day.

Table 1: Adverse events in outpatient cancer chemotherapy

| | 2001 | 2002 | 2003 | 2004 |
|---|---|---|---|---|
| Total Patients | 782 | 845 | 921 | 949 |
| Grade 1 | 44 | 52 | 31 | 22 |
| Grade 2–3 | 18 | 13 | 7 | 4 |
| Grade 4 | 2 | 1 | 0 | 0 |
| Grade 5 | 0 | 0 | 0 | 0 |

Grade of adverse events: 1. need observation; 2. need minor treatment; 3. need major treatment; 4. serious aftereffects; 5. death

**Conclusion:** Consequently this method brought a great profit to our cancer patients and hospital.

**1349** PUBLICATION

**APSI Project: research and development of a Robot Assistant for the Preparation of Injectable Solutions (APSI): application to chemotherapy in the clinical setting**

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Injectable chemotherapeutic agents are often required in cancer treatment: an arsenal of high added value medications with intrinsic toxicity to which patients as well as operators handling these drugs are exposed. Conventional preparation systems (clean air hoods or isolators) are however fallible. At the end of serious thought which began in 1998, we considered that personnel and environmental exposures were no longer tolerable. Finally, the APSI Research and Development (R&D) programme: a Robot Assistant for the Preparation of Injectable Solutions, was born in February 2001. Our objectives were not only to respond to the needs of the Institut Gustave Roussy (IGR), one of the leading research and anticancer centres.

Applying robotics to the preparation process was a venture aimed at creating a solid and flexible machine able:

1. Eliminate risks of toxicity by preserving operators and the environment
2. Manage the toxic waste more efficiently
3. Eliminate human-related errors
4. Optimise production costs
5. Guaranteeing the tracability of TOs (Therapeutic Objects) e.g. bags, syringes
6. Enhance the quality of the process
7. Increase the production rate
8. Comply with regulatory requirements.

In 2004, prescription processing in the Department of Clinical Pharmacy (DCP) gave rise to ~35,000 TOs. In 2007, the DCP will generate ~65,000 TOs per year. The APSI program is funded by a co-development exclusivity contract between IGR via its DCP and BioTOM S.A., a High-Tech industrial partner. The Project Group (pharmacists, engineers, technicians) operates in a concurrent engineering context according to 12 items:

1. modelling
2. rapid prototyping, direct production, virtual validation
3. mechanical confinement, aeraulic
4. electronics
5. electromechanics, robotics
6. ergonomics, design
7. peri-robotics logistics
8. Man-Machine Interface development
9. development of a supervisor at the interface with APSI and computerised patient prescriptions
10. study of burden, simulation and management of drug preparation
11. process performance analysis, operation qualification
12. cost evaluation and business plan. After 30 months, the prototype is in the operational qualification phase.

We are launching the production of the first of 3 machines designed to equip the future DCP production unit (January 2006). We feel that we have overcome practically all the technical stumbling blocks: the milestone schedule has been followed. APSI is a "technological breakthrough" and the result of a model hospital-industry partnership with an R&D budget totalling 1.2 M.

**1350** PUBLICATION

**Indications for treatment by electrochemotherapy; results of the ESOPE European trials**

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**Background:** Electrochemotherapy is a therapeutic approach providing delivery of nonpermeant cytotoxic drugs like bleomycin or cisplatin into the cells by electroporation of tumors.

**Materials and methods:** A European consortium (ESOPE: European Standard Operating Procedures of Electrochemotherapy) was set up to test a new clinical electroporator (Cliniporator, IGEA, Italy) and establish common European guidelines for treatment of cancer patients using electrochemotherapy. At the 5 centers, protocols for treatment were approved by the respective regional ethical committees. Cancer patients with tumors of all histologies were permitted, with cutaneous nodules in skin or subcutis. Patients had progressive and metastatic disease, and the patients were all offered standard care.

**Results and Conclusions:** Physico-chemical basis of this therapy allows prediction that electrochemotherapy has good antitumor effect on all tumor types, which was demonstrated in several clinical studies. Antitumor effectiveness of electrochemotherapy either with bleomycin or cisplatin in patients with recurrent cutaneous and subcutaneous tumors was shown to be in the range of 70–80% local tumor control rate. This enlists electrochemotherapy in line with other local treatments like radiation therapy and surgery with equally or even higher effectiveness.

The clinical experience gained so far in the ESOPE project provided evidence that electrochemotherapy is successful treatment in various clinical indications:

- Easy and effective treatment of single or multiple tumor nodules of any histology in the cutaneous and subcutaneous tissue.
- Treatment that increases quality of life in patients with progressive disease.
- Treatment of choice for tumors refractory to conventional treatments.
- Neoadjuvant treatment in form of cytoreductive therapy before conventional treatment.
- Organ sparing and function saving treatment.
- Treatment of hemorrhagic or painful nodules, since it reduces bleeding and in some cases pain level.

All these indications provide electrochemotherapy broad spectrum of use, predominantly because electrochemotherapy is effective local therapy and additionally quick and easy to perform.

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