Compilation of lex Maria- and HSAN-cases, parenteral cytotoxic drugs, 1996-2008, Swedish cases.

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METHOD AND MATERIAL

Cases reported to the national error reporting systems have been used for a retrospective qualitative analysis. The inclusion criteria for this study are: A medication error reported according to the lex Maria Act or to the Medical Responsibility Board (HSAN) between 1996 and 2008 involving a cytotoxic drug (ATC classification L01) and administered parenterally at a hospital. Problems with blood tests or other necessary tests during the treatment period are included if they result in the wrong treatment. Misdiagnoses, subcutaneous drug extravasation of the infusion, or problems with peripheral or central venous line during administration are excluded.

An ME leading to reports according to both lex Maria and HSAN, or reported according to lex Maria from both a healthcare professional and the patient, were filed as one error. An ME starting with the prescription and prepared at the pharmacy, or starting at the pharmacy and administered on the unit were also counted as one ME, even if they were reported separately according to lex Maria.

The material consists of ME reports obtained in the following ways:

- Reports retrieved from the national risk database from 1996 to mid 2006. A total of 101 reports were found; of these 44 met the inclusion criteria. Most of the reports excluded involved oral cytotoxic drugs.
- Reports retrieved from the NBHW database as the result of a search for reports involving the word “cytostatika” for 2006-2008. A total of 12 reports were found; of these eight met the inclusion criteria.
- Eight reports were found using other sources: in a report retrieved from the national risk database (1), a colleague informed from another hospital pharmacy (4), the incident occurred at the university hospital where one of the authors worked (3).

A total of 60 MEs meeting the inclusion criteria were found. The case reports were read and this table was compiled. From this tables were later compiled based on:

- Cytotoxic drugs involved.
- Type of error: dose too high, too low or wrong dose, wrong drug, wrong patient, wrong ambulatory pump, other.
- Where the error occurred in the medication use process (i.e. in prescribing and transcribing, preparation or administration).
- The error detection mechanisms (i.e. how and by whom the error was discovered).
- The consequences for the patient according to the NCC MERP Index for Categorising Medication Errors[19] of the National Coordinating Council for Medication Error Reporting and Prevention, USA. This index was used for classification of the severity of the outcome: Category B-D *Error, No harm*; Category E-H *Error, Harm*, and Category I *Error, Death* (i.e. an error occurred that may have contributed to or resulted in the patient’s death). Category A is *No Error* and thus was not included.

	Report No	Drug	Where	What happened/*Discovered*/Consequences	Contributory causes
1	Lex Maria 1996	Melphalan and carboplatin	University Hospital	Too high doses were prescribed, 4 times for melphalan and 3 times for carboplatin. Treatment before stem cell transplantation. *The condition for the patient detoriated.* She died on the 7th day in the picture of "capillary leak syndrome".	Treatment protocol was misinterpreted; total doses became doses per day. An MTO-analysis was performed. Main causes: No rule for countersignature for high-dose treatments, no treatment protocol for the treatment, ambiguity in the protocol. Contributory causes: defective cooperation with pediatric oncologist and deficient routines for documentation.
2	Lex Maria 1996	Fluorouracil	Pharmacy	Pump run at high a speed was used during preparation, Baxter LV pump with flow 5 mL/h instead of 2 mL/h. *The drug was delivered during 2 days instead of 5.* The patient showed no adverse reaction.	The pharmacists were not aware of the difference between the LV2 and LV5 pumps. They misinterpreted the marking of the pumps without reflection. There is a direct need for education. Staffing levels need to be addressed.
3	Lex Maria 1996	Vincristine	University hospital	Too high dose was prescribed, dose 1.4 instead of 0.4 mg/sqm per day for 4 days in row. Patient treated with EPOCH-regime. *After 1 week adverse reaction from drug*. The patient was hospitalised with intestinal paralyses and neuropathy.	Treatment scheme was wrong. The doses not controlled during proofreading. A reasonable assessment of dose was not done. The level of the dosage is used in other lymphoma treatments and therefore difficult to discover as wrong. Not clear to everyone how to use the scheme for treatment. Unclear corrections were done. Patient documentation insufficient.
4	Lex Maria 1996	Cisplatin	County hospital	Double dose prepared and administered by nurse. Treatment with cisplatin day 1 and ifosfamide day 1 to 3. By mistake cisplatin was given also on day 2. *Nurse discovered the mistake when the treatment was finished, and informed the doctor*. Patient suffered from hearing-loss, and renal damage.	Doctors' prescription was correct. Error when it was transcribed to a cytotoxic treatment card by a nurse. Transcription not done according to the routine. The dose should have been controlled during preparation against booth documents. Very hard work-load, preparing nurse disturbed during preparation.
5	Lex Maria 1996	Cytarabine should have been ifosfamide	Pharmacy	Wrong drug used during preparation, 800 mg ifosfamide and 800 mg cytarabine were used. Prescription was ifosfamide 1600 mg in 500 mL saline. *The pharmacist discovered and infusion was interrupted, 25 % was given*. No harm.	Control during preparation did not function as intended. The quality of the doctors' prescription was poor. Routines for documentation must be improved.
6	Lex Maria 1996	Cisplatin should have been cyclophosphamide	University hospital	Patient received another patient's drug, 30 mg of cisplatin instead of cyclophosphamide. *Nurse discovered during further preparation and informed the doctor.* The patient had to stay in hospital for 1 night. The treatment was delayed for 1 week. No permanent harm.	Patient's id not checked. Inadequate organisation of doctors, patient's responsible doctor was not available. Vacation period had begun, and the ward was to be closed the same day. A stressful day with high work-load. Unsatisfying working conditions with preparation unit on other floor.

7	Lex Maria 1996	Doxorubicin	University hospital	Doctor administered a dose that was 2.5 times higher than prescribed. Intra-arterial infusion with doxorubicin 50 mg instead of 20 mg at x-ray department. The preparation was done at another department by a nurse. *Patient felt pain.* No permanent harm.	The doctor gave the infusion without controlling the prescribed dose. A doctor from x-ray department and one from oncology used to do the treatment together. The oncologist did not show up. Deficient organisation built on oral agreement and mutual trust. Routines lacking, a responsibility of the directors.
8	Lex Maria 1997	Cytarabine	Pharmacy	Dose was 2.5 times higher than intended. Wrong strength used during preparation, 50 instead of 20 mg/mL. *Discovered by a pharmacist before start of treatment day 2.* Doses for following days reduced.	Two strengths available. No double-check, see # 12.
9	Lex Maria 1997	Fluorouracil	Pharmacy	Pump with too high speed used, pump delivered during 12 instead of 24 hours. *Nurse discovered and the dose could be adjusted.* Probably no influence on treatment result.	Infusor pump delivering during 12 hours was commonly used, the other one seldom. See # 12.
10	Lex Maria 1997	Etoposide	Pharmacy	Label stated that the drug was ifosfamide, preparation was correct with etoposide. The preparation was relabelled, should have been remade. *Mother discovered and was worried. Not given.*	See # 12.
11	Lex Maria 1997	Doxorubicin and vincristine	Pharmacy	Double dose prepared, a reduced dose (50 %) of the normal dose was prescribed but the normal doses were prepared. *Nurse discovered and it was NOT given.*	Unclear requisition, pharmacist unable to get in contact with the ward. See # 12.
12	Lex Maria 1997	Fluorouracil should have been methotrexate	Pharmacy	Preparation with wrong drug, methotrexate 70 mg became fluorouracil. *Nurse discovered due to the colourless solution (methotrexate yellow) and it was NOT given.*	No double-check. Most extensive preparation of cytotoxic drugs in Sweden. Shortcomings in routines, work environment, and organisation have led to unnecessary risks, and individual pharmacists have to take unreasonable responsibilities. Lack of barriers is most obvious during high work-load. Liability ratio unclear and should be clarified. Disturbance from phone and visitors, space shortages. The workload should be more balanced throughout the day.
13	Lex Maria 1997 HSAN 1996	Cisplatin	County hospital	Nearly double the intended dose was prescribed, 70 mg instead of 40 mg per day for five days. The dose prescribed at the University hospital was misinterpreted as dose per square meter, not as intended as the total dose. *The patient had serious adverse reactions and was hospitalised day after treatment.* He died after ten days due to bleedings and infection. There is no immediate casual nexus between the high dose of cisplatin and the death.	The doctor at the county hospital had not access to the protocol. Collaboration between the hospitals must be more explicit. This type of mistake happens. The patient's adverse reactions were noticed but not followed up on. Responsible doctor had a pressed working situation. The dosage could not generally be regarded as unreasonably high.

14	Lex Maria 1997 HSAN 1998	Dactinomycin	Pharmacy	Preparation of a dose that was four times higher, correct dose 0.07 mg. Error in calculation before preparation. *Nurse discovered and it was NOT given.*	Sick-leave leading to double-check by inexperienced staff, failing routine. Requisition arrived late. Miscalculation.
15	Lex Maria 1997	Daunorubicin	County hospital	Nearly twice the intended dose was prescribed, 165 mg, Dose should have been 45 mg/square meter, maintenance treatment to be given at the county hospital. *Discovered at the University hospital.* Treatment had to be adjusted. No serious harm.	The patient's record had disappeared, only treatment protocol available. The University hospital should have been contacted. Dosing by mg/square meter was unfamiliar to the doctor. Used drug information in FASS for calculation. The doctor had not met the patient before, Friday afternoon, and the doctor was stressed. Summer vacations. Routines for treatment of patients with chemotherapy were missing.
16	Lex Maria 1997	Doxorubicin	Pharmacy	Pump run at too high a speed used during preparation; Homepump delivered drug during 1 instead of 48 hours. *Discovered by patient/nurse when the infusion was so quick.* Extra treatment prescribed. Probably no harm.	Prescription clear but model of Homepump not given. There are nine different volume/speed combinations. They are very similar in appearance – double-check by pharmacist or nurse before administration did not discover the mistake. Preparing pharmacist says she is inexperienced. Routines insufficient.
17	Lex Maria 1998 HSAN 1999	Carboplatin should have been ifosfamide	University hospital	Patient received another patient's drug. One nurse prepared the infusions and another nurse fetched it and administered wrong infusion to the patient. *Nurse discovered her mistake, the infusion was stopped, and right drug was given.* No harm.	Nurse did not check right drug, right dose to right patient. Nurses used to prepare infusions for each other – bad routine. High work-load, stress, increases in amount of infusions with 33 % last year.
18	Lex Maria 1998 HSAN 1998	Vincristine	University hospital	Dose that was 10 times higher than prescribed. A dose of 2.0 mg became 20 mg when prepared by a nurse. *Discovered the same afternoon during nursing rounds: her colleagues reacted.* Serious neurological harm; treated in respirator for a period. The patient died after 7 months.	Inexplicit written prescription led to the mistake. Junior doctor wrote it and a consultant signed it. Nurse inexperienced in oncology, did not know that max dose is 2 mg. The use of 10 ampoules (1 mg/ml, 2 ml amp) during preparation is not unusual. Deficient treatment card and routines for prescription.
19	Lex Maria 1998 HSAN 2000	Cisplatin	Pharmacy	Double dose prepared. Prescription "Cisplatin 0.5 mg, 190 mg, 380 mL to be diluted in 2x1000 mL NaCl 9 mg/mL" was interpreted as a dose of 380 mg. *The first pharmacist pondered the dose in the evening, contacted the hospital and the error was discovered.* Patient got total permanent hearing loss.	Three pharmacists involved. Normally the strength 1 mg/ml was used. The prescription should have been controlled. Work-load very high, stress. The pharmacy had vacations, diseases, poor staffing. Computers not functioning.
20	HSAN 1998	Fluorouracil	University, county hospital + Pharmacy	Half dose given during second course and double dose during fourth course. Patient had a*dverse reactions and was hospitalised.* Complications with infections probably due to the high dose the patient received. The	Clinical trial where the strength 25 mg/mL should have been used instead of the normal 50 mg/mL, which was used. Prescription not correct but used by pharmacy. The doubled dose given was known before next dose was

				patient died by this and her cancer.	prescribed but no correction in dose was done. Follow-up from doctor poor. Patient's bad condition coincided with a weekend when her doctor was on vacation.
21	Lex Maria 1999	Doxorubicin and cyclophosphamide	County hospital	Double dose prescribed. Cyclophosphamide 1200 mg and doxorubicin 40 mg was prescribed for two days, should have been only for one day. *Discovered at the University hospital.* Affected general condition, sepsis, intensive care. No remaining harm.	New year and the patient refused transport to University hospital. Phone prescription, routines for communication between hospitals poor. Doctor at the county hospital read in the records that earlier treatment with the drugs had been for two days and assumed the same for this course.
22	Lex Maria 1999	Methotrexate	County hospital	High-dose treatment with poor diuresis *leading to very high blood level of methotrexate.* Transport to University hospital, no harm.	Child of xx years. Major reorganisation leading to loss of competent nurses and doctors. Many in the staff involved in treatment, unclear reporting between shifts. Every shift focused on their period and did not see the whole picture. Junior doctor inexperienced and with high work-load. Organisational considerations.
23	Lex Maria 1999 HSAN 1999	Vincristine should have been cytarabine	University hospital	Patient received another patient's drug. Preparations collected from pharmacy to two different patients. A nurse gave vincristine subcutaneously, should have been cytarabine. *Discovered by nurse when patient no 2 arrived.* Patient hospitalised for two days. No serious harm.	Patient id., right drug and dose not controlled. High work-load, staffing low. Beds placed in the corridor. The nurse was responsible for four patients at the same time.
24	Lex Maria 1999	Melphalan	University hospital	Melphalane should be used immediately but was given 3 hours after preparation, which was done by a nurse. *Patient did not respond to the treatment as expected.* Relationship was not certain.	Nurse and her checking colleague new at the ward, worked for 6 months. Information about the preparations shelf-life on the backside. First time she prepared this drug. Another patient acutely ill, needed surveillance.
25	Lex Maria 1999	Fluorouracil	County hospital	Prescription of 2.5 times the intended dose. Fluorouracil 1000 mg, 50 mg/mL, volume 50 ml. Nurse prepared and gave according to the prescription (2500 mg). Should have been 20 mL. *Nurse discovered next day.* Corrective actions taken, no harm.	Prescription came from another hospital, and was normally checked by a consultant but this time she was on vacation. Miscalculation by doctor, nurse is not to blame.
26	Lex Maria 1999	Onco Tice should have been mutamycin	County hospital	Nurse prepared wrong drug and installed it in the urinary bladder. *Nurse realised the mistake after 5 minutes and made corrective action.* No harm.	Patient had forgotten his drugs at home. Nurse found the drug at department shelf and prepared it. Very high work-load, phones were constantly ringing, computers not functioning. A day care that was growing, lots of routines to be written.
27	Lex Maria 2000	Doxorubicin should have been cyclophosphamide	Pharmacy	Preparation marked with wrong label, doxorubicin. The content was cyclophosphamide.	The doctor's name on the label was wrong. A new label was written but it contained wrong drug name. Mix-up label/preparation. Double-check did not notice the mistake. Routine for this situation was missing, other

					routines not followed.
	Lex Maria 1999	Doxorubicin should have been cyclophosphamide	University hospital	See above #27. Prepared at pharmacy, marked with wrong label. *Nurse reacted on the mismatch of the marking and the colourless solution. It should have been red (doxorubicin).* NOT given.	
28	Lex Maria 2000	Doxorubicin should have been epirubicin	Pharmacy	Preparation with epirubicin contained also doxorubicin. *Pharmacist discovered during next preparation.* Patient received more than half of the dose before it was interrupted and corrected.	A new bottle was fetched from the refrigerator. Drugs similar in colour and strength. Double-check noticed a different batch number but did not react. Control of the part number has been introduced.
29	Lex Maria 2000	Cladribine should have been cyclophosphamide	University hospital	Patient received another patient's drug. *The patient discovered the mistake nearly immediately and the infusion was stopped.*	Many treatments this Saturday. Both patients had had treatments before. The nurse did not check patients' id.
30	Lex Maria 2000	Cytarabine	Pharmacy	A ten-fold error in calculation from mg to mL, 26 mg became 260 mg during preparation. Wrong dose was given three times during a weekend. *Another pharmacist discovered the error on Monday morning.* On-going treatment adjusted.	July a Friday afternoon. Three pharmacists involved. Such low doses are rare. Different prescriptions for adults and children. Computer program not user-friendly and gave no support with calculations. One pharmacist not fully trained. An increase in the amount of preparations during last years, preparation room crowded.
31	HSAN 2000	Carboplatin	County hospital	Prescription for three days should have been only for one day. Patient earlier treated with cisplatin three consecutive days, now impaired renal function and there is a change to carboplatin. *Patient had a serious infection after 10 days.* The mistake did not affect the development of the tumour disease.	Change of treatment after discussion between treating junior doctor and a consultant. Bad communication between the doctors. Prescribing doctor was not aware of how to prescribe carboplatin.
32	Lex Maria 2001	Ifosfamide	University hospital	Treatment started too early, before blood counts were known, with ifosfamide, carboplatin and etoposide (only ifosfamide given). Oral answer that blood tests were ok and treatment started. *Patient asks for the test results and it was discovered that they were too bad.* Further treatment delayed.	Happened 2-3 January. High work-load, lack of nurses. Communication did not work properly, oral answer to the prescribing doctor it was ok. Chronology of events unclear, three nurses involved. Routines unclear. Responsibilities unclear.
33	Lex Maria 2001	Cytarabine	University hospital	Ten-fold error during transfer of prescribed dose to batch record, 120 mg became 1200 mg. *Discovered by a pharmacist during next preparation the next day.* On-going treatment adjusted.	Happened day before Easter. The transfer error was not discovered by four pharmacists, one inexperienced. Cytarabine is prescribed both in low and high doses. Routines not followed. Heavy work-load, acute illness.
34	Lex Maria 2002	Carboplatin	University hospital	Too high doses were prescribed **to two patients** due to dosing errors, creatinine clearance was wrongly calculated. *Discovered by a doctor before the next treatment, 1-2 months later.* One of the patients had sepsis and cerebral infarct.	Doctor new at the ward and had not been trained in how to calculate the dose. The treatment had to be started without delay. For the first patient a consultant double-checked the calculations, next patient only by looking at the figures. Routines changed.

35	Lex Maria 2002 HSAN 2003	Melphalan should have been cyclophosphamide	University hospital	Wrong protocol was used leading to prescription of wrong drug. Patient with myeloma should first be treated with cyclophosphamide before stem cell harvest and then melphalane. Doctor prescribed melphalane first, dose 200 mg/sqm. *Discovered at round next day.* Allogeneic stem cell transplant was performed, with lethal complications.	Doctor took wrong protocol, checked by a consultant. Nurse inexperienced in haematology. Other patients with myeloma were treated at the ward being in different treatment stages. Protocol was not clear enough. After the mistake was discovered, an extensive work to find an allogeneic stem cell donator began.
36	Lex Maria 2002	Fluorouracil should have been cytarabine	Pharmacy	Wrong drug, Fluorouracil instead of cytarabine, was used during preparation of an Infusor. *Another pharmacist discovered and the infusion was stopped after 1.5 hour.* No harm.	High work-load. During preparation there was a leakage and the preparation had to be redone. The pharmacist had already finished for the day but would prepare this first – stress. Four pharmacists involved. Routine was lacking for how to do when a preparation had to be redone.
37	Lex Maria 2002	Etoposide should have been vinblastin	Pharmacy	Wrong drug prepared, Vepeside 20 mg/mL, 12 mL should have been Velbe 1 mg/mL, 12 mL. *Given as an injection, patient felt discomfort and pharmacy was contacted and the error was discovered.* Patient hospitalised for one day. Moderate impact.	Pharmacist in training. It was stressfull, many in staff on vacation. Deficiencies in the routines for introduction, control of right drug not included in double-checks. System error.
38	Lex Maria 2002	Methotrexate	Pharmacy	Too low dose was prepared at the pharmacy. Wrong strength was used during preparation, Emthexate 5 mg/mL, 2.8 mL (14 mg) instead of 25 mg/mL, 2.8 mL (70 mg). *Discovered short after delivery by a pharmacist but they could not get into contact with the ward.* Given to the patient, probably no harm.	Two pharmacists, high work-load with many interruptions, phone calling and a time study. The working room has to be changed for greater privacy.
39	Lex Maria 2002	Docetaxel should have been paclitaxel	University hospital	Prescription of wrong drug. Docetaxel 400 mg was prescribed, should have been paclitaxel 400 mg, appr. Three times too high dose. First treatment, lung cancer. Patient had adverse reactions, hospitalised for two weeks. *Next course the pharmacy questioned the dose and the error was discovered.* Corrective actions taken.	New routine to prescribe by generic name. Similarity between the generic names, drug not often used at ward. Patients' adverse reaction did not lead to control of earlier prescription, instead the dose was reduced.
40	HSAN 2002	Etoposide	University hospital	Total dose for the course became dose per day, 330 mg, 3 times per day for 3 days, should have been 110 mg, 3 times per day for 3 days. *Nurse suspected that the dose was too high and treatment was not given on day 3.* Patient suffered from anaemia, hospitalised for two weeks.	Very high work-load, shortage of doctors. Nurse gave the doctor the cytotoxic treatment card to prescribe on during meeting, incomplete information. Irritation, doctor misunderstood earlier prescription. Nurse wanted to start the treatment as soon as possible.
41	Lex Maria 2003	Cytarabine	County hospital	Patient received another patient's drug. The same drug but half of the intended dose. *Discovered next morning and the patient received rest of the dose.* Moderate impact.	Mistake. Routines for control before administration not clear enough.

42	Lex Maria 2003 HSAN 2004	Fluorouracil	University hospital	Prescription of full doses when they should have been reduced, also for Hydrea. Palliative treatment where creatinine values and serious adverse reactions were not attended to. *Patient's condition deteriorated and led to death.*	Routines for examining lab samples were missing, directors' responsibility. Nurse noted the patients' adverse reaction; doctor did not prescribe new lab tests and misjudged the patients' condition. Given information not documented by doctor.
43	Lex Maria 2003	Cyclophosphamide should have been etoposide	Pharmacy	Wrong drug prepared by pharmacy. Prescription of etoposide 65 mg became cyclophosphamide 65 mg. *Discovered by a pharmacist after 2.5 hours, infusion stopped and antidote was given.* Moderate impact.	Routines for double-check were not followed. Bottles should have been marked with a six-digit code; due to vacation this was not done. Two pharmacists involved. The interpretation of the routines seems to be diffuse and shortcomings in the pursuit seem to be accepted.
44	Lex Maria 2003	Cyclophosphamide	University hospital	Ten-fold error during transfer of prescribed dose to the requisition to the pharmacy. A nurse wrote 4000 mg, this was signed by a doctor. The prescribed dose was 400 mg. The too high dose was prepared and given the first day. On the s*econd day a nurse discovered the error and treatment was interrupted.* On-going treatment adjusted.	Different dose levels are used at the ward but with different days for treatment. Error when transferring the data, routines followed. Interruption and stress for the nurse writing the requisition. Pharmacy did not control the prescribed dose, according to their routines. The doctor is responsible for control of doses.
45	Lex Maria 2003 Lex Maria 2003	Cytarabine and daunurubicin	University hospital	Wrong protocol was used. Prescription of daunorubicin for 3 days and high dose of cytarabine, prescription should have been daunorubicin day 1 and cytarabine for 5 days. Patient with AML. *Second doctor discovered the mistake next day and adjusted the prescription.* No serious consequences.	First doctor choose the wrong protocol. He claimed he had pressing working conditions. The routine said that the protocol for treatment should be retrieved from a database. Second doctor could not do so because of a non working computer due to a blackout. Better routines for sorting of the protocol will be implemented. The hospital had earlier had problems with mix-up of protocols.
46	Lex Maria 2003	Cytarabine	County hospital	Total dose for the course became dose per day during transfer of prescribed dose to the requisition to the pharmacy. Prescribed dose correct. *Discovered? Due to problem with adverse reactions?*	Transferring error. Routines initially from university hospital giving problems to use them on a county hospital. Drug is prescribed in different doses, the erroneous dose reasonable.
47	HSAN 2004	Doxorubicin and vincristine	University Hospital	Double doses of the drugs prescribed. Adverse reaction, bowel paralysis, which could be cured. *Prescription checked and the error was discovered.*	New protocol, first time to be used at the ward. Protocol unclear, not checked. The prescribed doses were reasonable.
48	Lex Maria 2006	Fluorouracil	University hospital	Double dose prescribed in a clinical trial. Prescription was "1088 mg in NaCl 9 mg/mL in 1000 mL x 2 x 5 days". *Discovered during a review seven months later.* Patient had serious adverse reactions and needed intensive care.	Protocol unclear "750 mg/m^2 as a continuous iv infusion days 1-5 is given…". According to rules at hospital infusions should be changed every 12th hour. Doctor thought 750 mg/m^2 was the dose to be given each time. Dose very high, some nurses or pharmacists should have reacted.
	Lex Maria 2005	Fluorouracil	Pharmacy	See above #48.	Four experienced pharmacists. Prescription was clear but wrong. Someone should have reacted on the high doses.

49	Lex Maria 2005 HSAN 2005	Carboplatin	University hospital	Prescription of double dose of carboplatin and missed prescription of necessary infusion with fluid. Follow-up with lab checks did not work. *Child died after six days.*	Event analyses performed. Protocol for treatment not clear, dose discussed but still too high, to be given for 4-5 days. Routines for lab tests not followed. Weekend with unclear responsibilities among doctors. Nurses not familiar with treatment of children. Staffing low. Lack of open communication. Hierarchical culture.
50	Lex Maria 2006	Irinotecan	University hospital	Prescribed dose wrong. *Discovered ?* Patient had diarrhoea that needed hospital care. Fully recovered.	Ongoing trial. Special protocol and flow sheet was used. Dose in wrong column leading to the error. Pharmacists and nurses did not discover.
51	Lex Maria 2006	Etoposide	University hospital	Prescription of full dose when it should have been reduced. A planned reduction in dose (20 %) was not done, deficiencies in the computer programme. *Discovered when patient had serious adverse reactions, died twelve days after treatment.* Causality uncertain.	Deficiencies in computer programme, not user friendly. No risk analysis was done before purchasing the computer programme. Deficiencies in training of how to use it. Logging function was missing.
52	Lex Maria 2006	Carboplatin should have been cisplatin	University hospital	Mix-up during preparation by nurse. Dose three times higher than planned. *Discovered two hours after treatment by a nurse, dialysis, and adverse reactions treated with the patient hospitalised for two weeks. Radiotherapy delayed.* Probably no long term harm.	Low nurse staffing, did not follow routines regarding possibilities to prepare infusion undisturbed. Both drugs have similar names –platin and appearance. Contact with Medicinal Product Agency – they did not agree.
53	Lex Maria 2007	Carboplatin	County hospital	Prescription for five days should have been only for one day. Due to hearing disturbances from cisplatin there was a switch to carboplatin. Dose 800 mg per day. *Discovered when the patient came back with adverse reactions, hospitalised for a week.* Probably no long-term harm.	Event analyses performed. Two versions of protocol were found. Doctor discussed with a consultant, miscommunication led to the mistake. Routine saying that double control by doctors should have been done was not followed. Prescribing doctor was stressed. The nurse was inexperienced. Routine for monitoring during treatment was lacking.
	Lex Maria 2007	Carboplatin	Pharmacy	See above #53. Prepared according to the prescription for 5 days.	Staff reacted on the high dose but they did not have any protocol to check against. They trusted the doctor. They did not demand double-control by the doctors since they had no routine for that.
54	Lex Maria 2008	DaunoXome should have been daunorubicin	Pharmacy	Wrong drug prepared. Mix-up during documentation before preparation. Prescription of daunorubicin 82 mg in NaCl 9 mg/mL became DaunoXome. *Nurse discovered the mistake and the drug was NOT given.*	An error when drug name was transferred to a computer programme for preparation. Not discovered during double-check. Very high work-load, working conditions pressed. See below.
55	Lex Maria 2008	Amsacrine should have been melphalan	Pharmacy	Wrong drug prepared. Mix-up during preparation. Prescription of melphalan 300 mg became amsakrin prepared in NaCl 9 mg/mL. *Nurse discovered since there was a precipitation in the infusion, NOT given.*	A mix-up between “Amekrin” and “Alkeran” when drugs were picked from the shelf. “Amekrin” incompatible with sodium chloride. Double-check did not work. Working conditions pressed, see below.
56	Lex Maria	Vincristine	Pharmacy	Wrong drug prepared. Mix-up during documentation	An error when drug name was transferred to a computer

	2008	should have been vinblastine		before preparation. Prescription of vinblastine 10 mg iv injection became vincristine 2 mg. *Nurse noticed that the prescription and what had been delivered did not conform, NOT given.*	programme for preparation. Not discovered during double-check. Similarity in drug names. Very high work-load, working conditions pressed. See below.
57	Lex Maria 2008	Fluorouracil	Pharmacy	Infusor pump with too high speed used, content delivered during 2 instead of 7 days. During preparation wrong Infusor was used. *Patient came back when the pump delivered its content in only 2 days, nausea, problems with feeding.* Probably no harm.	Wrong Infusor used, they look alike. Documentation not clear regarding type of pump. Double-check did not work. Working conditions pressed, see below.
58	Lex Maria 2008	Clinical trial	Pharmacy	Wrong drug prepared. Ready-to-use kit for the trial. Vial with fluid not used. *Discovered one month later during check of the trial by pharmacist. Patient had had an injection unclear with what. Site for injection was swollen and red.*	A routine has been more specified. Time-lapse to control should be shorter. Working conditions pressed, see below.
59	Lex Maria 2008	Paclitaxel should have been trastuzumab	Pharmacy	Wrong drug prepared. Mix-up during documentation before preparation. Paclitaxel with the dose for trastuzumab, meaning that recommended dose for paclitaxel was to be exceeded and that no premedication would have been given. *Nurse discovered the error and it was NOT given.*	Acute phone prescription. An error when drug name was transferred to a computer programme for preparation. Not discovered during double-check. Working conditions pressed, some improvements were done. See below.
60	Lex Maria 2008	?	County hospital	Lab results were missing leading to four unnecessary treatments with cytostatics. A d*octor missed the lab results, searched for them and found them after 5 months.* No information on patients' condition.	The patient met 8 doctors during treatment period. There was global problems of the clinic, e.g. with lack of consultants leading to high work-load for doctors. Administrative routines were poor. There was no monitoring of test results.

Number 54-59, pharmacy: All events happened in connection with a planned transfer of preparation from one pharmacy (another hospital) to this pharmacy. The transfer should have been done during six weeks but plans were changed and the time shortened to three weeks. The volume of preparations would increase from 19 000 to 30 000 per year. New preparations, regimens, and documents were introduced. The transfer from one pharmacy to another meant that time for preparation was shorter; time for transportation were to be included in the time for delivery. Risk analysis had not been performed before the transfer, and not before the decision to decrease time for transfer. Precautions should have included more staffing, changed working schedule, better transport times, unambiguous routines of the different parts in the preparation process , change in stock.