

FarmaSafe@: design, development and deployment of a Hospital-wide CPOE system



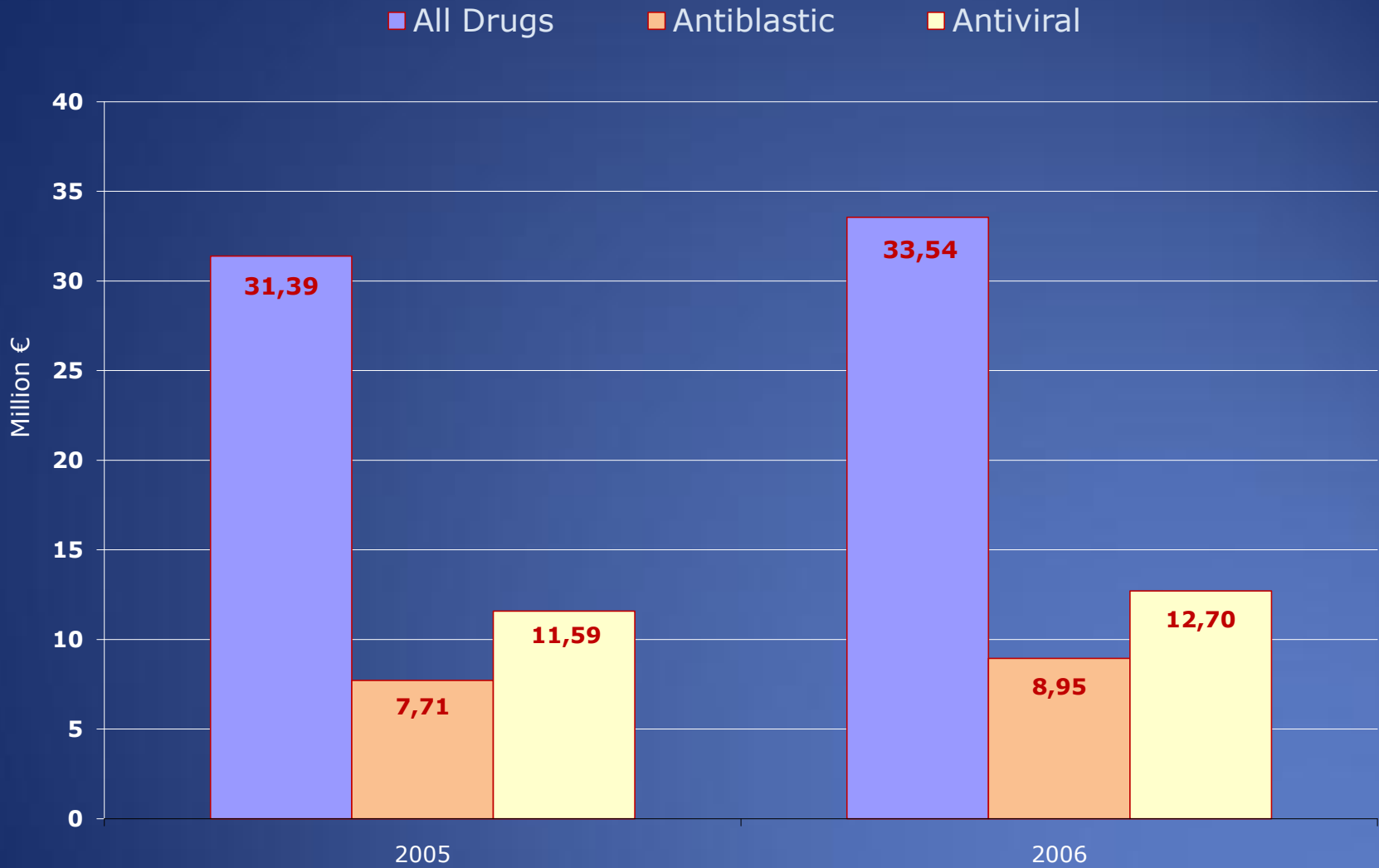
Ing. Antonio Fumagalli
Ospedali Riuniti di Bergamo - Italy

Manama - Bahrain, May 6th 2009

- Bergamo Hospital contest
- FS@: project and objectives
- FS@: workflow, clinical and patient benefits
- FS@: "hospital virtual drug"
- FS@: daily use and traceability
- FS@: "up to date" key informations
- FS@: technical elements ad system architecture
- FS@: training, roll-out and users assistance
- FS@: experience, evolution and conclusion

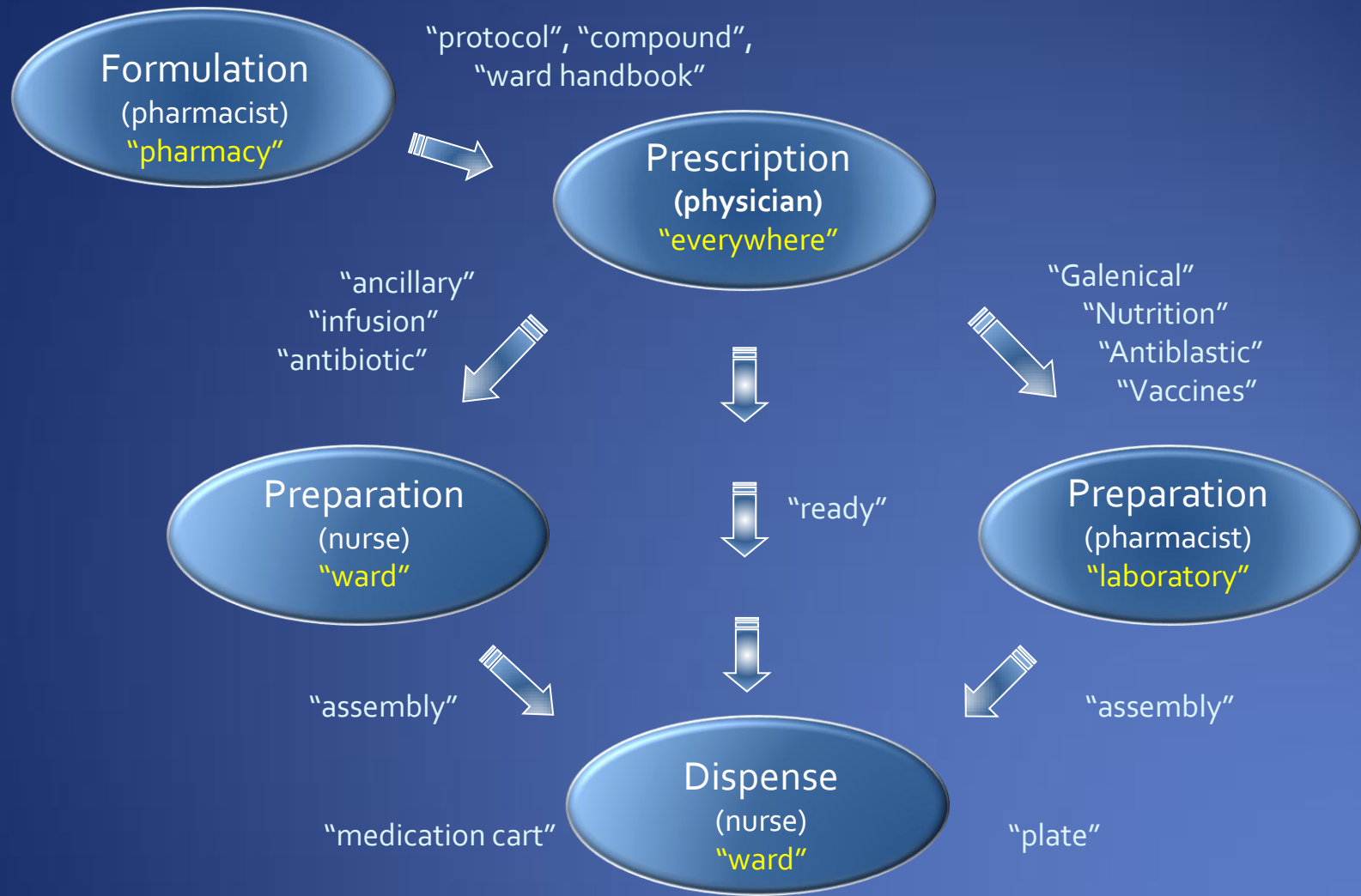
- ✓ Realization 1927-1930, pavilions building
- ✓ Beds: 906
- ✓ Operating rooms: 32
- ✓ Intensive Care units: 6
- ✓ Personnel > 4000
- ✓ Bergamo's County residents > 1.000.000

- ✓ Ordinary 2008 activities:
 - ✓ Inpatient: 38.396
 - ✓ Day Hospital: 14.984
 - ✓ Surgery: 34.354
 - ✓ Outpatient: 3.665.534
 - ✓ Hospitalization day (avg): 7,56 days
 - ✓ Bed occupation ratio: 83,94%
 - ✓ Transplant: 168
 - ✓ Bone marrow transplant: 102
 - ✓ Pharmaceuticals expense > 33 M€



- ✓ Organizational and functional Analysis: Sept.-Dec. 2004
- ✓ Start up of **pilot project** (2 clinical units + pharmacy): **May 2006**
- ✓ Go-live (2 clinical units + pharmacy): November 2006
- ✓ Safety and Risk analysis engineering test: November 2006
- ✓ Progressive **expansion to other units**: **January 2007**
- ✓ Official release 1.0: June 2007
- ✓ Release 1.9: December 2008
- ✓ **Hospital-wide extension**: **December 2009**

- ✓ **Complete therapy system** from **prescription**, through **preparation**, to arrive at **dispense** action
- ✓ Organizational process improvement/optimisation among nurse, clinician and pharmacist
- ✓ **Patient safety increase** (i.e. therapy error reduction), assistance time dedicated to the patient
- ✓ **Complete traceability of therapy process** with plenty of report
- ✓ Paperless operations
- ✓ User clearly identified for clinical/legal matter
- ✓ System available everywhere, **real time therapy progress at patient location**
- ✓ **No therapy transcription**



- **Protocol schema and compound clearly defined**, based on therapeutic/pharmacological validation from physician/pharmacist
- **Dose calculated** in mg based on anthropometric parameter
- Compound, drugs handbook defined for single clinical specialty
- **Clear and detailed e-prescription**
- Univocal preparation label by patient/drug
- **Patient and drug unambiguous identification**
- Dose, dispense route and time defined
- **Patient therapy usable**, always up to date in real time to users everywhere they are working

"bedside"



"ancillary"
"infusion"



"ward"



"Galenic"
"Nutrition"
"Antiblastic"



"laboratory"



"assembly"



"assembly"

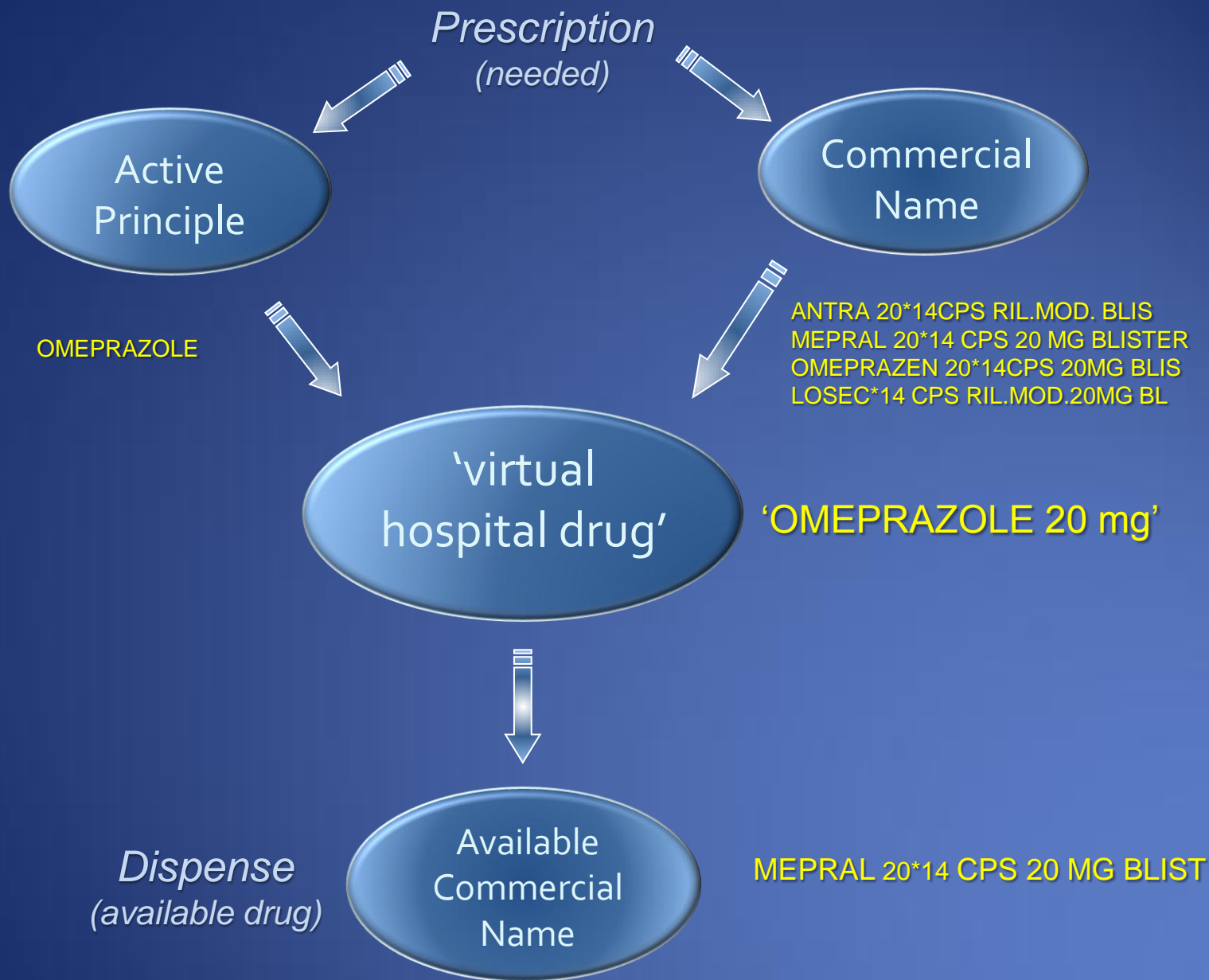


"bedside"

Drug coding extended to “7th ATC level”: ATC + pharmaceutical shape + dose

ATC Level	ATC Code	ATC Group	ATC Description
1°	A	Anatomic	Alimentary tract and metabolism
2°	02	Therapeutic	Drugs for acid related disorders
3°	B	Therapeutic	Drugs for peptic ulcer
4°	C	Therapeutic	Proton pump inhibitors
5°	01	Chemical	Omeprazole
6°		Pharmaceutical Shape	Oral capsule
7°		Dose	20 mg

**The “virtual hospital drug”
guarantee real equivalence of grouped specialty !!!**




- ✓ **Protocols and compounds are always valid** due to independence from commercial drug name
- ✓ With dose and pharmaceutical shape **is possible to convert pieces/mg and viceversa** for a complete dispense safety
- ✓ During prescription the **physician does not care about the commercial specialty** available to dispense
- ✓ **Therapy is always valid**: physician does not need to change anything due to commercial product logistic modification (new brand in Hospital for example)


To get patient data  read barcode from label on prepared drug



Barcode is **the unique link**
among drug and patient inside the system



A.O. Ospedali Riuniti di Bergamo - Reparto
Ematologia - Reparto di degenza Prescr.
da: [REDACTED]
Paz: [REDACTED]
[REDACTED] 15/04/1972 [REDACTED]
Protocollo: BEAM - Giorno: 6 - Sequenza: 5
P.A.: SODIO BICARB. 1/6M 500ML - 500 ML
SOD B1,4%SAL*IV 500ML 1FL - 500 ML
Somm: 17/04/2007 Via somm.:ev-infusione in 30 min.
Prep. 16/04/2007 21:57 Scad. -
NOTE: -



A.O. Ospedali Riuniti di Bergamo - Reparto
Ematologia - Reparto di degenza
Prescr. da: [REDACTED]
Paz: [REDACTED] 20/06/1944 RI: [REDACTED]
Protocollo: - - Giorno: - - Sequenza: -
P.A.: OLIGOELEMENTI MULTIPLI 10ML - 1 F
P.A.: SACCA NPT C/LIP 2.000 ML 2080 KCAL N.P. - 1
SAC
ADDAMEL N*IV 20 F 10 ML - 10 ML
OLICLINOMEL N7-1000E 2000ML 2080 KCAL NP
- 2.000 ML
ACTRAPID*100UI/ML 1FL10ML - 0,3 ML
Somm: 17/04/2007 Via somm.:ev-infusione in 1440 min.
Prep. 17/04/2007 10:49 Scad. 18/04/2007 10:49

FLC - I/I VOL. TOT. 2.010,3 ML

LISTA PROTOCOLLI

Acronimo	Descrizione
FEC 100	5FU+EPI+CTX
FEC 75	5FU+EPI+CTX
FEC GIM2 (G) B	5FU+EPI+CTX, IIO PEGFILGRASTIM
FEC GIM2 (G) D	5FU+EPI+CTX COII PEGFILGRASTIM
FLUDA 1-5 + EDX	CTX+FDR
FLUDA 5 GG	Fludarabina per 5 giorni
FOLFIRI COII CVC (G)	CPT11 + ALF + 5FU con granisetron
FOLFIRI IIAAG (G) COII CVC	Prot. IINTERGRUPPO IIAZIONALE ADIUVANTE GASTRICO
FOLFIRI IIO CVC (G)	CPT11 + ALF + 5FU con granisetron
FOLFIRI SEMPLIFICATO (G)	CVC. CPT-11+ALF+5FU BOLO D1+IC 2400 mg/mq
FOLFOX AVAII (G)	FOLFOX IV: OHP + ALF + 5FU con granisetron
FOLFOX COII CVC (G)	FOLFOX IV: OHP + ALF + 5FU con granisetron
FOLFOX IIO CVC (G)	FOLFOX IV: OHP + ALF + 5FU con granisetron
FOLFOX VI COII CVC (G)	FOLFOX IV: OHP + ALF + 5FU con granisetron
FOTEMUSTINA CARICO	FOTEMUSTINA

550+ protocol schema available to prescribe

Oncologia Medica- Day hospital

Cognome: [redacted] Nome: [redacted] Sesso: M Età: 39

Episodio clinico: Letto: - Numero Ricovero: [redacted] Data ingresso: 19/03/2007 - 09:44 Stato: Aperto

NUOVO CICLO

Medico: [redacted] Reparto: 453 Oncologia Medica- Day hospital

Peso Kg Altezza cm Sup. corporea m² Sup. corporea Ideale m²

Diagnosi: [redacted] Data inizio: 23/05/2007 22:31

> Nuovo ciclo sulla base del protocollo std selezionato

> CICLI ASSOCIATI AL PAZIENTE

Data	Protocollo	N. ciclo	Stato
19/03/2007 09:49	PEB [1,2,3,4,5,9,16]	1	Concluso
10/04/2007 09:59	PEB [1,2,3,4,5,9,16]	2	Concluso
30/04/2007 09:55	PEB [1,2,3,4,5,9,16]	3	Concluso

> Visualizza

Dose based on patient anthropometric parameter



"every chemotherapy drug owns a progressive unique number for the dispense"



Patient selection by drug barcode label



Dispense sequence check



Drug (right) check when dispense is ready to start using patient barcode

Ospedali Riuniti di Bergamo

Paziente: ██████████

Data nascita: 19/07/1967

Num. pratica: ██████████

Reparto: Ematologia - Reparto di degenza

									27/03/2009									
	Farmaco (periodo: 1)	Via	Tipologia	Inizio	Ogni	Dose STD	UM	ml/h	06	07	08	10	12	15	18	20	22	23
C	MORFINA CLOR.MG 10/ML.1 IM/EV EPIDURALE	INF	estemporanea	27/03		10	MG					10						
C	FISIOLOGICA 100ML	INF	estemporanea	27/03		100	ML					100						
A	IMPENEM 0,5 G + CILASTATINA NA 0,5 G EV...	INF	7-15-23	23/03	tutti i giorni	2.000	MG		2.000				2.000					2.000
A	FISIOLOGICA ML. 250	INF	7-15-23	23/03	tutti i giorni	250	ML		250				250					250
A	VANCOMICINA 500 MG E.V.(DIL IN 10 ML) IL...	INF	6-12-18-24	26/03	tutti i giorni	500	MG	500					500		500			500
A	FISIOLOGICA 100ML	INF	6-12-18-24	26/03	tutti i giorni	100	ML	100					100		100			100
A	INSULINA ACTRAPID - 100 U.I./ML. INSULIN...	INF	10	21/03	ogni 2 giorni	30	UI					30						
A	OLIGOELEMENTI MULTIPLI 10ML CR-CU-FE-MN...	INF	10	21/03	ogni 2 giorni	10	ML					10						
A	SACCA NPT C/LIP 2.000ML 2080KCAL N.P. N7...	INF	10	21/03	ogni 2 giorni	2.000	ML					2.000						
A	INSULINA ACTRAPID - 100 U.I./ML. INSULIN...	INF	10	22/03	ogni 2 giorni	0,3	ML											
A	POLIVITAMINICO LIOF. N.P.T.	INF	10	22/03	ogni 2 giorni	5	ML											

Stampato il: 27/03/2009

1/12

 SS
ast09

Ospedali Riuniti di Bergamo

Ematologia - Reparto di degenza

Piano di lavoro somministrazioni per il giorno: da 27/03/2009 07:00 a 28/03/2009 06:59

Letto: 04



R. I.



Turno	data	Farmaco	Dose	Via	Stato
M	27/03/2009	07:00 ACICLOVIR 250 MG E.V.(+10ML) LIOFILIZZATO DA DILUIRE in FISIOLÓGICA ML. 250	3 FLC in 1 FLC(PA 750 MG,30 ML)	INF	Somministrato
		07:00 IMPENEM 0,5 G + CILASTATINA NA 0,5 G EVIII SCELTA (MOD.1434) in FISIOLÓGICA ML. 250	2 FLC in 1 FLC(PA 2.000 MG,40 ML)	INF	Somministrato
		08:00 G-CSF MCG.300 E.V./S.C. SIRINGA PRONTA (FILGRASTIM) SOSTITUISCE COD.3270 (70%)	1 SIR(PA 0,3 MG,0,5 ML)	SC	Somministrato
		08:00 FLUCONAZOLO MG.200 EV	1 FLC(PA 200 MG,100 ML)	INF	Somministrato
		08:00 OMEPRAZOLO 40MG O PANTOPRAZOLO 40MG+5ML FIALOIDE LIOFILIZZATO in FISIOLÓGICA 100ML	1 F in 1 FLC(PA 40 MG,5 ML)	INF	Somministrato
		10:00 OLIGOELEMENTI MULTIPLI 10ML CR-CU-FE-MN-I-F-MO-SE-ZN, SACCA NPT C/LIP 2.000ML 2080KCAL N.P. N7-1000E - (NPT-MOD.788) in INSULINA ACTRAPID - 100 U.I./ML. INSULINA AD AZIONE RAPIDAS.C./E.V.	1 F, 1 SAC in 30 UI(PA 2.000 ML)	INF	Da somministrare



Ospedali Riuniti di Bergamo
 AZIENDA OSPEDALIERA
 di rilievo nazionale e di alta specializzazione

Reparto: Ematologia - Reparto di degenza

FOGLIO UNICO DI TERAPIA

██████████, sesso M, nato il 19/07/1967 - n° ricovero ██████████, data ingresso 13/03/2009 08:17

13/03/2009

ALLOPURINOLO 300MG

13/03/2009 10:28 - 19/03/2009 11:08, ore 8, 1 CPR, per bocca, prescritta da ██████████

Somministrazioni

13/03 10:28 ALLOPURINOLO TEV*300MG 30CPR (CLASSE A)

13/03 11:44 somministrato 1 COMPRESSA ██████████

SODIO BICARBONATO 1/6M 500ML (1,4%)

13/03/2009 10:41, Prot. BEAM, ev-infusione, prescritta da ██████████

Somministrazioni

13/03 10:41 SOD B1,4%MNC*IV 500ML 1FL (CLASSE C)

13/03 11:43 inizio sommin. 1 / 1 FLACONE 300574 (500 ML) ██████████

13/03 12:14 somministrato

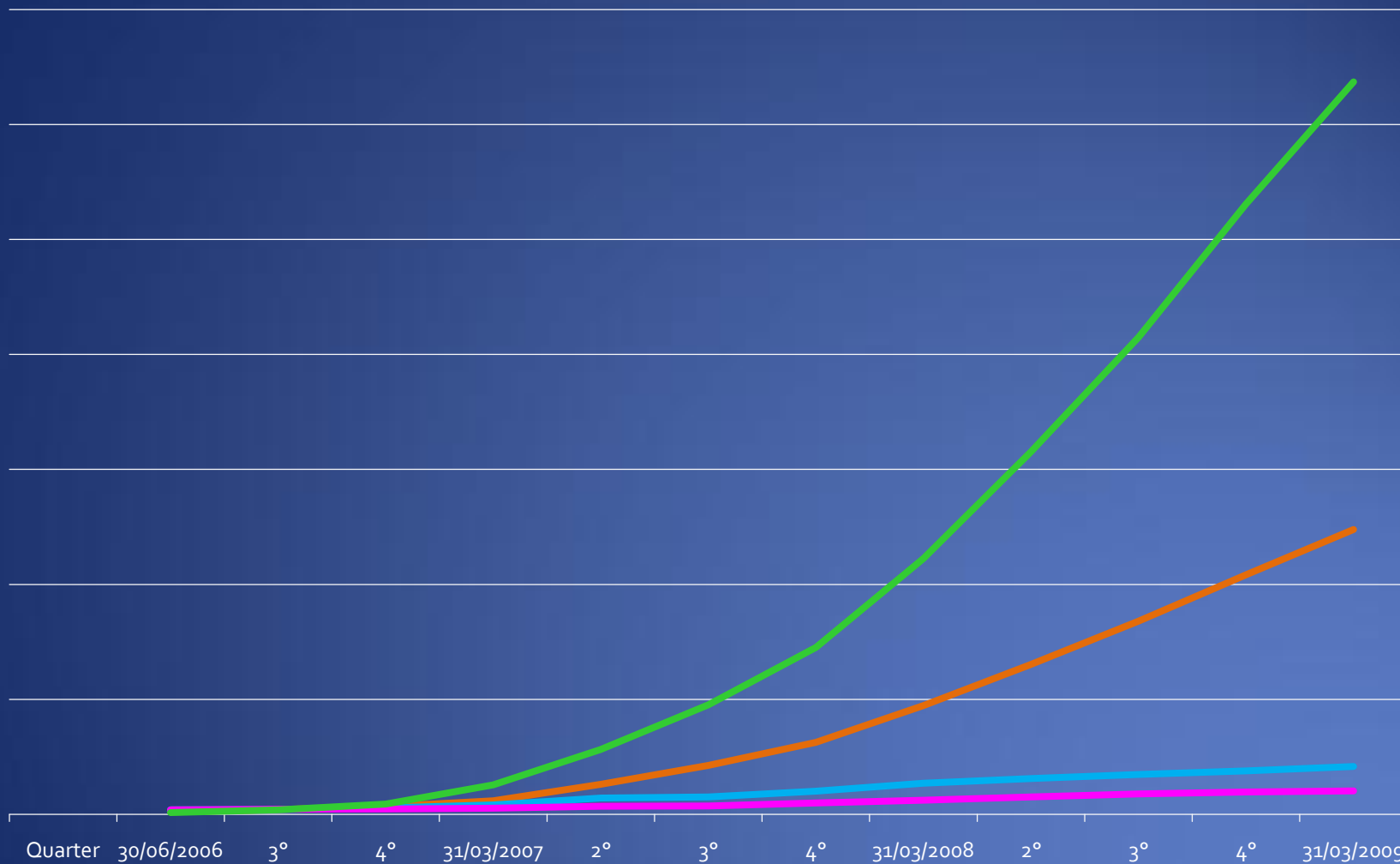
ELETTROLITICA EQUILIBR.C/GLUC.5% 2000 ML

13/03/2009 10:41, Prot. BEAM, ev-infusione, prescritta da ██████████

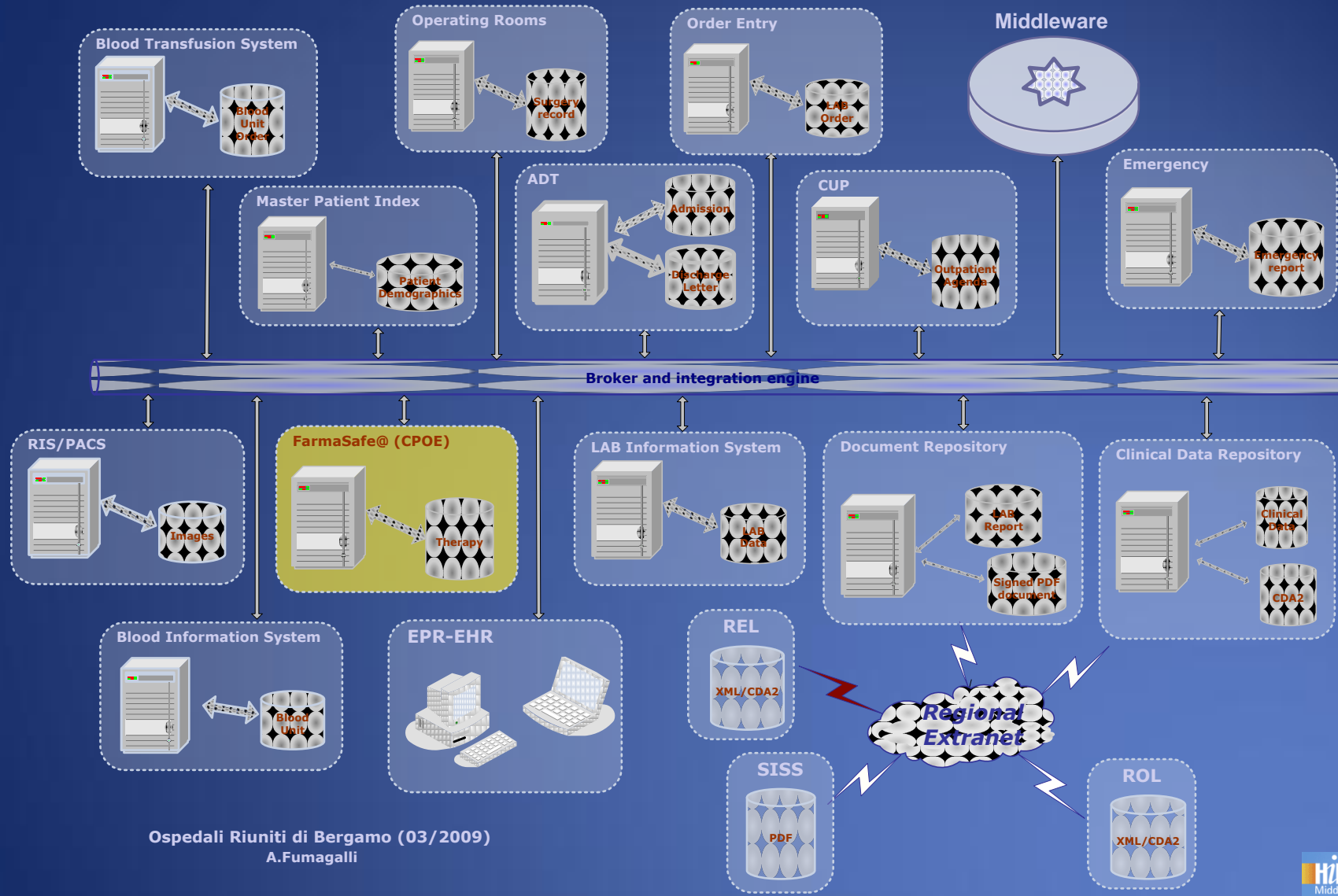
- ✓ Clinical event operated: more than 47.000
 - ✓ Labeled pharmacologic preparation : more than 850.000
 - ✓ Chemotherapy protocol schema available to prescribe: 579
 - ✓ Pharmacologic compound ready to prescribe: around 1000
 - ✓ Prescribed chemotherapy schema: more than 25.000
 - ✓ Recorded dispense : more than 2.700.000
-
- ✓ **Paperless ward: 40** today
 - ✓ Remaining ward: 10 to roll-up by 2009 end
 - ✓ Users: 414 physician, 859 nurse, 7 pharmacist, 4 IT
-
- ✓ **Different enrolled patient in FS@: 31.500 !!!**

FarmaSafe@: key data graph

— Patient — Nurse — Physician — Dispense



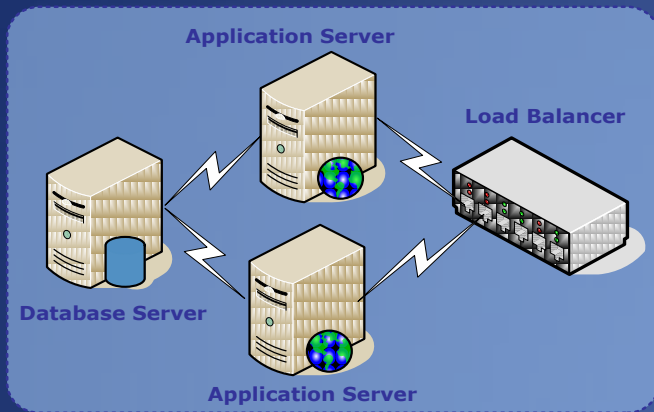
Bergamo: "Hospital Information System"



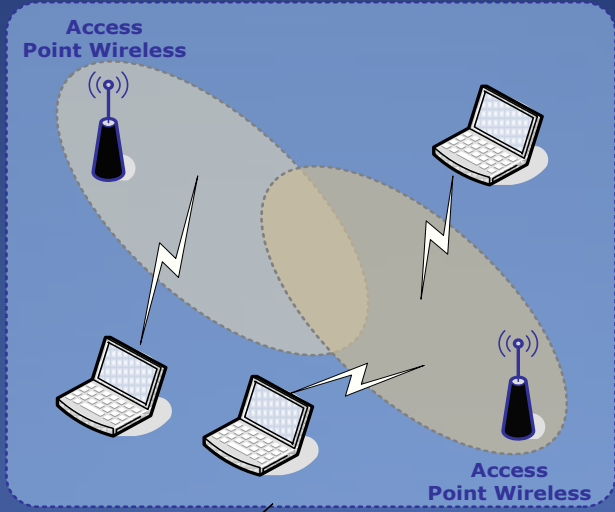
Ospedali Riuniti di Bergamo (03/2009)
A.Fumagalli

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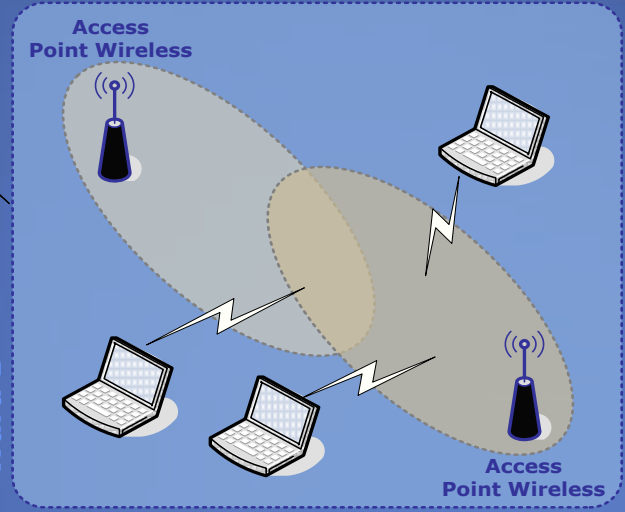
Server Farm



Ward A



Ward B



Ospedali Riuniti di Bergamo (03/2009)
A.Fumagalli

- ✓ 'access point' installation to **guarantee signal distribution** on whole ward area (60+ equipment today)
- ✓ Equipment configuration to guarantee **connection availability to mobile device** (e.g. tablet, computer on cart)
- ✓ Use of standard "802.11g"
- ✓ Large use of wireless device for complete nurse/clinicians mobility (**120+ notebook**)

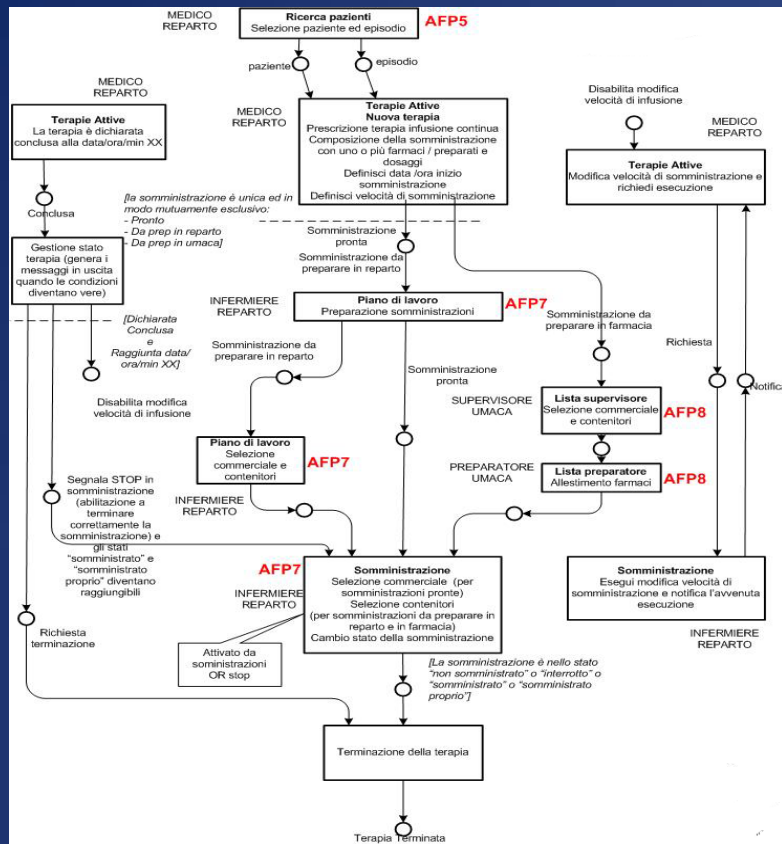
✓ Functionality testing

- ✓ For single software function (e.g. patient search)
- ✓ For process (e.g. prescription/dispense of continuous infusion therapy)
- ✓ For state/transition of application element (e.g. drug state change inside a chemotherapy protocol: prescribed, running, suspended, ended, ...)

✓ Safety testing

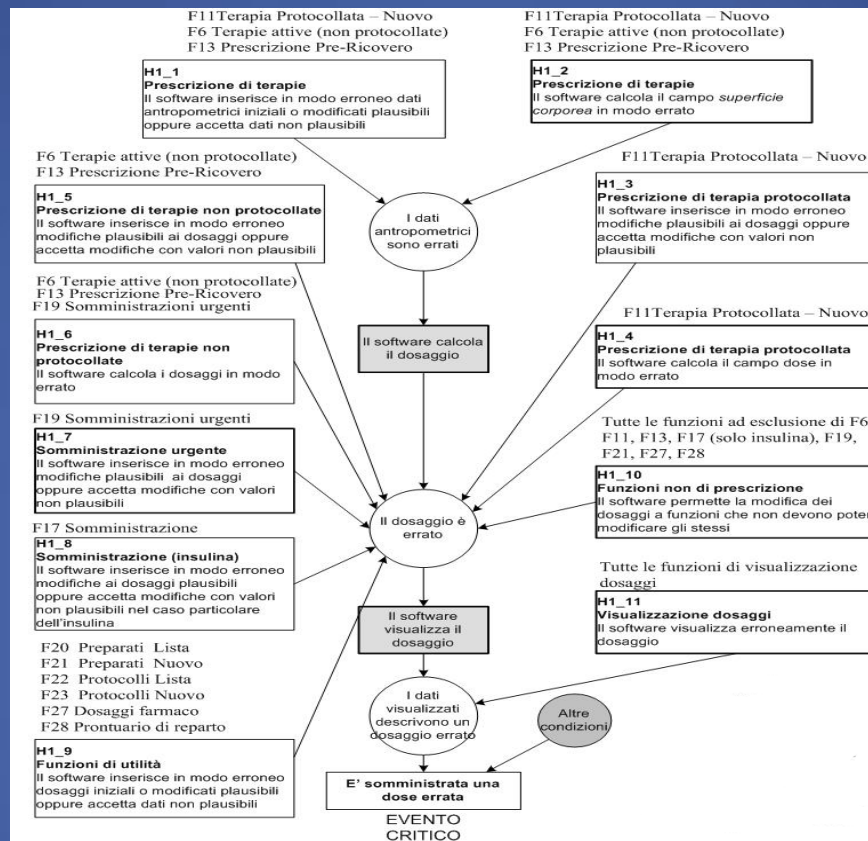
- ✓ Critical event identification (wrong dose, wrong patient, ...)
- ✓ Model to simulate critical events (improper behavior of software, ambiguous data, ...)
- ✓ Utilization of test case to check a possible critical event generation

✓ Executed tests: around 2.700



Safety test:
wrong dose critical event

Process test: prescription/dispense of continuous infusion therapy



- ✓ Complete training to physician and nurse: 8 classroom hour per user
- ✓ **Field roll-out and assistance Team** (IT, pharmacist and nurse): presence for 8 weeks directly in ward
- ✓ **A number of PC available to guarantee "visit round", preparation and dispense in the same time**
- ✓ One PC on every therapy cart, one PC in every Day Hospital room
- ✓ Phone Help-desk and user documentation available
- ✓ IT assistance 24x7

“UNINTENDED TRANSFORMATIONS OF CLINICAL RELATIONS WITH A COMPUTERIZED PHYSICIAN ORDER ENTRY SYSTEM”

(WENTZER, ET AL., INTERNATIONAL JOURNAL OF MEDICAL INFORMATICS, 2007)



- ✓ Transformation of clinical activities ➔ bedside ➔ wireless computing
- ✓ Actors collaboration ➔ complete paperless workflow
- ✓ Logistic and pharmaceutical centered ➔ “virtual drug” concept
- ✓ System availability ➔ robust IT architecture, paper backup available
- ✓ Clinical Specialty ➔ different functionality
- ✓ Social and technological evolution ➔ iterative revision process with Project Team
- ✓ Tool usability ➔ continuous analysis and improvement
- ✓ Care continuity ➔ e-prescription to keep on therapy after hospitalization

- ✓ **RFID identification and tracking on patient and pharmaceutical preparation:** analysis already completed, ready to start field experimentation
- ✓ **Drug allergy** recording and use during prescription with international standard HL7 e WHO ATC
- ✓ **Drug interaction analysis** during prescription using an online and up-to-date database : alert to the physician
- ✓ Complete process traceability with **digitally signed document**
- ✓ Integration with Hospital EPR (some integration already active with departmental EPR)
- ✓ **Single drug dose**
- ✓ **Patient personalized single dose drug**

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Thanks to the 'incomparable' project Team

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Roncelli, Rozzoni, Sala, Soliveri, Suardi, Taddei, Teocchi,
Tondini, Tribbia, Trussardi, Viero...



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