

Traceability of Drugs:

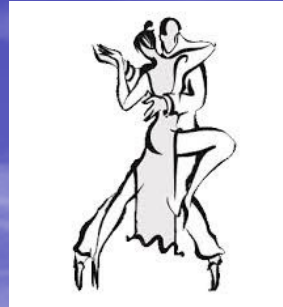
“Implementation in a hospital
pharmacy in Argentina”



Global GS1 Healthcare Conference
San Francisco, USA 1-3 October-2013

Dra. Heidi Wimmers
Hospital Alemán

Buenos Aires ...



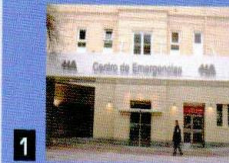
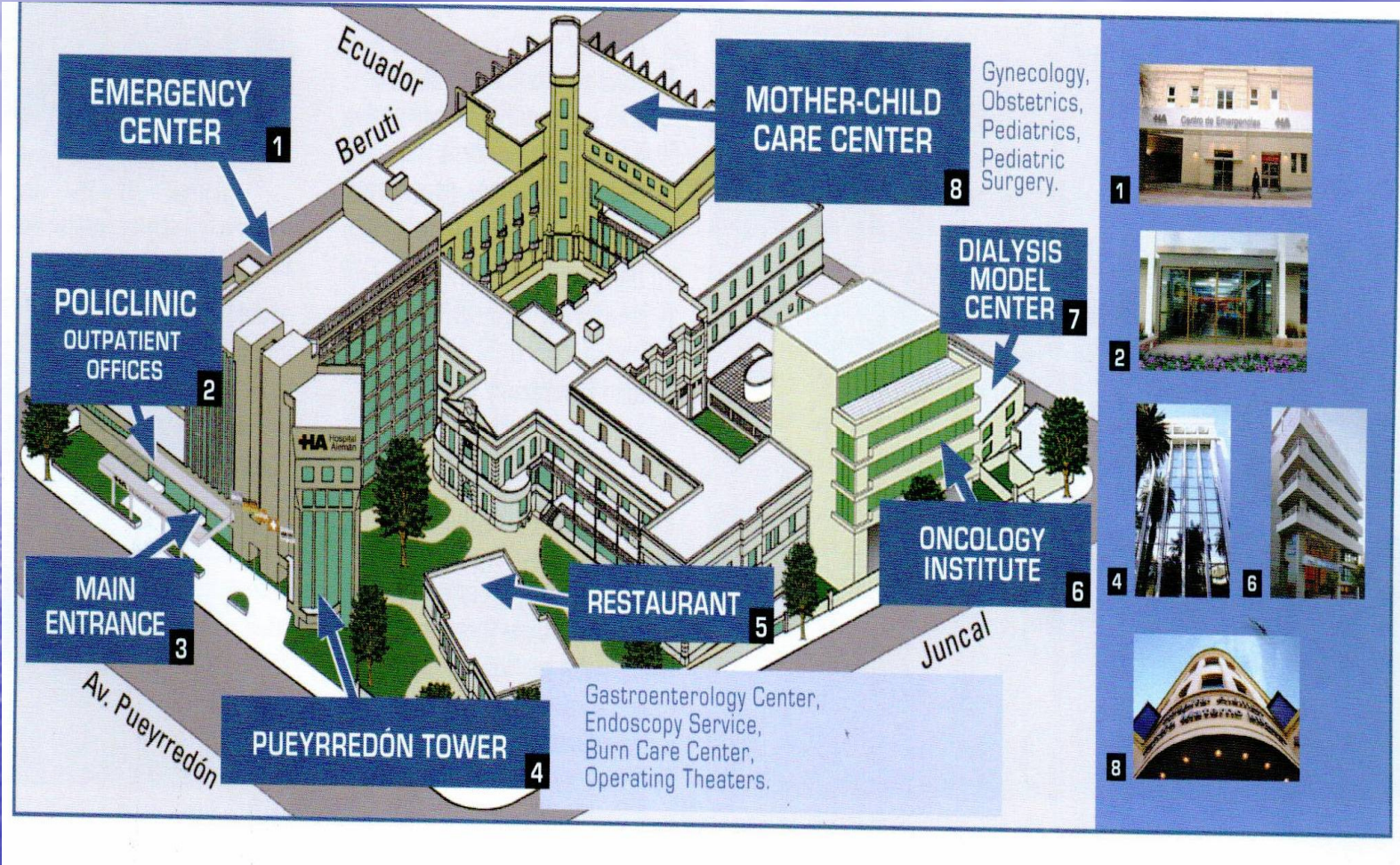
Argentina ...



The Hospital Alemán of Buenos Aires:

- Opened its doors on **August 26, 1867** just as a cholera epidemic devastated BsAs.
- University Hospital of high complexity.
- More than 700 professional doctors.
- All specialities and care for the acute sick.
- Diagnosis and treatment with advanced technology.





What is traceability of drugs?



- It is a tool that allows us to know the history of the drug along all its steps:
 - verification of its ORIGIN.
 - register of records all along its DISTRIBUTION CHAIN.
- Patients have the right to receive legal drugs.



Acquisition of drugs
directly from audited
laboratories and
drugstores (**GLN**).

Reception of traceable drugs
with record of lot and
expiration date, **GTIN** and
serial number.

Traceability

**Dispensation and
Administration** of right
drug in daily dose.

Drug traceability, why and how to use it in a hospital?



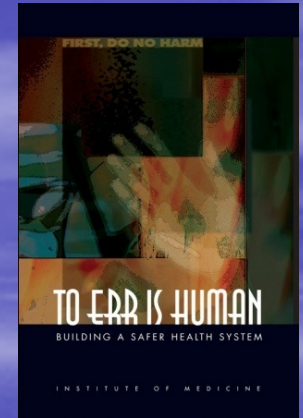
Traceability as an implementation of healthcare improvement:

- plays a vital part in providing patients with best quality of medicines.
- traceability is part of a safety culture, enables trust.



To Err is Human - 1999

Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson, Editors;
Committee on Quality of Health Care in America, Institute of Medicine



Building a safer Health System

“first, do no harm”

- Experts estimate that **more people die annually from medication errors in hospitals, than from workplace injuries, motor vehicle accidents, breast cancer, etc.**

The traceable medicine helps to prevent use of expired and recalled medication.



WHO / 2006 Action on Patient Safety High 5s



What is patient safety?

- *Patient safety* is the absence of preventable harm during the process of healthcare.

The vision:

- Every patient receives safe healthcare, every time, everywhere.



Drug safety: global scenario

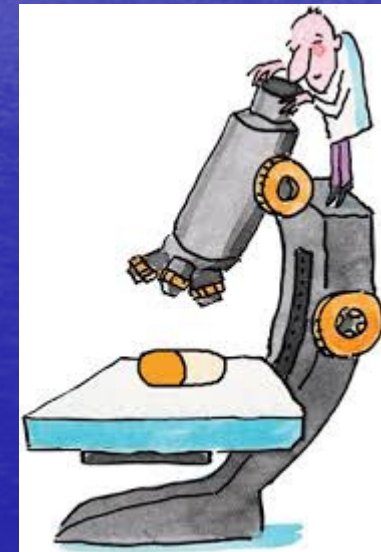


Note N°275 /May 2012 / OMS

- Counterfeit drugs Country/Year
 - 1- **Avastin**
(Ca treatment) U.S., 2012.
 - 2- **Viagra and Cialis**
(erectile dysfunction) U.K., 2012.
 - 3- **Truvada and Viread**
(HIV/Aids) U.K., 2011.

Drug safety

- Unsafe drugs prevent patients from relieving their suffering and improving their quality of life.
- **Counterfeit medicine is fake medicine.** It may be contaminated or contain the wrong or not active ingredient.



“Never Events” patient safety network PSNet

accessed August 20, 2013



- The term “Never Event” was introduced in reference to **particularly shocking medical errors.**
- These errors should never occur in **a healthcare organization**
- The list has been **expanded in 2011 to include adverse events:**

For example: **Product or device events:**

- Patient death or serious injury associated with the use of contaminated drugs...

International background :FDA

- The FDA has recommended pharmaceutical laboratories to start using **Radiofrequency Identification Technologies (RFID)** to improve the traceability of their products.
- (WHO N°275/ Feb. 2006).
- RFID chip next to a grain of rice



National background

- Apr-2011
The National Ministry of Health established the creation of the SNT of drugs, in order to *ensure the control of these products and limit the use of illegal drugs.*
- It has been instrumented by ANMAT :
National Administration of Drugs, Food and Medical Devices of Argentina

What did the first stage of the SNT include until June 15th, 2012?

- The traceability of about 200 medicines with “**high cost and low incidence**”, such as Cancer, HIV, Hemophilia, Rheumatoid Arthritis, Cystic Fibrosis.





... in March-2012

and deadline also 15-JUN-2012 !!

- ANMAT added:

...2.300 more traceable
medicines



And finally the last stage of the SNT
this year ...

- The Ministry of Health added
11 more Active Pharmaceutical
Ingredients (API)

This is equivalent to **500 additional
medicines.**

How to implement traceability at the Hospital Alemán?



The traceability-system involves 4 specific steps in our hospital :

- hospital reception
- single dose fractioning
- dispensing
- administration

... its a big teamwork !!



It is possible to make changes,
recognizing the positive effects...



And implementing traceability with
the 4 E's:

- Engage
- Educate all levels of staff
- Execute standardising processes
- Evaluate

Teamwork



- Providing safe healthcare depends on highly trained individuals
- They are working together for patients *to improve health and wellbeing.*

Patients come first in everything we do.



The Quality Program: “standardising processes”

- the Traceability Manual is drafted
- all multitask personnel is trained
- it is focused towards a continued improvement.
- Applicable systems: ISO 9001, accreditation Joint Commission, etc.



Reception and administration
of traceable medicines in hospital
directly linked to ANMAT Website

The history of the drug goes from its reception to the moment it is used by patients: traceability inside the hospital.

The system based on GS1-Standards.



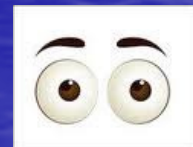
GTIN: Global Trade Item Number

- Each individual package has a unique, unrepeated random code :

(01)GTIN_ and (21)serial number

- It is placed by the laboratory/drugstore.
- It will allow the **patients to verify the authenticity of the product.**

human readable
barcode



This unique identification is placed on the secondary packaging with one of the three Data-Carriers:

- Linear bar code
- DataMatrix
- RFID



Data Capture

scanner



GTIN/serial number is read at the reception with:

- A) batch/lot number
- B) expiry date

associated with GLN Code

GLN is the identification number of the institutional provider

Once the drug is **received**, ANMAT is informed and an ID is obtained:



- The traceability of the drug is verified at ANMAT's Website using the transaction **ID**:



-from **GLN of origin**



-to **GLN of destiny** (Hospital Alemán as informant agent)

GLN of origin to GLN of destiny

CONSULTA DE MOVIMIENTOS

ID transacción:	<input type="text" value="108153587"/>	Evento:	<input type="text"/>
Origen:	<input type="text"/>	Destino:	<input type="text"/>
	Razón Social:		Razón Social:
Fecha transacción desde:	<input type="text"/>	hasta:	<input type="text"/>
Fecha evento desde:	<input type="text"/>	hasta:	<input type="text"/>
Fecha vencimiento desde:	<input type="text"/>	hasta:	<input type="text"/>
Lote:	<input type="text"/>	N° serial:	<input type="text"/>
Agente Informador:	<input type="text"/>	Medicamento:	<input type="text"/>
	Razón Social:		Descripción:
Provincia:	<input type="text"/>	Estado:	<input type="text"/>
<input type="button" value="Buscar"/> <input type="button" value="Exportar"/> <input type="button" value="Limpiar"/>			

MEDICAMENTO				EVENTO	ORIGEN		DESTINO	
GTIN	LOTE	NRO SERIAL	NOMBRE	DETALLE	GLN	RAZON SOCIAL	GLN	RAZON SOCIAL
07792089027021	DM7837	51689887	LECTRUM® 7.50 MG	RECEPCION DE PRODUCTO DESDE UN ESLABON ANTERIOR	7792089000017	SANDOZ SOCIEDAD ANONIMA	7798175540003	HOSPITAL ALEMAN ASOCIACION CIVIL
07792089027021	DM7837	88530835	LECTRUM® 7.50 MG	RECEPCION DE PRODUCTO DESDE UN ESLABON ANTERIOR	7792089000017	SANDOZ SOCIEDAD ANONIMA	7798175540003	HOSPITAL ALEMAN ASOCIACION CIVIL
07792089027021	DM7837	78378036	LECTRUM® 7.50 MG	RECEPCION DE PRODUCTO DESDE UN ESLABON ANTERIOR	7792089000017	SANDOZ SOCIEDAD ANONIMA	7798175540003	HOSPITAL ALEMAN ASOCIACION CIVIL

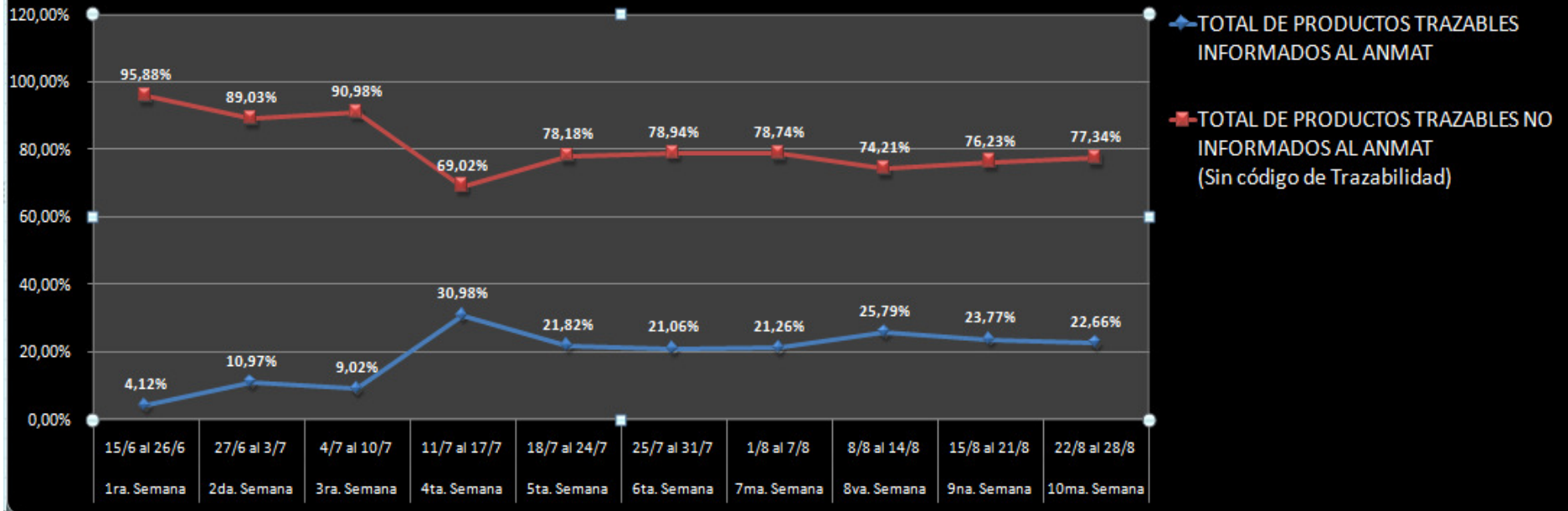
Reception of traceable drugs in the HA:

Inicial status (JAN-15-2012) and current
(up to JUN-15-2013)

TOTAL TRACEABLE PRODUCTS INFORMED TO ANMAT

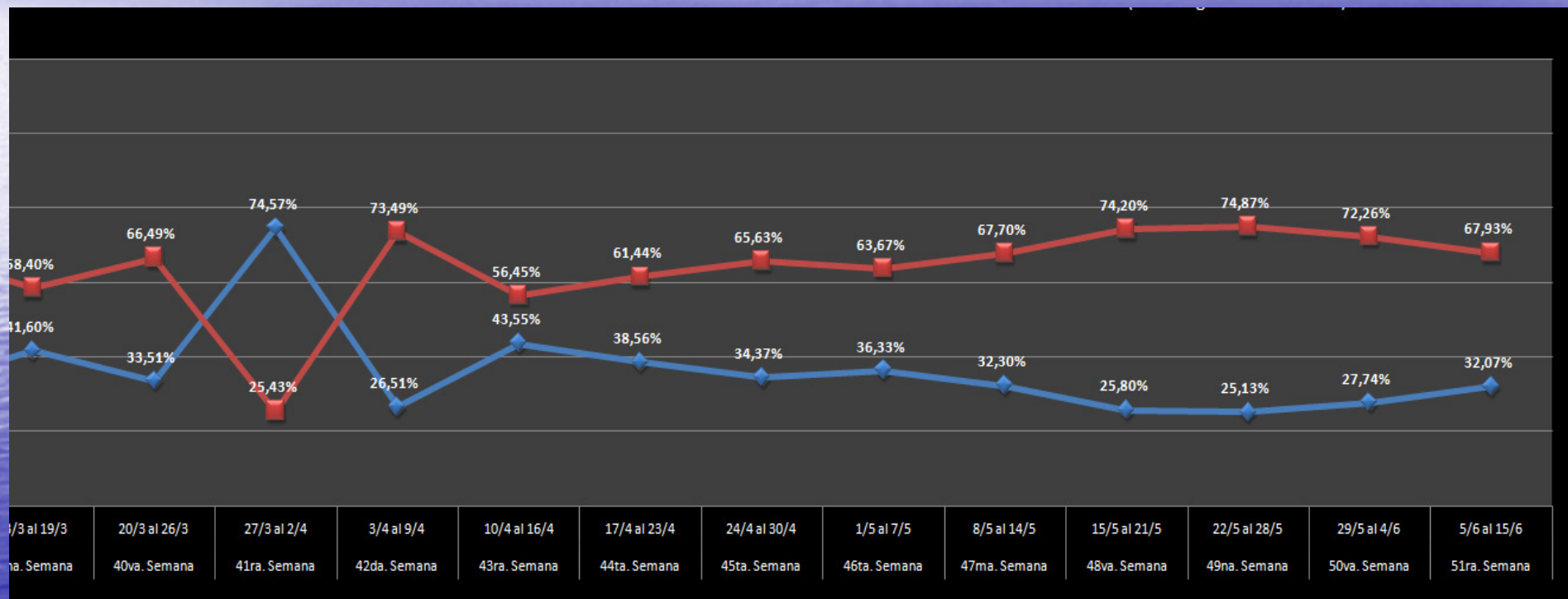
June 2012

PRODUCTOS TRAZABLES RECEPCIONADOS EN EL HOSPITAL ALEMAN



TOTAL TRACEABLE PRODUCTS INFORMED TO ANMAT

June 2013



Single dose fractioning at the Pharmacy in the Inpatient Ward



Unit dose re-packaging is done through an aseptic process where the original blister packs are cut and each unit dose individually overwrapped.



This single unit packages for pills,
tablets or capsules :

- Identify their contents accurately.
- Protect their contents from environmental effects.
- Allow quick, easy and safe use.



For this single-unit packages: drugs were re-labeled with GS1-code:

- we can only print these labels for the number of units indicated in the original package.

- 60 tablets = 60 labels with the same DataMatrix code



We hope that in the future we will have regulation for the primary packaging based on the GS1 DataMatrix identification.



We also labeled each vial or ampoule...
with a DataMatrix-code printer



- It was hard work to adapt the size of the label so that it could be read by the scanner in the case of the smallest ampoules.

curvature



Quality of the re-packaging-process:

technology-related vulnerabilities compromise patient safety

- A programme of preventive maintenance is implemented in order to control the machine, the printers and the labels.
- The work of the technician is under the close surveillance of a pharmacist.



Administration to inpatient from the Nurses' Station



The main objective is to achieve the five well-known rights:

- Right patient,
- Right drug,
- Right route,
- Right time
- and Right dose



The role of the Nurses in the Traceability Process

- is fundamental in the HA- programme.
- Prior to administering the medication to a patient, **nurses read the barcode of the medicine dispensed by the pharmacy.**
- Then they confirm usage of the drug in the electronic system.

Electronic prescription orders at 3 p.m.

Farmacia - Haydee Wimmers :: Historia Clínica de Internación (HCI) ::

1 **Consulta**

Pabellón: Servicio: Probable Egreso:

Paciente: Ingreso: Habitación: Ing/Días:

Internados en Pabellón

Habit. Cama	Paciente	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	0	s/h
IEP 450	VINITSKY HORACIO LUIS			E				E																		
ITE 451	KRAENZLEIN JUAN SANTIAGO							E																		
IE 452	PELSMAJER DELIA REGINA							E																		
	OCAMPO ALEJANDRO MARIA																									
ITE 455	NUÑEZ RICARDO SEBASTIAN																									
E 456	MANZUR GLADYS BEATRIZ																									
	DARBESIO HECTOR																									
IE 458	CHERVO NILDA TERESA																									
IE 459	CHAHER RENEE																									
IE 460	PETROSINO LUCIA TERESA																									
E 461	LORDI MAGDALENA TERESA																									
C 462	PEÑA HERNANDEZ RAFAEL																									
ITE 463	MERANI JUAN ANTONIO																									

- Agenda vencida mayor a 60 minutos
- Agenda vencida entre 0 y 60 minutos
- Agenda pendiente
- Agenda cumplida totalmente
- Agenda cumplida parcialmente
- Indicaciones sin horario

Agenda: - Hoy + Detalle -->

Asignar Cama Probable Egreso Realizar Traslado Enviar Pedido Pedido Pabellón

C: Internado con acompañante. E: Internado con solicitud de estudios complementarios.
 P: Internado con items pendientes de pedido. T: Internado con solicitud de traslado.
 A: Internado con prealta. I: Internado con interconsultas pendientes

NOTA: El refresco de los paneles se realiza en forma automática cada 60 segundos.

Sugerencias!

Detalle de Agenda

Hora Programada	Medicación
06/09/2013 20:00	KEPPRA IV VIAL AMP
06/09/2013 20:00	FENOBARBITAL 100 MG AMP
06/09/2013 20:00	CLEXANE 40 MG JER PRELL

Indicaciones: Administrar 3 AMPOLLAS por vía EV a las 20 y 8hs.

Cumplido Por:

Hora (marcado): Hora (cumplido):

Medicación trazable

No Cumplido Cumplido Volver

Ingreso de Códigos de Trazabilidad

Debe ingresar 3 código/s de trazabilidad para **KEPPRA IV VIAL AMP** utilizando el lector de códigos de barra.

Código de Trazabilidad

<input checked="" type="checkbox"/>	<input type="text"/>
<input checked="" type="checkbox"/>	<input type="text"/>
<input checked="" type="checkbox"/>	<input type="text"/>
<input checked="" type="checkbox"/>	<input type="text"/>
<input checked="" type="checkbox"/>	<input type="text"/>



Continuar Cancelar

Dispensation to outpatient from Outpatient HA-Pharmacy:

Scan reveals possibility of counterfeit, expired
and recalled medication



Bill that the outpatient receives with GTIN/serial after buying his medicine

 <p>Hospital Alemán Deutsches Hospital Pueyrredon 1640 - (C1118AAT) Buenos Aires Tel: 4821-1700 FAX 4805 - 6087</p>		X		<table border="1"> <tr> <td>FECHA</td> <td>HORA</td> <td>DUPLICADO</td> </tr> <tr> <td>06/09/13</td> <td>08:39</td> <td></td> </tr> </table>		FECHA	HORA	DUPLICADO	06/09/13	08:39															
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<p>IVA RESPONSABLE INSCRIPTO</p>		<table border="1"> <tr> <td>COMPROBANTE INTERNO</td> <td>NUMERO</td> <td>Pagina</td> </tr> <tr> <td></td> <td>487341</td> <td>1 1</td> </tr> </table>		COMPROBANTE INTERNO	NUMERO	Pagina		487341	1 1	<p>CUIT N° 30-54584303-6 Ing. Brutos Conv. Mult N° 901-186139-5 C.N.P.S.P N° 0020029 - Inicio Actividades 2/3/1867</p>															
COMPROBANTE INTERNO	NUMERO	Pagina																							
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<table border="1"> <thead> <tr> <th>DESCRIPCION</th> <th>UNIDAD</th> <th>PRECIO UNITARIO</th> <th>CANTIDAD</th> <th>PRECIO TOTAL</th> </tr> </thead> <tbody> <tr> <td>TOPAMAC 50 MG COMP X 28 (01)07795314029986(21)G717061051</td> <td>COMP</td> <td>8.95</td> <td>28</td> <td>250.60</td> </tr> <tr> <td>TOPAMAC 100 MG COMP X 60 (01)07795314027784(21)G116056233 (01)07795314027784(21)G950358695</td> <td>COMP</td> <td>11.94</td> <td>120</td> <td>1432.80</td> </tr> <tr> <td>Descuento 100%</td> <td></td> <td></td> <td></td> <td>-1683.40</td> </tr> </tbody> </table>		DESCRIPCION	UNIDAD	PRECIO UNITARIO	CANTIDAD	PRECIO TOTAL	TOPAMAC 50 MG COMP X 28 (01)07795314029986(21)G717061051	COMP	8.95	28	250.60	TOPAMAC 100 MG COMP X 60 (01)07795314027784(21)G116056233 (01)07795314027784(21)G950358695	COMP	11.94	120	1432.80	Descuento 100%				-1683.40	<p style="text-align: center; transform: rotate(-30deg); font-weight: bold;">POR FAVOR, DEVOLVER FIRMANDO ESTE DOCUMENTO</p>			
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MEDIO DE PAGO	IMPORTE																								
<p>C.A.I. Fecha Vto.</p>																									

The patient can validate the legitimacy of the medicine at ANMAT's webpage before consuming it.



Conclusion



clover

- The system is focused on guaranting genuine products, **preventing counterfeit, fraud and smuggling.**
- It gives greater transparency, safety and quality to the healthcare supply chain.

To continue improving the traceability process in the hospital it is essential...

- to train the personnel constantly, keeping a great compromise between all members of the multitask team.
- The continuous improvement create confidence, in patients and Management that the drug fulfills the **quality requirements**.



The New Global Health

...reflects the realities of globalization, especially the increased movement of persons and goods...



“People are beginning to understand there is nothing in the world so remote that it can’t impact you as a person.”

William H. Foege, Director, US Centers for Disease Control, 1977–1983

Emerging Infectious Diseases • www.cdc.gov/eid • Vol. 19, No. 8,
August 2013

In Hospital Alemán:



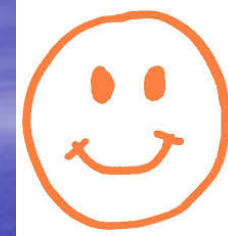
- decisions about the traceability process are first taken with patient safety in mind,

but...

- it is a daily challenge !!



As an industry expert described recently
when implementing serialisation:



"Serialisation is like having children... people tell you what to expect, but you don't know until you have your own..."



**Introduction for the Pharma-IQ's Serialisation and traceability
Conference – Geneve (6-7th Nov 2013)*

