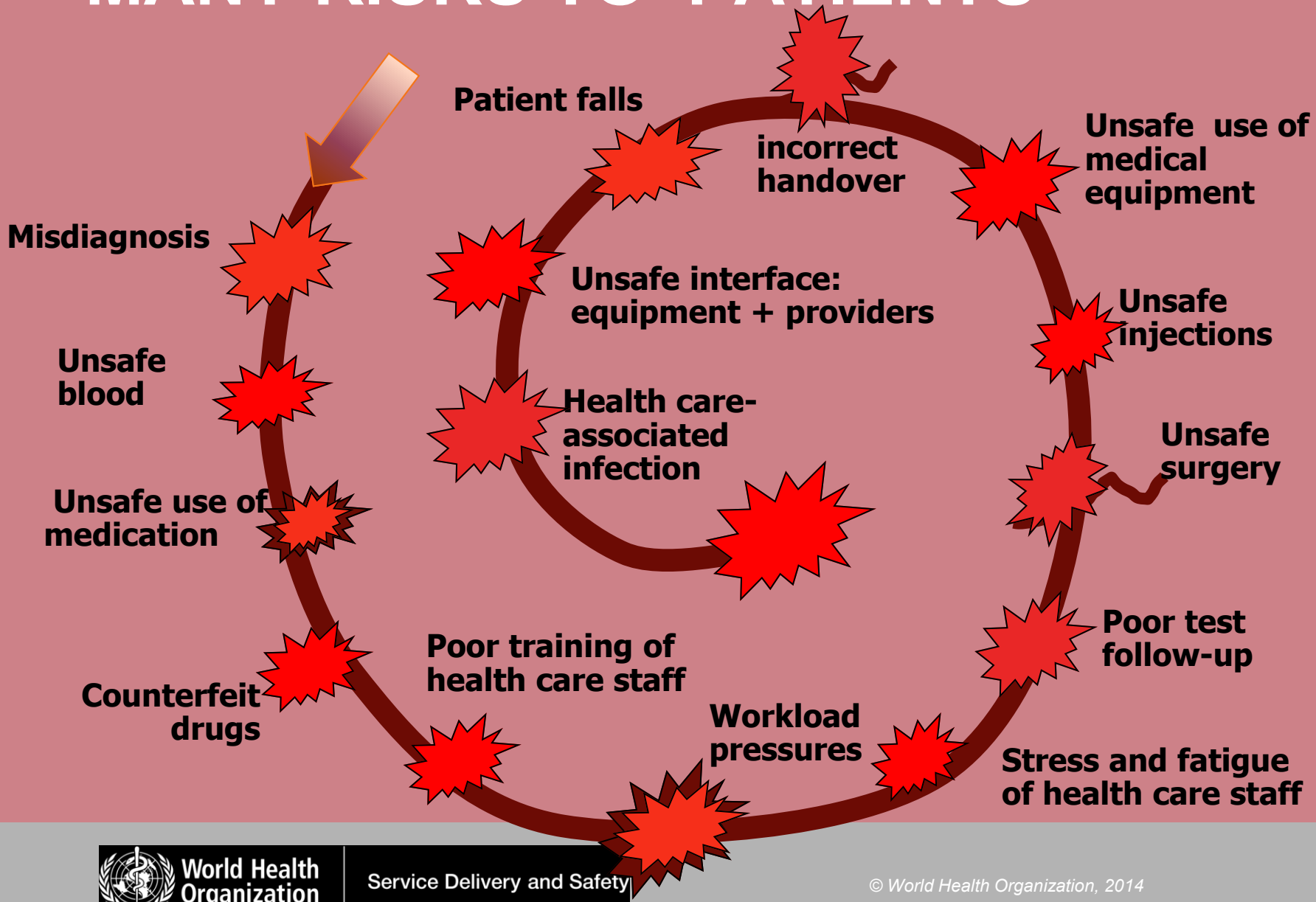
PATIENT SAFETY CHALLENGES

Dr Agnès Leotsakos

World Health Organization | Service Delivery and Safety

MANY RISKS TO PATIENTS



PATIENT SAFETY CHALLENGES

- WHO global study of burden of harm to patients (2009)
- Identified types and causes of AE
- Most evidence comes from developed and little from developing countries. Main WHO findings:

A) **AE/ Errors** • **related to unsafe medical care**

B) **Structural factors contributing to unsafe care**

C) **Poor processes contributing to unsafe care**

Main findings:
Unsafe care is everywhere

PATIENT SAFETY: AREAS FOR CRITICAL INTERVENTION

Much can be improved through patient safety interventions

- **Interventions for unsafe medical care**: address HCAI, med. safety, unsafe surgery, unsafe blood, unsafe injections etc

  Have an immediate impact

- **Improvements on underlying structural factors:** use of accreditation, regulation, training/education of HC workforce, addressing fatigue and stress, workload pressures, improving communications and efficiency HC teams

  Have lasting impact

- **Improvements on underlying processes of care:** misdiagnosis, test follow up, counterfeit drugs, involvement of patients etc

  Have long-term impact

It is likely that a combination of efforts in the 3 areas is needed to improve patient safety

AE/ERRORS RELATED TO UNSAFE MEDICAL CARE

1. **Unsafe medications/treatment ***
2. Injuries due to medical devices
3. **Surgical and anaesthesia errors ***
4. **Health care-associated infection ***
5. **Unsafe injections ***
6. **Unsafe blood products ***
7. **Pregnant women & newborns ***
8. Injuries from patient falls
9. **Poor care for elderly ***

* Areas addressed with WHO interventions (solutions)

1. UNSAFE MEDICATIONS/ TREATMENT

- 1.5 million patients are harmed and thousands are killed every year in USA
- 67% of patients' medication histories have errors
- 10% of patients in acute care settings in developed and transitional countries experience an ADE
- 28–56% of ADE are preventable

- **Use standardized protocols for prescription, use, administration etc**
- **Computerized physician prescribing can be used to prevent ADE. This could be implemented in most countries**

WHO interven-tion/ solution

Case study: Wrong medication in the labour ward

- Mary, 25y, primipara, at 32 weeks had contractions every 8 min
- Went to ER, obstetrician recommended a tocolytic drug infusion to decrease uterine activity
- All midwives were busy and case was given to student midwife to provide infusion
- Student failed to assess fundal height
- Staff midwives were not available to assess
- Student prepared infusion with OXYTOCIN instead
- Error not recognized and Mary gave birth hours later
- Baby had severe breathing problems and died

2. AE/INJURIES DUE TO MEDICAL DEVICES

- Devices: simple or complex
- Used in conjunction with others and with drugs
- Categorized into:
  - ✓ manufacturer-related errors
  - ✓ user-related errors (staff fatigue, busy, under-trained)
  - ✓ use or design errors (design deficiencies provoke errors)
- More than 1 million events/year in USA
- AE are a problem in developing countries, where medical equipment is often unusable owing to lack of resources

- Surveillance programmes to track the types, frequency and clinical settings of events would be a first step to understand impact on patient safety and design of safety interventions

- In-depth staff training on device operation/usage

Misconnection of medical gases: ventilating with nitrous oxide and not O2 -anesthesia

October 2012

- 9-year Salah went to hospital for a routine intervention
- After receiving general anesthesia he became cyanotic so an endotracheal intubation was done - this did not improve the condition and after 17 minutes Salah passed away …
- ..late enough because the anesthesiologist discovered that he was ventilating Salah all the time with **Nitrous Oxide** and not **Oxygen**. The source of gas was mixed up

- Engineers, years back, made it impossible to mix up gases by providing a different connection pin so that oxygen outlet can never be connected to nitrous oxide
- Still the system in the "state of the art hospital "failed to save Salah" he passed away … from a simple error.

3. SURGICAL AND ANESTHESIA ERRORS

- **Surgical errors**: wrong site, wrong patient, wrong organ, SSI, venus thromboE, anesthesia errors
- 7 m surgical complications, 1 m deaths/year worldwide
- In US: 50 cases of unsafe surgery/week (informal data)
- In resource-poor countries: surgical errors account for 50% of all adverse events; preventable 74% of the time

WHO strategy :

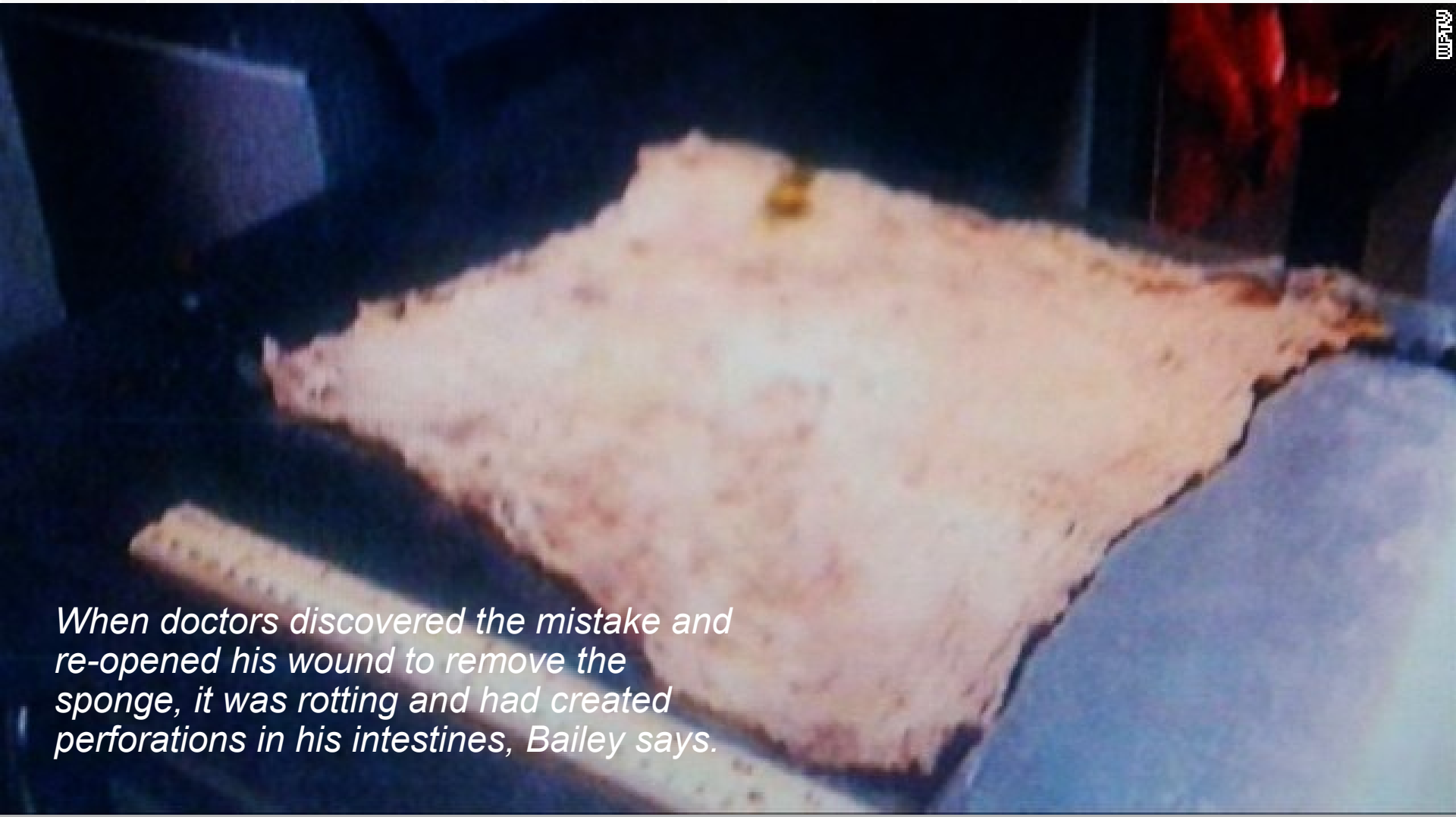
Use of Safe Surgery Checklist

WHO interven-tion/ solution

Surgical souvenirs: Miscounts of equipment used and left inside a patient during surgery

CNN Health: http://us.cnn.com/2012/11/05/health/medical-mistakes-nov/index.html?hpt=hp_t4

Surgical souvenirs: Miscounts of equipment used and left inside a patient during surgery



When doctors discovered the mistake and re-opened his wound to remove the sponge, it was rotting and had created perforations in his intestines, Bailey says.

CNN Health: http://us.cnn.com/2012/11/05/health/medical-mistakes-nov/index.html?hpt=hp_t4

Operating on the wrong body part

This boy needed an eye operation. The surgeon cut into the left eye instead of the right. According to his mother, the surgeon told her that she had lost her sense of direction and didn't realize she'd operated on the wrong eye until after the operation

CNN Health: http://us.cnn.com/2012/11/05/health/medical-mistakes-nov/index.html?hpt=hp_t4

4. HEALTH CARE-ASSOCIATED INFECTION

- 1 in 4 patients in intensive care will acquire an infection during a stay in hospital (worldwide)
- Doubled in developing countries(25% - more than 40%)
- 5–15% of patients admitted to hospitals get HCAI (developed countries)

WHO strategy :

- regulation and implementation of control measures (5 moments for hand hygiene-

- education of health-care workers

- well-organized surveillance system

WHO interven-tion/ solution

Health Care-Associated Infection

Josh fractured his skull and broke his leg in a skydiving accident. He was getting better in the hospital when he caught HCAI in the hospital. He died after doctors were powerless to fight HCAI.

CNN Health: http://us.cnn.com/2012/11/05/health/medical-mistakes-nov/index.html?hpt=hp_t4

5. UNSAFE INJECTIONS

- Unsafe injections: 33% of new HBV infections, 42% of HCV and 2% of all new HIV infections
- Unsafe injections cause1.3 million deaths/ year
- 40 % of injections given with syringes and needles reused without sterilization (worldwide); in some countries it is 70%

WHO strategy :

- Increase use of safety engineered injection devices

- National approaches to reduce overuse of injections

- Use of needle stick injury prevention technology

- Changing the behaviour of HCW and patients

- Managing waste safely of injection materials

WHO interven-tion/ solution

6. UNSAFE BLOOD

Crucial safety issues in blood transfusion are:

- ✓ poor access to blood and blood products when required
- ✓ unsafe blood and blood products, with risk for transfusion-transmissible infections, HIV and HBV and HCV
- ✓ poor laboratory procedures for testing donated blood for infection, blood group and compatibility testing between the donor and the recipient
- ✓ unsafe transfusion practices at the patient's bedside

- Well-organized programme of voluntary blood donation and assessing suitability of donors

- Screening for HBV, HCV, HIV,

- Rational + safe transfusion of blood to right pati

WHO interven-tion/ solution

7. PREGNANT WOMEN AND NEWBORNS

- 7.6 million perinatal infant deaths/ year and 500 000 deaths in women due to pregnancy or childbirth (99% in developing countries)
- Maternal and infant mortality rates attributed to lack of access to medical facilities and unsafe care

  - **Improving patient safety among pregnant women and newborns is critical to reducing morbidity and mortality rates.**

  - **WHO strategy: Safe childbirth checklist**

WHO interven-tion/ solution

8. INJURIES FROM PATIENT FALLS

- Patient falls in hospitals are the commonest patient safety injury reported
- USA: 10% of fatal falls for the elderly occur in hospitals
- These falls result in injuries, increased lengths of stay, malpractice lawsuits, and more than $4,000 in excess charges per hospitalization
- Outcomes: injuries, prolonged hospitalization and legal liability
- In UK: 2/ 5 patient safety events, with costs of £ 92 000 /year

Improve use of physical restraints to reduce the incidence of falls and the severity of injury. Reduce use of psychoactive drugs in the elderly.

9. POOR CARE FOR THE ELDERLY

- The elderly and patients with dementia have increased risk for adverse events in every clinical setting
- Adverse drug events disproportionately affect the elderly (changed metabolism; complex medication regimens etc)
- Rate of 10 ADE/100 resident–months in US nursing homes
- Falls, decubitus ulcers, delirium, etc

- Good communication on treatments for the elderly (among multidisciplinary teams) caring for elderly patients

- Expertise to address the real needs of the elderly

- Education and training of HWP

WHO interven-tion/ solution

Lost Patients: Patients with dementia are prone to wandering

Nursing home patient Mary C. turned up missing during a bed check. She was found four days later locked in a storage closet. She was severely dehydrated and died soon after. The family's lawyer says Cole, who suffered from Alzheimer's disease, wandered into the closet and got trapped.

STRUCTURAL FACTORS CONTRIBUTING TO UNSAFE CARE

1. No regulation, accreditation, quality improvement strategies
2. No culture of safety
3. **Poor training, education of HCW**
4. Stress and fatigue of HCW
5. Production pressures/ Fast moving environments
6. Lack of appropriate knowledge and its transfer
7. **Devices and procedures with no human factors**

* Areas addressed with WHO interventions (solutions)

1. Accreditation and regulation

- Accreditation and regulation: well suited for achieving patient safety
- **Accreditation:** external entity assesses whether a healthcare organization meets specified standards
- **Regulation:** governmental standards to which health-care providers must adhere
- Regulation: more widespread than accreditation, sets min standards
- New generation of robust strategies and processes for quality of care and safety: six sigma, lean management, change management

Make use of accreditation, regulation, or other strategies to improve quality of care and patient

2. Culture of safety

- **The 'blame culture':** the way health care traditionally managed errors was by 'blaming' individuals
- But **errors have multiple causes** and underlying system failures (Swiss cheese model)
- A positive safety culture is a fundamental of safety

To build a safety culture (structures, practices, processes and systems) the following elements should be considered:

1. **Leadership commitment to patient safety**
2. **Open communication**
3. **Blame-free culture**
4. **Safety focus**
5. **Employee & physician involvement & accountability**

3. Training and Education

- Inadequate numbers of qualified health-care providers and incomplete knowledge about safe clinical practices
- The global health care workforce-100 million persons of which 24 million doctors, nurses and midwives, is the primary resource for making care safer

- Education and training (student + in-service) can help create safer health-care

- Plan for regular training of hospital HCP on Quality Improvement and Patient Safety

WHO interven-tion/ solution

4. Stress and fatigue

- **Extended shifts** increase risk of physicians and nurses making errors
- **Excessive nurse workloads** are associated with increased risks for adverse events:
- Nurses working more than 12 h make up to 3x as many medical errors as those working less than 12 h
- Physicians **working 24-h shifts** make 36% more serious medical errors in patient care and 5x as many serious diagnostic errors
- **Sleep deprivation** of HCP is a source of hazards in care

Set up hospital regulations to reduce working hours of HCP and enforce them (eg. in some EU countries residents can not work more than 80h/week)

5. Production pressures

- Errors happen when the capacity of a facility to care for patients is exceeded
  - large number of patients (eg. overcrowding in ER)
  - fewer HC providers (eg. nurse-patient ratios)
  - reduction of work space
- Providers: increased cognitive workload → human error

- Generate knowledge on links between production pressures and safety

- Optimal nurse-patient ratios data still inconclusive

6. Lack of knowledge and appropriate transfer of knowledge

- Knowledge (best practices, clinical guidelines, operating medical equipment, reference materials, patient records, etc) at different levels affects how it is transferred
- Communication problems were identified as the cause of 70% of sentinel events (study 2005)
- Good communication, effective teamwork and patient handovers between providers is critical to patient safety

- Effective communication: techniques used:

- **Call out, read-back confirmation, ISHBAR(**(**I**ntroduction, **S**ituation, **B**ackground, **A**ssessment, **R**ecommendation),
- **interruption-free 'time-outs'**
- **cross-monitoring**

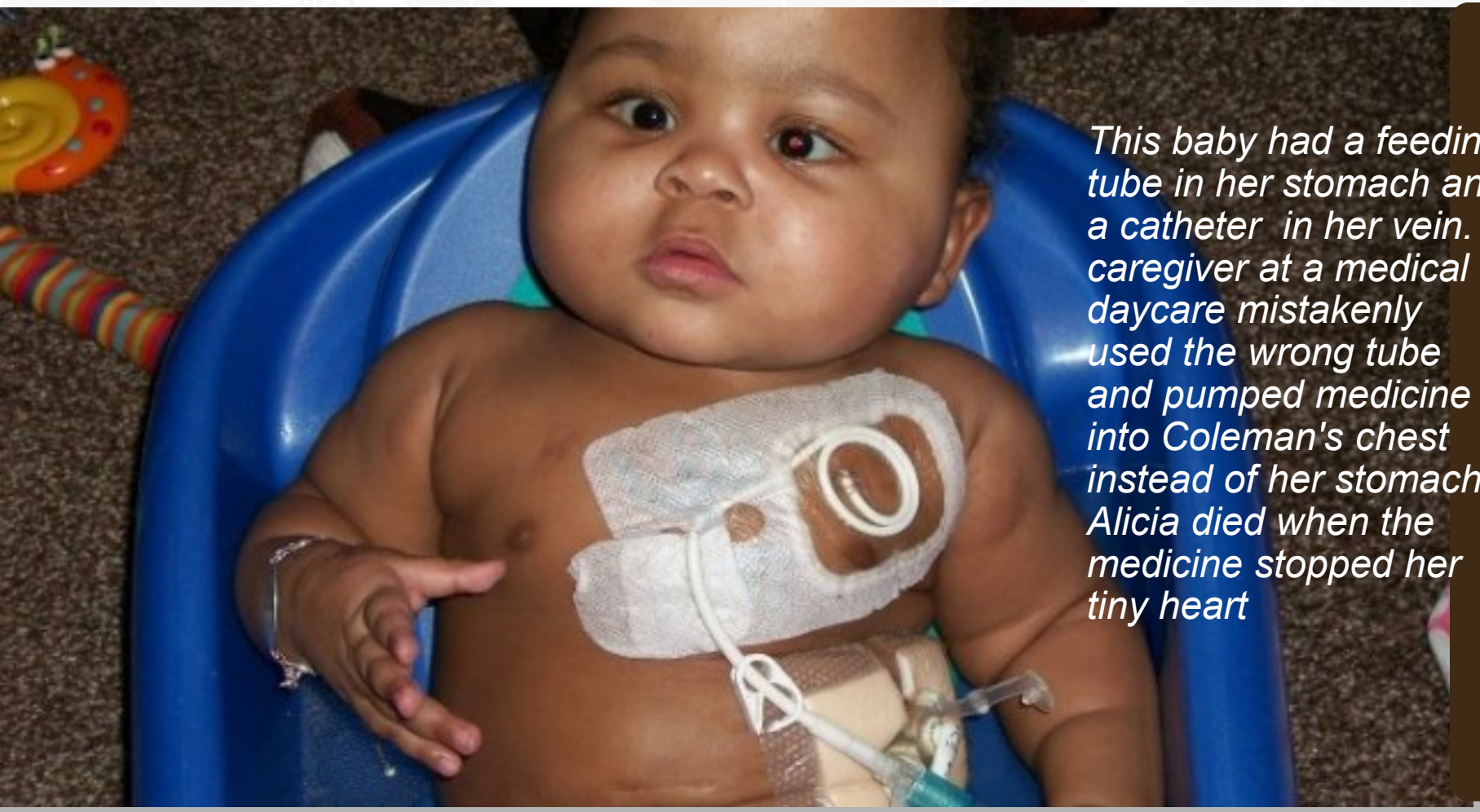
7. Devices and procedures with no human factors

- Human factors engineering: interaction of individuals at work, their tasks and the workplace
- Interface between HCP with processes, tools and equipment in the workplace e.g.
  - packaging/prescribing/administering medications, human-machine interactions etcg
- Problems with human factors design are everywhere in equipment, work areas and care processes contributing to errors

Some principles for safety include:

- **Consistent design of equipment controls, clear and understandable warnings/labels, intuitive design operations**
- **Avoid reliance on memory, make visible equipment instructions, review-simplify- standardise care processes and procedures, routinely use checklists etc**

Bad design of chest and feeding tubes: medicine meant for the stomach goes into the chest



This baby had a feeding tube in her stomach and a catheter in her vein. A caregiver at a medical daycare mistakenly used the wrong tube and pumped medicine into Coleman's chest instead of her stomach. Alicia died when the medicine stopped her tiny heart

CNN Health: http://us.cnn.com/2012/11/05/health/medical-mistakes-nov/index.html?hpt=hp_t4

POOR PROCESSES CONTRIBUTING TO UNSAFE CARE

1. Misdiagnosis
2. Poor test follow up
3. Counterfeit drugs
4. Poor/No involvement of patients in their care

1. Misdiagnosis

- Misdiagnosis is a huge patient safety challenge
- Six areas of importance are:
  - misdiagnosis of major infectious diseases (eg malaria, TB, HIV)
  - misdiagnosis of life-threatening medical, surgical, trauma emergencies in time
  - knowledge failures in making the correct diagnosis
  - delays and misdiagnosis of cancer
  - errors in interpreting radiological images, specimens etc
  - poor follow-up on the results of diagnostic tests

Strategies to minimize diagnostic errors:

- **reduce dependence on human memory (use of IT)**
- **blame-free learning from diagnostic errors**
- **new processes to minimize delays of diagnostic emergencies**
- **training to improve clinicians knowledge and skills**

2. Poor test follow up

- Taking place both in inpatient, transition to outpatient and outpatient settings and resulting in serious lapses in patient care
- Delays and miscommunication of test follow up particularly in resource-poor countries
- Poor test follow up results in significant number of adverse events (e.g. delayed initiation of treatment)

Improvement actions include:

- **Use of rapid diagnostic testing (when relevant)**
- **Standardise processes of communication between labs, doctors and patients**
- **Patients express preference on how providers will contact them**

Case study: delays in diagnosis /treatment

-Pat Sheridan had surgery to remove a tumor in his neck. He was told the tumor was benign

-Unknown to Pat the pathologist was conducting further tests that would not be ready for 3 weeks after surgery

-The pathology report said “sarcoma”

-The surgeon never saw the final report nor did Pat Sheridan. The report was filed in the physician’s office

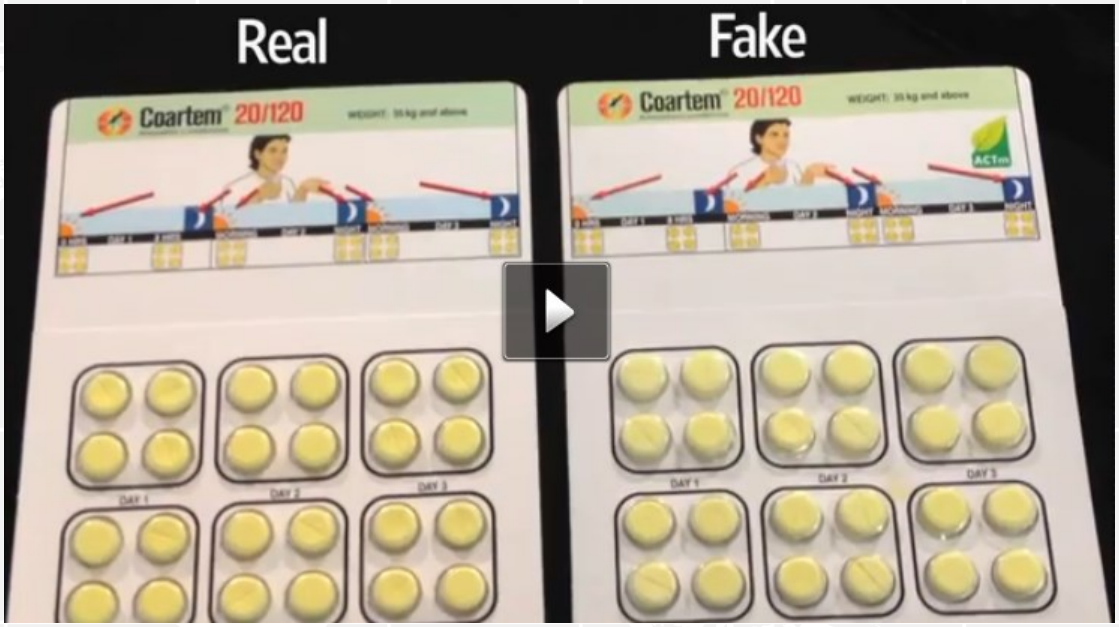
- Pat died six months later at the age of 45. Had Pat’s cancer been treated after the first surgery, he would likely be alive today.

3. Counterfeit and substandard drugs

- Counterfeit drugs are those ‘produced with an intention to cheat’, which include:
  - mislabelling
  - missing or wrong active ingredients
- 10% of the global medicines market is counterfeit; its commerce grows 13% annually; counterfeit drug sales grow at nearly twice the rate of legitimate pharmaceuticals
- In 2010 this illegal business generated $75 billion
- In China, alone 200,000 to 300,000 people die each year due to counterfeit medicines- the true number of cases is likely to be far higher.

3. Counterfeit and substandard drugs

Counterfeit drugs are threatening to undermine years of progress in tackling malaria in Africa. A WSJ investigation followed the route of drugs from Congolese exporter in Guangzhou Port to Angola



- **Improvement efforts include:**

- **policy and drug regulatory authorities need to exercise severe control of manufactures, importation, distribution and sale of counterfeit medicines**
- **vigilance by health care providers and pharmacists on the origin of medicines available in the market**

4. Lack of involvement of patients in patient safety

Patients have a role to play by giving providers insight:

- diagnosis, medications history, prevent adverse events from happening

Improvement actions include:

- Increasing public awareness about patient's role in decreasing adverse events/errors
- Collaborate with patient associations
- Improve health literacy of patients and their families: provide information, establish websites, share information with patient associations etc
- Hold meetings between HCP and patients for sharing patient experiences , lessons learned and safety suggestions

CONCLUDING: PATIENT SAFETY CHALLENGES

A) **AE/ Errors**

- **related to unsafe medical care**

Interventions for unsafe medical care: HCAI, med. safety, unsafe surgery, etc **have an immediate impact**

B) **Structural factors contributing to unsafe care**

Improvements on structural factors: regulation, culture of safety, training/education of HC workforce, improving communications **have lasting impact**

C)

Poor processes contributing to unsafe care

Improvements on processes of care: misdiagnosis, test follow up, involvement of patients etc **have long-term impact**

It is likely that a combination of efforts in these 3 areas is needed to improve patient safety

Thank you