



高警訊藥品與藥物安全

High-Alert Medications & Drug Safety

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Outline

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Definition of High-Alert Medications

- 定義:

Drugs that bear a heightened risk of causing significant patient harm when they are used in error.

凡經由不當使用或管理, 會有很高的機率對病人造成嚴重傷害的藥物, 就稱為高警訊藥物 (High-Alert Medications)



High-Alert Medications

- Guideline

- Joint Commission on Accreditation of Healthcare Organizations (美國醫療機構評鑑聯合會, 簡稱 **JCAHO**) 2010 National Patient Safety Goals : Goal 3 - Improve the safety of using medications
- **ISMP** (Institute for Safe Medication Practice , 美國用藥安全作業協會) 之 list of High-Alert Medications

應提高警覺之19類藥物

Classes/Categories of Medications	
adrenergic agonists, IV (e.g., epinephrine, phenylephrine, norepinephrine)	epidural or intrathecal medications
adrenergic antagonists, IV (e.g., propranolol, metoprolol, labetalol)	hypoglycemics, oral
anesthetic agents, general, inhaled and IV (e.g., propofol, ketamine)	inotropic medications, IV (e.g., digoxin, milrinone)
antiarrhythmics, IV (e.g., lidocaine, amiodarone)	liposomal forms of drugs (e.g., liposomal amphotericin B)
antithrombotic agents (anticoagulants), including warfarin, low-molecular-weight heparin, IV unfractionated heparin, Factor Xa inhibitors (fondaparinux), direct thrombin inhibitors (e.g., argatroban, lepirudin, bivalirudin), thrombolytics (e.g., alteplase, reteplase, tenecteplase), and glycoprotein IIb/IIIa inhibitors (e.g., eptifibatide)	moderate sedation agents, IV (e.g., midazolam)
cardioplegic solutions	moderate sedation agents, oral, for children (e.g., chloral hydrate)
chemotherapeutic agents, parenteral and oral	narcotics/opiates, IV, transdermal, and oral (including liquid concentrates, immediate and sustained-release formulations)
dextrose, hypertonic, 20% or greater	neuromuscular blocking agents (e.g., succinylcholine, rocuronium, vecuronium)
dialysis solutions, peritoneal and hemodialysis	radiocontrast agents, IV
	total parenteral nutrition solutions

-Institute for Safe Medication Practices 2008

應提高警覺之13項特定藥物

Specific Medications
colchicine injection***
epoprostenol (Flolan), IV
insulin, subcutaneous and IV
magnesium sulfate injection
methotrexate, oral, non-oncologic use
opium tincture
oxytocin, IV
nitroprusside sodium for injection
potassium chloride for injection concentrate
potassium phosphates injection
promethazine, IV
sodium chloride for injection, hypertonic (greater than 0.9% concentration)
sterile water for injection, inhalation, and irrigation (excluding pour bottles) in containers of 100 mL or more

-Institute for Safe Medication Practices 2008



高危險性藥品安全管理辦法



Strategies for high-alert medications

- High-alert medications require special safeguards to reduce the risk of errors.
 - **Improving access to information** about these drugs
 - **Limiting access** to high-alert medications
 - Using **auxiliary labels** and **automated alerts**
 - **Standardizing** the ordering, storage, preparation, and administration of these products
 - Employing redundancies such as automated or independent **double checks** when necessary

-Institute for Safe Medication Practices 2008



高危險性藥品安全管理辦法

- 給藥者應遵守三讀五對。
- 藥品藥盒上的藥籤應標示清楚，包括藥品名稱(中英文)藥理作用。
- 適當位置分開儲存，特定藥品應上鎖。
- 依業務需求設定存放庫存量。
- 專人管理且每日點班。
- 建立高危險藥物查核辦法、高危險藥物查核表。



高危險性藥品安全管理辦法

- 病房單位不存放高濃度電解質製品(濃度>0.9%)
- 高濃度電解質藥品在醫院內領用必須有作業標準化及限制的規定
- 高濃度電解質藥品必須對劑量作管制,藥師做監控
- 每年至少檢視及確認一次院內使用藥品中,外觀相似或發音相似的藥品清單並採取易導致混淆錯誤的防範措施
- 麻醉藥品依[麻醉藥品管理辦法]管理

高危險性藥品安全管理辦法

管理措施:

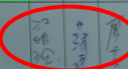



- 集中專區管理, 以紅色之警告標示提醒藥師注意, 並於儲存位置加貼紅底黃字之注意標籤
- 每月不定期一次, 由藥劑科執行高危險藥物管理安全查核。每次查核結果呈報於藥物安全小組會議
- 需雙重核對之「高危險性藥物」UDD給藥後, 於交換車時配合確實點交簽收並在高警訊交接紀錄單上雙重簽名, 一欄為藥事人員簽名, 另一欄為護理人員簽名。
- 提供護理人員相關資訊, 加強對此藥物的認識, 以增進病人的用藥安全

高警訊藥品管理及注意事項

* 高危險藥物安全管理查核表

台北縣立醫院 高危險性藥物安全管理查核表

- 一、依據：台北縣立醫院 高危險性藥物安全管理辦法
- 二、對象：備有高危險性藥物之單位
- 三、每月不定期一次, 由藥劑科執行
- 四、每月查核結果於病人安全管理委員會報告
- 五、查核內容依據訂定的執行辦法內容

單位	日間病房	七病房	六病房	五病房	麻酔科	加護病房	血液透析	胃鏡室	碎石中心	放射科	急診室	外科門診
存放位置上鎖	✓	X	X	X	X	✓	X	✓	X	✓	✓	✓
存放的庫存量正確	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
標示的內容	✓	X	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
專人管理	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
每日點班	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
查核者簽名	<div style="display: flex; justify-content: space-between;"> <div style="border: 1px solid red; border-radius: 50%; padding: 2px;">  </div> <div style="border: 1px solid red; border-radius: 50%; padding: 2px;">  </div> </div>											
查核日期:	<div style="display: flex; justify-content: space-between;"> <div style="border: 1px solid red; border-radius: 50%; padding: 2px;">  </div> <div style="border: 1px solid red; border-radius: 50%; padding: 2px;">  </div> </div>											

護理站受查核者簽章

藥劑科查核者簽章

96年7月制定

高警訊藥品管理及注意事項

各護理站高警訊藥品交接紀錄單

日期	次別	藥品名	數量	藥師簽章	護理人員簽章
1/3	I-11	KCL	1	張嘉祥	
	I-11	KCL	4	張嘉祥	

本院「高危險性藥物」經篩選為 15% KCL 20ml Amp、3% NS 500ml Bot、10% Magnesium Sulfate 20ml Amp、Morphine 10mg 1ml Amp、Demerol 50mg 1ml Amp、Heparin 5000U/ml 5ml vial、Humulin N 100IU/ml 10ml vial、Humulin R 100IU/ml 10ml vial、Fentanyl Amp、Alfentanil Amp、Amiodarone Amp、2% Xylocaine 5ml Amp、Methotrexate vial、Coumadin tab.

各樓層每日藥師記載給予高警訊藥物名稱及數量

各樓層護理站核對高警訊藥物名稱及數量無誤後需簽章

高危險用藥安全防範識別管理措施

管理措施：

- 高危險藥品制定全院統一標籤並公告於院內網站。
- 藥盒上的標籤應標示清楚，包括藥品名稱(中英文)藥理作用並有高危險藥品識別標示。
- 儲存位置有高危險藥品識別警示標示。
- 管制藥品儲存位置加有管制藥品識別警示標示。
- 疫苗及生物製劑儲存位置加有疫苗及生物製劑之識別警示標示。
- 包裝或外觀相似藥品不擺放在一起，儲存位置加有相似藥品識別警示標示
- 字體相似或發音相似者應分開放置，依相似藥品管理辦法規定實行。

各種危險性藥品識別標示

高危險特定藥品	識別標示：	藥名加註	●	紅底黃字標籤	標籤註記：	危
高危險藥品	識別標示：	藥名加註	◆		標籤註記：	危
化療之注射用藥	識別標示：	藥名加註	化◆		標籤註記：	化
T P N注射用藥	識別標示：	藥名加註	◇		標籤註記：	T
管制藥品	識別標示：	藥名加註	★	紅底黃字標籤	標籤註記：	管
毒劇藥品	識別標示：	藥名加註	▲		標籤註記：	毒
生物製劑 疫苗	識別標示：	藥名加註	△		標籤註記：	疫
生物製劑 血清	識別標示：	藥名加註	△		標籤註記：	清
藥名相似藥品	識別標示：	藥名加註	# * § ※	綠底標籤	標籤註記：	名
外觀相似藥品	識別標示：	藥名加註	○□ ◎⊕	綠底標籤	標籤註記：	觀

特定藥物危險因素及其防範方法

藥物項目	危險因素	防範重點
Amiodarone Amp	劑型看錯，易與口服藥混淆	建立雙重核對程序
Heparin 5000U/ml 5ml vial	1. 濃度及劑量標示不明確 2. 使用不尋常劑量	1. 建立雙重核對程序 2. 使用單一劑量
Humulin N 100IU/ml 10ml vial Humulin R 100IU/ml 10ml vial	1. 沒有劑量核對的機制 2. 單位劑量看錯、IU及ML看錯	1. 建立核對制度 2. 訂定查核程序
2% Xylocaine 5ml Amp	易與2% Xylocaine 20ml vial混淆	1. 建立雙重核對程序 2. 位置分開放
10% Magnesium Sulfate 20ml Amp	1. 使用不尋常的濃度 2. 不尋常的治療方式 3. 不當性的放置位置	1. 劑量由藥局作監控 2. 護理站限量管制 3. 依規定位置上鎖管制 4. 新人訓練內容：認識藥物
15% KCL 20ml Amp	1. 使用不尋常的濃度 2. 不尋常的治療方式 3. 不當性的放置位置	1. 劑量由藥局作監控 2. 護理站限量管制 3. 依規定位置上鎖管制 4. 新人訓練內容：認識藥物
3% NS 500ml Bot	1. 與玻璃瓶0.9% NS擺放在一起 2. 與其他同廠牌500ml放在一起	1. 護理站限量管制 2. 依規定位置上鎖管制 3. 新人訓練內容：藥物指導
Coumadin tab	易與他藥產生一級藥物交互作用	1. 教育對藥物的交互作用專業知識 2. 電腦建立一級藥物交互作用警訊

特定藥物危險因素及其防範方法

*麻醉管制藥物危險因素及其防範方法

Morphine 10mg(1ml) Amp Demerol 50mg(1ml) Amp	1. Morphine 與 Demerol 外觀包裝相似 2. 常被安排同一抽屜上 鎖管理	1. 建立雙重雙人核對程序，核對內容有藥品、劑量、途徑 2. 專人管理及點班 3. 限量管制 4. 一種藥品放置一個盒子，標示清楚 5. 教育對藥物的認識
Fentanyl Amp Alfentanil Amp	1. Alfentanil 當作 Fentanyl 2. 使用不尋常劑量	1. 教育對藥物的認識 2. 建立雙重核對程序 3. 不能將此藥放在一起

本院高警訊藥品品項

<ul style="list-style-type: none"> ●Adrenergic agonists, IV (epinephrine) 	<ul style="list-style-type: none"> ◆針劑Bosmin 1mg/1cc(Adrenalin)安得理那 ◆Dopavate(Dopamin)40mg/ml 5ml(多博威) ◆Levophed 4mg/4ml(力復非他注射液) ◆Utamine 12.5mg/ml 20ml (Dobutamine) ◆針劑Yutopar 50mg/5ml
<ul style="list-style-type: none"> ●Adrenergic antagonists, IV (propranolol) 	<ul style="list-style-type: none"> ◆Trandate 5mg/ml 5ml(崙泰低)
<ul style="list-style-type: none"> ●Anesthetic agents, general, inhaled and IV (propofol) 	<ul style="list-style-type: none"> ◆DROPEL 2.5MG/1CC (卓普) ◆Isoflurane(Forane) 100ml ★Ketalar 50mg/ml 10ml ◆Marcaine Heavy 0.5% 4cc麻佳因注射液重型 ◆Marcaine 0.5% 20ml ◆Pentothal 25mg/cc 20ml ◆Provive 1% (普麻敏) ◆Ultane(Sevoflurane)250ml
<ul style="list-style-type: none"> ●Antiarrhythmics, IV 	<ul style="list-style-type: none"> ● Cordarone 150mg/3ml (臟得樂注射液) ● (心律不整用藥) 2% Xylocaine 5cc/AMP
<ul style="list-style-type: none"> ●Antithrombotic agents (anticoagulants) 	<ul style="list-style-type: none"> ◆Actilyse 50mg (TPA) ● Heparin 5000U/cc(Agglutex) 5cc/VIAL ● Warfarin 5mg(Coumadin)(瓦化寧錠)
<ul style="list-style-type: none"> ●Cardioplegic solutions 血液成分及血液代用輸液 	<ul style="list-style-type: none"> ◆Albumin 20% 100ml ◆Plasmanate 5% 250ml(血漿注射劑) ◆Biseko(百合血清蛋白3%) ◆Gelofusine"柏朗"佳樂施注射液 ◆L. M. D. D 500ml

<ul style="list-style-type: none"> IV ●Chemotherapeutic agents化療治療藥物, parenteral 	<ul style="list-style-type: none"> 化◆Abiplatin(ciplatin)10mg 20ml 化◆Adriplastina 10mg (Adriamycin) 化◆Endoxan 200mg 化◆Epicin 10mg 化◆Fluorouracil 5-FU 500mg/ 10ml 化◆Genaxol 30mg 5ml 化◆(自費)Leuplin 3.75mg (GNRH) 化◆Mitomycin-C 2mg 化◆Oxalip 50mg 10ml (oxaliplatin) 化◆Pharmorubicin 10mg 化◆Phyxol 90mg 15ml 化◆Taxotere 20mg/0.5ml 化◆Vepesid 100mg/5ml
<ul style="list-style-type: none"> oral 	<ul style="list-style-type: none"> ◆CASODEX 50MG ◆FT-207(FUTRAFUL)(富多拉富) ◆Tamoxifen 10MG(Nolvadex)(諾瓦得士錠) ◆Ufur(友復膠囊)
<ul style="list-style-type: none"> ●Dextrose, hypertonic, 20% or greater 	<ul style="list-style-type: none"> 20%◆G/W 20ml(VITAGEN)(美達研) 50%◆G/W 20ML(Vitagen)(美達研注射液)
<ul style="list-style-type: none"> ●Dialysis solutions, peritoneal and hemodialysis 	
<ul style="list-style-type: none"> ●Epidural or intrathecal medications 	

<p>●Hypoglycemics, oral</p>	<p>◆Actos 30mg(愛安糖) ◆Amarine 2mg (糖健寧) 降血糖◆Ansures 500MG 1000mg◆Anxoken (諾消糖) ◆Avandia 4mg (梵帝雅) 代賦◆Dail (Glicron)80mg ◆Deglu 50mg(抵克糖錠) ◆Diazone(糖立敏錠)15mg ◆Diamicon MR tab 30mg(岱靈克龍) ◆Euglucon 5mg(佑而康錠) (必樂得)◆GLIDIAB 5mg ◆可利賦錠Glibide 5mg 降血糖500mg◆Glucomine(Glucophage) ◆Antigluco 850mg (Glucophage) 降糖錠 (糖瑞平錠)◆Glurenorm 30mg ◆Glucobay 50mg(糖糖錠) ◆Glutazone 30mg(欣促賦) ◆Gluco Met (克糖美錠) 降血糖◆NovoNorm 1mg(諾和隆錠) ◆Starlix tab. 120mg(使糖立釋) ◆Supernide 1mg (達克糖)</p>
<p>●Inotropic medications, IV (digoxin, milrinone)</p>	<p>● 針劑 Lanoxin (Digoxin)0.5mg in 2ml</p>
<p>●Liposomal forms of drugs (liposomal amphotericin B)</p>	
<p>●Moderate sedation agents, oral, for children (chloral hydrate)</p>	<p>管3 ★Concerta 18mg(專思達) ★Lendormin 0.25mcg(恩多眠) ★Ritalin Tablets 10mg(利他龍) 管4 ★Alepan 15mg(安樂平錠) ★Ativan 0.5mg(安定文) ★Erispan 0.25mg(悉利舒盼) ★德樂丁 Eurodin 2mg ★Mogadon (眠確當)5mg ★Phenobarbital 30MG(苯巴比妥) ★Rivotril 0.5mg(利福全) ★Serenal 10mg(心益) ★Stilnox 10mg(使芬諾斯) ★2mg Diazepam (Valium) Tab (預靜) ★Xanax 0.5mg (粉紅色 Alpraline)(安柏寧) ★(安眠諾登) Zodem tab 10mg ★(熊比克) ZOLON 膠衣錠 7.5mg</p>

<p>●Moderate sedation agents, IV (midazolam)</p>	<p>管4： ★Anxicam inj. 2mg/ml(安心平) ★Dormicum 5mg/ml 3ml(導眠靜) ★針劑 Dupin(Valium) Inj 10mg(樂平)</p>
<p>●Narcotics/opiates, IV, transdermal, and oral (including liquid concentrates, immediate- and sustained- release)</p>	<p>管1： ★Morphine 10mg 1ML AMP 管2： ★Codeine Phosphate 15mg 針劑★Demerol 50MG/1CC AMP ★Fentanyl Citrate 10ml/amp ★ Methadone美沙冬(10mg/ml) ★Rapifen 2ml/amp (Alfentanil) 管4： ★TRAMTOR Inj 50mg/cc 2cc(頓痛特注射液) ★Tramal 50mg(克能達)</p>
<p>●Neuromuscular blocking agents (succinylcholine)</p>	<p>◆Genso(健亞 健舒注射液 10mg/ml) ◆Relaxin 500mg/vial</p>
<p>●Radiocontrast agents, IV</p>	
<p>●Total parenteral nutrition solutions (TPN)</p>	<p>◇Kabiven PI emulsion for inj(克必思) ◇Lipofundin MCT/LCT 20%(力保肪寧) ◇Moriain SN 200cc ◇Nephrosteril 7% 250cc ◇Parenteral A 400cc ◇Parenteral B 400cc ◇Taita NO.2 500cc(台大2號) ◇Taita NO.5 400cc(台大5號) ◇Taita No.4 500ml(台大4號)</p>

2. 特定藥物：	13項
● Colchicine injection	
● Epoprostenol (Flolan), IV	
● Insulin, subcutaneous and IV	(VIAL)●Humulin N 10cc/Vial(中效型)綠色 (VIAL)●Humulin R 10cc/Vial(常規型)黃色 ● Levemir (瑞和密爾諾易寧)100IU/ml 3ml ● Mixtard 30hm 100iu/lcc 10cc(密斯它30) ● NovoMix 30 Penfill 3ml (筆型胰島素)
● Magnesium sulfate injection	● MgSO4 10% 20cc/Amp(magnesium sulfate)
● Methotrexate, oral, non-oncologic use	● Methotrexate(滅殺除癌錠) 2.5mg
● Opium tincture	
● Oxytocin, IV	Oxytocin 10IU/1ml
● Nitroprusside, sodium, for injection	
● 注射用濃縮氯化鉀Potassium chloride for injection concentrate	●KCL 20CC/AMP (氯化鉀注射液)
● 注射用濃縮磷酸鉀Potassium phosphates injection	
● Promethazine, IV	
● 注射用濃縮濃度大於0.9的氯化鈉 Sodium chloride injection, hypertonic, more than 0.9% concentration	●3% Sodium chloride 500cc/BOT
● Sterile water for injection, inhalation, and irrigation (excluding pour bottles) in containers of 100 ml or more	

* 3. 毒劇藥品：	▲Cafergot Tablets (R)(加非葛) ▲秋水仙素 Colchicine 0.5mg(可樂毒) ▲(喜克濱)Cytotec 200mcg (Misoprostol) Digoxin 0.25mg▲Lanoxin隆我心 ▲Eltroxin 0.1mg (Thyroxin)(昂特欣) ▲Ergonovine 0.2mg(縮蘋果酸麥角新鹼) 桃紅色▲Esidri (安血利) ▲Mifegyne(RU486) 200mg(Apano)保諾錠 ▲Pilocarpine oph. soln. 2% 10ml(毛果芸香? 2 雙滋蒙▲Disemone(Primodian Depot) ▲Proges. Terone 50mg 1CC (黃體荷爾蒙) ▲ Sandimmun Neoral(新體睦軟膠囊)25mg ▲T. Toxoid 20cc/Vial(l.c.c)
* 4. 疫苗	自費三合一DPTc 0.5ml△Infanrix △Gardasil(嘉喜)(子宮頸癌疫苗) △Havrix 1440 (自費A肝疫苗)新赫寶克 H. B. V. 1 dose(△Engerix-B)B肝疫苗 △Infanrix-IPV/Hib(自費五合一疫苗) 自費△KKB/KI-Flu "國光/北里"流感疫苗 自費△Priorix 派立克 (M-M-R II)(GSK) △Hiberix (HIB) 0.5cc/vail 自費△Pediaceel(巴斯德五合一疫苗) △Pneumovax 23(肺炎鏈球菌疫苗) △Prevenar(沛兒肺炎疫苗) 水痘疫苗△Varilrix 1dose 自費流感△Vaxigrip 0.5ml
5. 生物製劑(血清)	△Antivenin of d. acutus 百步蛇 △Anti. of B. multicinctus&N. naja兩傘節 △Anti. of Tr. mucrosquamatus&Tr. g.龜殼花
6. 相似藥品： 依 相似藥品管理辦法 執行	




ISMP 2007 survey

ISMP 2007 survey on HIGH-ALERT medications


Differences between nursing and pharmacy perspectives still prevalent

- 770 practitioners, Feb~Apr 2007
 - **Epidural and intrathecal medications** - top ten drugs that practitioners felt should be considered high-alert medications
 - **Epoprostenol, oxytocin, and promethazine IV**- least frequently considered high-alert medications
 - **General anesthetics**- **increase** in the frequency (from 77% in 2003 to 86% in 2007) which respondents felt should be considered high-alert medications
 - **Hypertonic sodium chloride** (from 91% to 83%)and **warfarin** (from 73% to 60%)- **decrease** in the frequency which respondents felt should be considered high-alert medications




ISMP 2007 survey on HIGH-ALERT medications
Differences between nursing and pharmacy perspectives still prevalent

- The **most common** drugs considered high-alert medications in practice sites
 - Parenteral chemotherapy (90%)
 - IV insulin (88%)
 - Potassium chloride for injection concentrate (86%)
 - IV unfractionated heparin (80%)
 - Epidural/intrathecal drugs (79%)
 - Neuromuscular blocking agents (78%)
 - Potassium phosphates injection (77%)



ISMP 2007 survey on HIGH-ALERT medications
Differences between nursing and pharmacy perspectives still prevalent

- The **least common** drugs considered high-alert medications in practice sites
 - Oral hypoglycemics (21%)
 - Colchicine injection (29%)
 - Epoprostenol (39%)
 - Dialysis solutions, peritoneal and hemodialysis (40%)
 - IV adrenergic antagonists (41%)
 - IV radiocontrast agents (43%)
 - Liposomal forms of drugs (44%)



ISMP 2007 survey on HIGH-ALERT medications
Differences between nursing and pharmacy perspectives still prevalent

- **Differences between nurses' and pharmacists' perceptions regarding which drugs they considered high-alert medications**
 - **65%** of nurses reported that **IV radiocontrast agents** should be considered high-alert medications, compared to **34%** of pharmacists
 - **73%** of nurses believed that **oxytocin** should be a high-alert medication, but only **38%** of pharmacists agreed.
 - **68%** of nurses felt that **epoprostenol** should be a high-alert medication, compared to **45%** of pharmacists.



內外科常見外型相似針劑

外型相似針劑

SABS (Metronidazole) v.s.
Cinolone (Ciprofloxacin)



外型相似針劑

Cefuroxime v.s.
Ansullina (Ampicillin & Sulbactam)



外型相似針劑

Marcaine v.s. Xylocaine



外型相似針劑

Vitagen (Glucose) 20% v.s. Vitagen(Glucose) 50%



外型相似針劑

Haldol (Haloperidol) 50mg/ml v.s.
Haldol (Haloperidol) 5mg/ml



外型相似針劑

Ephedrine v.s. Vagostin v.s. Atropine



外型相似針劑

Vethasone (Betamethasone) v.s.
Vitamin-B1



外型相似針劑-

Lilonton (Piracetam) v.s.
Calglon (Cal. Gluconate)



外型相似針劑-
Cefe (Cefmetazole) v.s.
Cekodin-A (Cephradine)



相似藥品管理辦法

本院相似藥品管理辦法

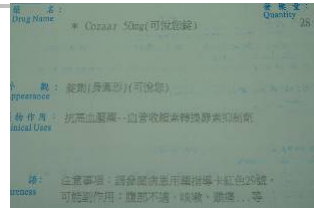
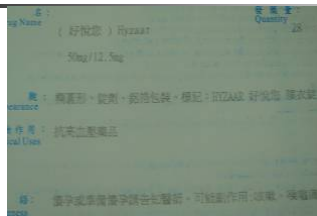
- 為提升用藥的安全性、加強藥物辨識性以降低藥物錯誤情形而制定本辦法
 - 每年至少檢視及確認一次醫院內使用藥品中，外觀相似或發音相似的藥品清單，並需採取因藥品外觀相似或發音相似導致混淆錯誤的防範措施。
 - 易混淆藥品於藥袋上之藥名前增加標示作用或顏色。配合製作易混淆藥品標籤提醒注意。
 - 製作相似藥品-外型相似資料：提供新進人員在職教育等相關人員作為參考。
 - 藥品名稱或包裝相似藥品：
 - 外觀相似藥品於進貨時，即固定加上標示以利區別。
 - 相似藥品之儲存位置以特殊或不同標籤分存放。

本院相似藥品管理辦法

- 易混淆藥品於藥袋上之藥名前增加標示作用或顏色。配合製作易混淆藥品標籤提醒注意。
 - 相似藥品：Hyzaar 與 Cozaar



藥品標籤與藥袋標示一致



易混淆藥品
籤以『中文
稱在前』提
注意



易混淆藥品標
籤以『特殊符
號之綠底標
籤』提醒注意

本院相似藥品管理辦法

- 藥品名稱或包裝相似藥品：
 - 外觀相似藥品於進貨時，即固定加上標示以利區別。
 - 相似藥品：Co-Diovan 與 Diovan

Co-Diovan 於進
貨時即拆除外
盒並於排藥上
加劃藍線並以
不同類型儲盒
存放



本院相似藥品管理辦法

易混淆藥品標籤以加註『複方』提醒注意



易混淆藥品標籤以『特殊符號之綠底標籤』提醒注意



本院相似藥品管理辦法

- 藥品名稱或包裝相似藥品：
 - 相似藥品之儲存位置以特殊或不同標籤分開存放。
 - 相似藥品：Doxaben XL 與 Doxaben

藥品名稱相似：存放不同抽屜



本院相似藥品管理辦法




易混淆藥品標籤以『特殊符號之綠底標籤』提醒注意



易混淆藥品標籤以加註『成分』提醒注意

最新用藥安全警訊 FDA Safety Alerts



Oral Bisphosphonates: Ongoing Safety Review of Atypical Subtrochanteric Femur Fractures

- The data that FDA has reviewed have not shown a **clear connection between bisphosphonate use and a risk of atypical subtrochanteric femur fractures.**
- Patients should continue taking oral bisphosphonates unless told by their healthcare professional to stop. **Patients should talk to their healthcare professional if they develop new hip or thigh pain** or have any concerns with their medications.

~Mar ,2010



Meridia (sibutramine hydrochloride): Follow-Up to an Early Communication about an Ongoing Safety Review

- Review of additional data indicates an **increased risk of heart attack and stroke** in patients with a **history of cardiovascular disease using sibutramine.**
- Sibutramine is not to be used in patients with a history of cardiovascular disease, including:
 - coronary artery disease
 - stroke or transient ischemic attack (TIA)
 - heart arrhythmias
 - congestive heart failure
 - peripheral arterial disease
 - Uncontrolled hypertension

~Jan ,2010



Clopidogrel (marketed as Plavix) and Omeprazole (marketed as Prilosec) - Drug Interaction

- **Interaction** between **clopidogrel (Plavix)**, an anti-clotting medication, and **omeprazole**, a proton pump inhibitor (**PPI**) used to reduce stomach acid.
 - The **effectiveness of clopidogrel is reduced**. Patients **at risk for heart attacks or strokes** who use clopidogrel to prevent blood clots will not get the full effect.
- Other drugs that are expected to have a similar effect include: cimetidine, fluconazole, ketoconazole, voriconazole, etravirine, felbamate, fluoxetine, fluvoxamine, and ticlopidine.

~ Nov ,2009



Clopidogrel (marketed as Plavix) and Omeprazole (marketed as Prilosec) - Drug Interaction

- 衛生署於98年11月19日公告要求所有含clopidogrel成分藥品仿單都必須加刊「Clopidogrel為一種prodrug，須於體內經CYP2C19酶代謝成活性代謝物以達到預防凝血的作用。而氫離子幫浦抑制劑（proton pump inhibitors, PPIs）是用於治療消化性潰瘍與胃食道逆流性疾病的藥物，這一類藥物可能會抑制CYP2C19酶的活性，而減少clopidogrel轉換成活性代謝物，進而影響其療效。已有臨床試驗顯示，**病人併用clopidogrel與PPIs可能會增加心血管血栓與心血管疾病再發風險**。因此，**除非必要否則應避免合併使用該二類藥品**。
- 至於是否所有氫離子幫浦抑制劑（包括omeprazole, esomeprazole, lansoprazole, pantoprazole及rabeprazole等成分）都會與clopidogrel產生交互作用，衛生署已經列入99年度委託計畫研究重點。



Sitagliptin (marketed as Januvia and Janumet) - acute pancreatitis

- Revisions to the prescribing information for **Januvia (sitagliptin) and Janumet (sitagliptin/metformin)** : reported cases of **acute pancreatitis**. (88 cases of acute pancreatitis, including 2 cases of hemorrhagic or necrotizing pancreatitis, reported between October 2006 and February 2009)
- **Monitor** patients carefully **for the development of pancreatitis** after initiation or dose increases of sitagliptin or sitagliptin/metformin.
- Sitagliptin has not been studied in patients with a history of pancreatitis. The medication should be used with caution and with **appropriate monitoring in patients with a history of pancreatitis**.

~Sep ,2009



Sitagliptin (marketed as Januvia and Janumet) - acute pancreatitis


- sitagliptin 所核適應症為「第二型糖尿病」，sitagliptin/metformin 所核適應症為「適用於配合飲食和運動，以改善下列第二型糖尿病患者的血糖控制：已在接受sitagliptin 和metformin合併治療者，或僅適用sitagliptin 或metformin 但控制不佳者。」該些藥品分別於96年7月13日，98年6月9日才核准其許可證，屬於新藥安全監視藥品，藥商於安全監視期間必須依「藥物安全監視管理辦法」之規定，定期檢送最新國內外使用安全訊息至衛生署。
- 臺灣尚未有因使用sitagliptin成分藥品而發生胰臟炎之不良反應通報案件，衛生署將加強該藥品上市後之安全監視，並要求藥商儘速辦理藥品仿單更新作業，將前述之不良反應刊載於仿單中。



Orlistat (marketed as Alli and Xenical): Early Communication about an Ongoing Safety Review


- New safety information regarding reports of **liver-related adverse events in patients taking orlistat**.
- Between 1999 and October 2008, **32 reports of serious liver injury, including 6 cases of liver failure**. The most commonly reported adverse events described in the 32 reports of serious liver injury were **jaundice, weakness, and abdominal pain**. Analysis of these data is ongoing and **no definite association** between liver injury and orlistat has been established at this time.
- FDA is **not** advising healthcare professionals to change their prescribing practices with orlistat.
- Consumers currently taking Xenical should continue to take it as prescribed.

~Aug, 2009



Orlistat (marketed as Alli and Xenical): Early Communication about an Ongoing Safety Review


- 衛生署核准Orlistat (中文藥品名稱：羅氏鮮) 有120mg與60mg，均屬需醫師處方藥品，所核准該藥品仿單之「上市後經驗」載明「...有極少數病人出現轉胺升高、鹼性磷酸升高及特殊嚴重肝炎病例報告...」。 **肝炎與orlistat 治療之間的因果關係或生理病理學機制都尚未確立**
- 衛生署曾於96年4月30日發布新聞提醒醫師及病人**使用「羅氏鮮」應小心膽結石之不良反應**，衛生署將加強監控orlistat藥品之安全性，亦會密切注意FDA之分析結果，必要時進行再評估。同時呼籲醫師為病人處方含orlistat 成分之藥品時，應謹慎評估其用藥之風險與效益。



Varenicline (marketed as Chantix) and Bupropion (marketed as Zyban, Wellbutrin, and generics)

- Smoking cessation aids **varenicline (Chantix) and bupropion (Zyban and generics)** - the risk of **serious neuropsychiatric symptoms**.
- These symptoms include **changes in behavior, hostility, agitation, depressed mood, suicidal thoughts and behavior, and attempted suicide**.
- Stop taking varenicline or bupropion and contact a healthcare provider immediately if they experience agitation, depressed mood, and any changes in behavior that are not typical of nicotine withdrawal, or if they experience suicidal thoughts or behavior.

~July, 2009



Varenicline (marketed as Chantix) and Bupropion (marketed as Zyban, Wellbutrin, and generics)

- 衛生署核准含varenicline 成分藥品（商品名：Champix R film coated tablet 0.5 mg 及1.0 mg）之適應症為「戒菸輔助劑」；核准Zyban R藥品之適應症為「治療尼古丁依賴症，作為戒菸之輔助」，均屬需醫師處方之藥品，仿單中亦已刊載前述精神方面之警語/注意事項。衛生署亦曾於97年2月5日、97年5月30日、97年11月10日發布新聞呼籲醫師為病患處方戒菸輔助藥品進行戒菸計畫時，**宜仔細瞭解病患是否有精神方面疾病之病史，評估其臨床效益與風險。**

Propofol Infusion Syndrome (PRIS)

Propofol輸注症候群

*~A rare, but highly lethal
complication of propofol use*

Propofol

Table 1 Pharmacological properties of propofol^a

- Pharmacodynamic properties**
- Rapid onset of action (approximately 30 seconds)
 - Decreased mean arterial pressure and heart rate with induction and maintenance of anesthesia
 - Ventilatory depression
 - Decreased cerebral blood flow
 - Decreased intracranial pressure
 - Decreased cerebral metabolism
- Pharmacokinetic properties**
- Rapid rate of distribution (half-life 2-4 minutes)
 - Rapid elimination (half-life 30-60 minutes)
 - Extensive distribution
 - Rapid total body clearance (1.5-2 L/min)
 - Metabolism mainly in the liver with formation and urinary excretion of inactive conjugates and quinols
 - Linear pharmacokinetics

Table 2 Adverse drug effects of propofol^a

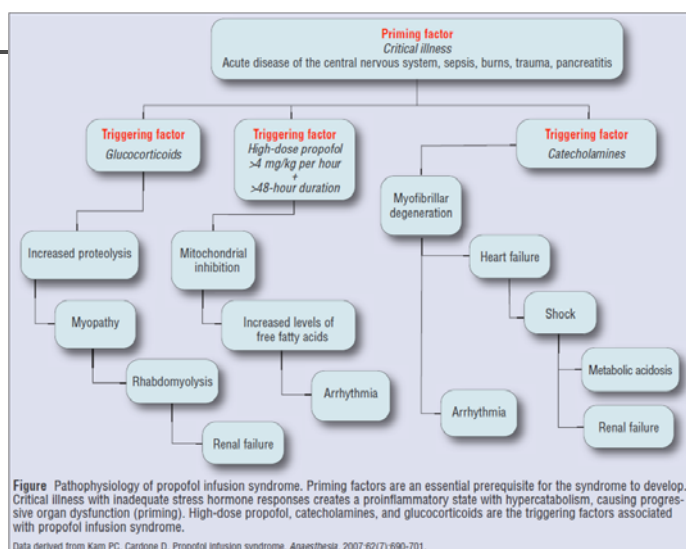
- Local pain on induction
- Hypotension
- Bradycardia
- Transient apnea during induction
- Nausea and vomiting
- Headache
- Thrombosis and phlebitis
- Epileptiform movements
- Rhabdomyolysis
- Pancreatitis
- Postoperative fever
- Discoloration of urine
- Anaphylaxis
- Sexual disinhibition
- Pulmonary edema

~Melissa M. Zaccheo, Donald H. Bucher. Propofol Infusion Syndrome. Critical Care Nurse, June 2008. Vol 28, No.3

Propofol Infusion Syndrome

- **Prolonged propofol administration (>48 hrs) at high doses (>4mg/kg/h)** may cause a rare but frequently fatal complication known as **Propofol infusion syndrome (PRIS)**.
- **History**
 - 1990- first case in Denmark(2-year-old girl)
 - 1992- Parke et al: 5 deaths in children(4 wks to 6 yrs)
 - 1998- Bray proposed the term “propofol infusion syndrome”(PRIS) to describe this clinical state associated with propofol infusions in children.
 - 2000- Perrier et al: first case of death related to propofol infusion in an adult.

Propofol Infusion Syndrome





Propofol Infusion Syndrome

- PRIS key features
 - Unexplained, severe **metabolic acidosis**
 - **Rhabdomyolysis**
 - **Hyperkalemia**
 - **Lipemia**
 - **Myocardial and renal failure**
 - **Hepatomegaly**
 - **cardiovascular collapse** (bradycardia, atrial fibrillation, ventricular and supraventricular tachycardia, bundle branch block and asystole)



Propofol Infusion Syndrome

- A retrospective cohort analysis, **67** patients met the inclusion criteria (**head-injured adults** aged between 16 and 55 years, alive at the time of analysis, sedated, and had been mechanically ventilated for 48 h after injury) for the study.
- **7** patients (**10%**) developed propofol infusion syndrome; **5** cases **occurred** after propofol formulation was **switched from a 1% to a 2%** injectable emulsion.
- The mean rate of propofol infusion in these 7 patients was **6.5** mg/kg/h compared with **4.8** mg/kg/h in the 60 patients without propofol infusion syndrome ($p = 0.002$).

~Cremer OL, Moons KG, Bouman EA, Kruijswijk JE, de Smet AM, Kalkman CJ. Long-term propofol infusion and cardiac failure in adult head-injured patients. Lancet 2001;357:117-8



Propofol Infusion Syndrome

- Common clinical features among the 7 patients included cardiac arrhythmias, metabolic acidosis, hyperkalemia, rhabdomyolysis, lipemia, and high-dose propofol infusion (>5 mg/kg/h).
- The authors suggested that the **propofol infusion rate should not exceed 5 mg/kg/h for sedating critically ill adults**

~Cremer OL, Moons KG, Bouman EA, Kruijswijk JE, de Smet AM, Kalkman CJ. Long-term propofol infusion and cardiac failure in adult head-injured patients. Lancet 2001;357:117-8



Propofol Infusion Syndrome

- PRIS must be kept in mind as a **rare**, but **highly lethal** complication of propofol use.
- PRIS can occur in both children and adults.
- key features : Severe metabolic acidosis, rhabdomyolysis, hyperkalemia, lipemia, renal failure, hepatomegaly, and cardiovascular collapse.
- **Lactic acidosis** of unknown origin could be an **early warning marker** of PRIS in the absence of other causes.



Propofol Infusion Syndrome

- Critically ill patients receiving high-dose propofol and **concurrent use of corticosteroids and catecholamines** increases the risk of PRIS.
- If high-dose propofol is needed for these patients, careful monitoring of serum levels of **creatin phosphokinase, myoglobin, and troponin** can detect early manifestations of muscle breakdown.
- Until further safety data become available, caution should be exercised when using **high-dose (>5 mg/kg/h) and long-term (>48 h)** propofol infusion in sedating critically ill adults.



Propofol Infusion Syndrome

- It is now suggested the selection of other pharmacological agents as an **alternative** to propofol for long-term sedation **especially in paediatric patients**.
 - **Midazolam**-most commonly used BZDs in PICU
 - **Dexmedetomidine**-newer agents
- To improve outcomes, recognize PRIS early and discontinue propofol infusion.
- Safe dosage of propofol may need **re-evaluation**, and **new studies** are needed



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Thank you for your listening!

