

行政院及所屬各機關出國報告  
(出國類別：實習)

赴美 University of California, Davis Medical Center

臨床試驗藥物管理暨藥事作業實習報告



服務機關：成大醫院藥劑部

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出國地區：美國

出國期間：民國九十一年七月十二日至九月一日

報告日期：民國九十一年十一月十一日

JO/C09105229

公務出國報告提要

頁數: 43 含附件: 否

報告名稱:

臨床試驗藥物管理暨藥事作業實習報告

主辦機關:

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出國類別: 實習

出國地區: 美國

出國期間: 民國 91 年 07 月 12 日 -民國 91 年 09 月 01 日

報告日期: 民國 91 年 11 月 11 日

分類號/目: J0/綜合(醫藥類) J0/綜合(醫藥類)

關鍵詞: 臨床試驗藥物管理、研究用藥、試驗委託者、藥品監測、查核作業

內容摘要: 職成大醫院藥劑部藥師林成新奉准於九十一年七月十二日至九月一日赴美 University of California, Davis Medical Center實習，參與Pharmaceutical Service Department之臨床試驗藥物管理。赴美期間在Investigational Drug Service藥師Vickie Bradley Pharm.D之指導下，深入瞭解藥品臨床試驗管理作項目及藥師所能發揮之角色。依該院之政策，所有臨床試驗藥物/研究用藥必須儲存於藥劑部並由藥師作適當的標示及核發。藥師不再侷限於藥品調劑工作，而有更重要的角色要扮演。在執行各臨床試驗階段包括人體試驗委員會臨床試驗計畫書之審核、計畫資料的建立、研究用藥庫存管理及核發、配合臨床試驗委託者藥品監測及政府查核作業，為達到藥品優良臨床試驗規範(Good Clinical Practice)，藥師之參與是不可缺乏的。UHC Pharmacy Research & Education Committee 於2001年針對全美教學醫院臨床試驗/研究用藥管理之概況調查發現Investigational Drug Service藥師之責任及工作較以往成長及增多，大多數醫院有專任研究用藥服務藥師，有專屬藥品儲存場所及設備，工作項目包括審核臨床試驗計畫書並參與人體試驗委員會、與研究者研擬給藥步驟、製備安慰劑、編制亂數碼、藥品儲存、藥品調劑及核發。多數醫院在藥師管理下執行超過100項臨床試驗計畫。

本文電子檔已上傳至出國報告資訊網

## 摘 要

職成大醫院藥劑部藥師林成新奉准於九十一年七月十二日至九月一日赴美 University of California, Davis Medical Center 實習，參與 Pharmaceutical Service Department 之臨床試驗藥物管理。赴美期間在 Investigational Drug Service 藥師 Vickie Bradley Pharm.D 之指導下，深入瞭解藥品臨床試驗管理作項目及藥師所能發揮之角色。

依該院之政策，所有臨床試驗藥物/研究用藥必須儲存於藥劑部並由藥師作適當的標示及核發。藥師不再侷限於藥品調劑工作，而有更重要的角色要扮演。在執行各臨床試驗階段包括人體試驗委員會臨床試驗計畫書之審核、計畫資料的建立、研究用藥庫存管理及核發、配合臨床試驗委託者藥品監測及政府查核作業，為達到藥品優良臨床試驗規範(Good Clinical Practice)，藥師之參與是不可缺乏的。UHC Pharmacy Research & Education Committee 於 2001 年針對全美教學醫院臨床試驗/研究用藥管理之概況調查發現 Investigational Drug Service 藥師之責任及工作較以往成長及增多，大多數醫院有專任研究用藥服務藥師，有專屬藥品儲存場所及設備，工作項目包括審核臨床試驗計畫書並參與人體試驗委員會、與研究者研擬給藥步驟、製備安慰劑、編制亂數碼、藥品儲存、藥品調劑及核發。多數醫院在藥師管理下執行超過 100 項臨床試驗計畫。

## 目 次

一、赴美實習目的 .....	-3-
二、過 程 .....	-4-
三、心 得 .....	-14-
四、建 議 .....	-15-
五、「美國藥事作業見習心得」演講內容 .....	-16-

## 一、赴美實習目的

職林成新藥師於成大醫院藥劑部負責臨床試驗用藥管理長達五年，在執行上均遵循藥品優良臨床試驗規範( Good Clinical Practice, GCP)。但隨著時代的進步及為提升國內臨床試驗水準，提供受試者最好的臨床試驗服務品質，職奉准於九十一年七月十二日至九月一日赴美 UC Davis Medical Center, Pharmaceutical Service Department 臨床試驗用藥服務組( Investigational Drug Service )實習，接受相關訓練並了解美國對於臨床試驗新發展趨勢。

此次實習主要實際參與 Investigational Drug Service 藥師所扮演的角色並充分瞭解：(1) 人體試驗委員會(Institutional Review Board)之功能；(2) 研究用藥管理藥師之職責；(3) 參與臨床試驗受試者之人權及用藥安全性之法律責任；(4) 評估、審核臨床試驗用藥計畫書；(5) 研究用藥之適當儲存、核發及用藥記錄。

另參加藥師臨床試驗訓練課程，人體試驗委員會會議及觀摩藥事作業現況包括衛星藥局、門診藥局、單一劑量調配中心、靜脈注射調配中心、臨床藥理諮詢服務及安全用藥服務作業。

## 二、過程

此次赴美主要實際參與臨床試驗藥物管理作業並參加臨床試驗訓練課程及觀摩衛星藥局、門診藥局、單一劑量調配中心、靜脈注射調配中心、臨床藥理諮詢服務及安全用藥服務作業。以下分別說明參與各項作業之過程及收穫：

### (一) 臨床試驗用藥服務( Investigational Drug Service, IDS )作業

美國加州大學 Davis 醫學中心成立於 1973 年，從 1986 年起提供臨床試驗用藥管理服務。最初負責 5~10 項臨床試驗計畫案至今已執行 1794 項計畫，而目前有 162 項臨床試驗用藥由 IDS 負責管理。依該院藥劑部之政策，所有臨床試驗藥物(研究用藥)必須儲存於藥劑部並由 IDS 藥師作適當的標示及核發。

所有送審之新藥臨床試驗計畫執行期限為一年。計畫書依規定必須包括試用藥品資料表，臨床試驗計畫敘述(試驗目的、方法、步驟、受試者族群、風險、效益、風險及效益之比、受試者出資的費用、主持人對研究計畫之各人興趣及金錢利益關係說明)及受試者同意書。同意書分別有受試者人權法案( Experimental Subjects Bill of Rights )、給參與研究者之書函( Letter to Research Participants )及參與臨床試驗同意書( Consent to Participate in a Research Study )。

臨床試驗計畫展延若不符合快速審查條件則須提供研究進度或藥物不良反應報告書重新送審。進度報告內容包函最新研究結果、研究策劃、難題、變更提案、最初受試者人數、已納入人數、性別或幼兒總參與人數、取得之受試者同意書件數、當前人體試驗委員會同意函及試驗計畫書、藥物

不良反應報告、試驗修正案、研究發現及多中心臨床試驗研究報告或相關醫學文獻。試驗計畫結束/終止一律須報備人體試驗委員會並附上結果報告。

然而 Investigational Drug Service 藥師於各臨床試驗階段之職責為：

#### 1. 參與人體試驗委員會( Institutional Review Board )

UC Davis 醫學中心之人體試驗委員會分為兩組臨床組(Clinical IRB)及一組社會組(Social IRB)。IDS 藥師是唯一參與兩組臨床人體試驗委員會之委員並獨立審核臨床試驗用藥計畫案。在此職察覺藥師的角色不再侷限於藥品調劑工作，而是能從初期就參與計畫書之審核。每項臨床試驗計畫案將指派二位委員事先書面審閱(Primary 及 Secondary Reviewer )，於會議中報告，經委員投票表決半數以上同意始得通過執行。各組人體試驗委員每隔兩週召開例行會議，每次審核超過二十項計畫案。

#### 2. 準備臨床試驗用藥核發作業

IDS 藥師在最短時間內備妥各計畫資料檔包括計畫書及核准文件、主持人手冊、藥品安全性資料、給藥記錄表、藥品儲存溫度記錄表、電腦資料輸入、設計專屬臨床試驗用藥處方箋、擬訂藥師給藥流程並教導其他參與之藥師及病房護理人員使得完全瞭解進行之研究用藥。

#### 3. 研究用藥管理及核發

所有用藥皆存放於臨床試驗專用藥架(儲存場所設有門禁)，試驗開始前/發藥前確保受試者已簽署同意書並隨

同處方傳真至藥局，隨時追蹤藥品庫存量，詳實記錄給藥日期及數量，確保研究用藥有適當的包裝、標示、批號，確認合格授權醫師開立處方，處方審核(藥品劑量、給藥途徑、頻率)、藥品調劑、核發及病患用藥指導，保管委託者交付之亂數碼以利緊急危機時盲性揭露，記錄病患剩藥以協助研究者評估服藥順從性並依試驗委託者之指示送還或銷毀病患退藥。

#### 4. 配合監測者訪視及衛生主管機關(FDA)查核作業

藥師與試驗委託者或廠商所派之監測員須維持良好之工作關係，任何訪視或電話聯繫事宜均以書面文字記載以利日後之追蹤查詢。最終，藥師將配合衛生主管機關(FDA)之臨床試驗查核作業。

是否已準備面對查核作業？藥師得先自我評估以下項目：

- 是否研究用藥管理記錄完整詳實？

確實記錄藥品簽收及退還，詳填病患給藥記錄，記錄表上未使用“修正液”塗改/訂正處已簽名及記錄表上結餘用藥與實際庫存量相符。

- 是否妥善保存所有記錄？

因醫療需求而轉移儲存場所之研究用藥應有完整之記錄，且研究用藥非經核准未曾被使用或轉移它處。所有研究用藥之收受、轉移及退還記錄憑證已存檔並妥善保存以供隨時查閱。

- 研究用藥儲存場所是否適當？

研究計畫之藥品依儲存條件存放於安全之場所，室溫、需冷藏或冷凍之藥品有詳細溫度記錄證明，研



究用藥與上市藥品分別儲存且只准許受權人員進出儲存場所。

- 藥品是否已退還試驗委託者？

依規定退回未使用/過期之研究用藥並於試驗終止或結束後將病患退藥銷毀或退還試驗委託者。

另介紹該院臨床試驗用藥管理收費標準可作為參考，說明如下：

1. 初次執行費用(Study Initiation Fee)：最少 US \$1000；
2. 年繳費用(Annual Fee)：依每年工作量估算，若工作量少於 10 小時或低資源使用率收 US \$500，10~20 小時工作量或一般資源使用率收 US \$1000，工作量超過 20 小時或高資源使用率收 US \$1500；
3. 個別費用(Individualized Fee)：極度複雜或高資源使用率之研究計畫將個案收費而 National Cancer Institute 進行之臨床試驗案免繳藥品管理費。

此外，依 UHC Pharmacy Research & Education Committee 於 2001 年針對美國教學醫院執行臨床試驗/研究用藥之概況調查，從 46 份回收之問卷結果發現：

1. 大多數醫院回覆有專任研究用藥服務( Investigational Drug service, IDS)藥師(87%)；藥劑部備有專屬藥品儲存場所及設備(89%)；藥劑部對醫院支持研究用藥服務之滿意度(67%)；研究用藥管理收取管理費(96%)；藥品管理費有意支付藥師薪資(84%)，但實際只有 29%達到此目的。
2. 研究用藥服務工作項目包括藥品儲存(96%)、藥品調劑/

核發(93%)；編制亂數碼(93%)；與研究者研擬給藥步驟(89%)；製備安慰劑(85%)；獨立或與研究者製訂藥品仿單(76%)；為人體試驗委員會成員(72%)；獨立審核臨床試驗計畫書(22%)；提供教學/教育訓練場所(65%)。

3. 另主要發現臨床試驗用藥服務藥師工作範圍較以往成長及增多；65%藥劑部參與研究計畫之審核；29%有電腦化資料記錄；藥劑部代表參與人體試驗委員會高達 91%且會議出席率為 72%；負責研究用藥之全職藥師有一位者(62%)、2~3 位者(22%)、4~5 位者(7%)；且大多數醫院在臨床試驗用藥服務管理下執行超過 100 項臨床試驗計畫。

## (二) 觀摩 UC Davis 醫學中心藥事作業現況：

### 1. Satellite Pharmacy Service (衛星藥局)：

目前設有兩個衛星藥局負責全院 528 床住院病患及夜間急診病患之用藥服務。衛星藥局藥師之專業服務項目及優先順序：(1) 藥品調劑、核發；(2)病患臨床用藥服務包括處方審核、評估，專業醫護人員藥品諮詢，特殊用藥血中濃度監測，病患衛教，出院用藥指導，各病房專屬藥事服務及專科藥師服務；(3) 藥學教學；(4) 策劃；(5) 研究計畫及發表刊物。

衛星藥局提供每日 24 小時用藥服務，藥品調劑主要由技術員負責，由藥師核對後定時（每小時由技術員）送至護理站。各護理站備有 1~2 台 Pyxis machine（電腦化藥車）儲備各病房常用藥品。所有處方均以傳真方式送至藥局由藥師輸入病患用藥。衛星藥局調劑單一給藥劑量之首日量（first dose unit-of-use medication）及需要

時使用量，而每日用藥及 Pyxis machine 儲備之藥品是由單一劑量調配中心 (Central Unit Dose Area) 或靜脈注射調配中心 (Central IV Area) 定時撥補。為避免電話鈴聲之干擾，遇有病患用藥短缺事宜，護理站將傳真 Nursing/Pharmacy Communication Sheet 與藥師聯繫。若於下一輪送藥時間尚未取得藥品，則可利用電話詢問。

因此藥師能有更充裕之時間負責臨床工作，除了各病房有專屬藥師外，還有臨床專科藥師分別為感染疾病藥師、抗凝血劑/藥物動力學藥師、臨床藥理諮詢藥師、藥物諮詢藥師、研究用藥藥師、疼痛/開刀房藥師、全靜脈營養供給藥師、小兒科藥師及腫瘤學藥師。臨床藥師每日偵測藥物血中濃度之品項有 Warfarin、治療用 Heparin、Aminoglycosides 初次使用劑量換算及每日血中濃度毒性偵測、Amphotericin B、Ganciclovir、Cyclosporin 及使用超過 3 種以上抗生素 (結核病、免疫缺乏症候群、嗜中性白血球缺乏症除外)。

## 2. Ambulatory Care Center Pharmacy (ACC 門診藥局)：

該院有兩處門診藥局，而 ACC 藥局位於新門診大樓，調劑醫師門診處方包括藥品及醫療衛材，每日約 300 張。藥局成員有主管、藥師、技術員及書記。令人耳目一新的是此藥局作業全面電腦化，由電腦協助提示問題處方、重複用藥、藥品交互作用等。技術員調劑檯各有電腦，從電腦畫面指示待調配之藥品及其儲存位置，包括存放於自動調配機內的藥品或位於藥架上之稀少用藥、口服水劑、外用藥及注射藥。技術員依規定使用安

全藥罐填裝藥粒，將調配完成之藥品置於指示之藥架。

藥師並依電腦畫面顯示之品項、原始醫師處方、各藥品基本資料檔、藥品外觀，核對無誤後，交付櫃檯核發。當病患有需求或病患初次服藥，服藥劑量、劑型、方式有變更時，藥師將以專業知識判斷提供病患藥品諮詢服務。

除藥罐標籤上會列印服藥注意事項、常見副作用外，藥師再利用粘貼式小標籤來告知病人服藥方法、儲存方式、注意事項以確保用藥安全。美國因兒童劑型(水劑)之藥品種類相當完整，因此毋需磨粉分包。藥師親自調製之品項有如 Aldactone 口服懸浮液及少許複方眼用藥水。

### 3. Primary Care Center Pharmacy (PCC 門診藥局)：

主要調劑一般內科門診、出院病患及該院員工之處方用藥，每日約 400 ~500 張。因門診處方用藥不受限於處方集，所以藥局儲備之藥品種類繁多，超過 1500 種。雖然沒有自動分包機，所有口服藥品均以桌上型數粒機協助調劑，但並未造成工作上之困擾。藥品之排放位置非常有序，標示很清楚，詳列藥名且便於查尋。

每一項上市藥品都有(美國之)國定藥品代碼(National Drug Code)很清楚的區別各廠牌學名藥、劑量、劑型、包裝規格。有此代碼協助辨識藥品，調配工作自然可由技術員執行，並可將藥品調劑錯誤率降至最低。未領回之藥品將由藥局保管一週，依病患姓名英文字母順序排列於專屬藥架上。

#### 4. Central Unit Dose Area (單一劑量調配中心)：

此中心補給各護理站藥車(Pyxis machine)之品項及住院病患 24 小時的口服和外用藥。所有調配工作由技術員負責，另由 1 位輪值藥師核對後，送達各區護理站。90%之口服錠劑為片裝，其餘包裝成單一劑量供應。每一單粒包裝上皆有藥名、批號、有效日期，極易辨認。口服液、糖漿也由藥廠或此中心供應單一劑量小杯包裝，可防止以大瓶裝提供所產生的浪費與污染。

#### 5. Central IV Area (靜脈注射調配中心)：

靜脈注射調配中心負責準備及分發全院病患之全靜脈營養輸注液、靜脈添加輸注液及特殊無菌製劑。與我們不同點在於美國多數醫院的靜脈輸注液添加作業集中由專門而熟練的技術員配製，提高效率，減少污染，並減輕護理人員自行處理輸注液之負擔。各項藥品調配細節、步驟、注意事項、安定性都有完整之明文規定讓所有技術人員依循。全靜脈營養輸注液之配製使用自動調配機。所有處方及配製之輸注液一律由藥師核對，可避免配伍禁忌及安定性的問題發生，且輸注液標籤說明非常詳細，除了病患姓名、病歷號、床號、藥品名稱、稀釋液等，更加註配製後有效期、輸入速率及時間、處方醫師、配製技術員及核對藥師。

#### 6. Clinical Pharmacology Consult Service (臨床藥理諮詢服務)：

臨床藥理諮詢藥師(一位為藥事委員會之委員)負責制定高價/高使用率藥品之處方用藥規範並督促醫師遵循

此規範開立處方，提供醫師必要之藥學專業知識及評估醫院處方集新藥申請案以呈報給藥事委員會。因各醫療保險制度之給付差異性，使得處方集主要是提供住院病患之用藥規範，而門診病患處方調劑不受限於處方集。

新藥申請可由醫師或藥劑部主任提出，經藥事委員會通過後使得列入該院住院病患處方用藥。新藥申請表除了填寫藥品基本資料外，必需註明所提之新藥在何種情況下可示為第一線或第二線用藥、建議使用原則、說明新藥優於原處方用藥之理由、提出可被刪除之品項、預估使用病人數、聲明是否有從廠商收取酬勞金並列出過去 12 個月內所收受(>\$ 250)之薪俸或禮品。為避免處方集品項不斷增多，由申請醫師提出可被刪除之品項是很合理可行的。

#### 7. Medication Safety Service (安全用藥服務)：

藥師、醫護人員透過該院網站 Incident Reporting System 申報藥物不良反應或處方用藥、調劑過失。藥物使用評估小組藥師檢閱這些事件並呈報給藥事委員會，必要時向 FDA 或廠商申報以作適當的評估、偵測及追蹤。鼓勵藥事人員確認出並申報藥物相關之不良事件可減少再發生率。當藥師察覺到藥物不良反應，必須通知負責之醫療單位，確認醫師已作適當的劑量調整或醫療處置，同時要求在 24 小時內申報。

另一方面則是從特殊用藥處方來追蹤藥物不良反應之發生如立刻使用之 Hydrocortisone, Methylprednisolone, Antihistamine, Naloxone, Epinephrine, Protamine, 口服

Vancomycin, Kayexalate, 50%葡萄糖, 維他命 K 或突然停止原慢性病處方如抗癲癇用藥、強心劑、茶鹼、非固醇類止痛劑、利尿劑等。

呈報給 FDA 之特定及嚴重藥物不良反應包括標籤或仿單未註明之副作用，嚴重、危及生命或致死之不良反應，異常增多之副作用，與先天畸形發展相關之反應，因藥物生體可用率所造成的醫療失敗或任何劑量之疫苗及類毒素所產生的嚴重副作用。

(三) 參加之訓練課程及會議：

1. “The Role of the Investigational Drug Service Pharmacist in Research” on July 23, 2002 於 Sacramento Heart & Vascular Research Center 舉行，主講者為 Katherine Timmerman, Pharm D 及 Angela Lee-Ow, Pharm D。
2. IRB Joint Meeting on July 26, 2002 討論主題：  
A Summary of the OHRP Guidebook, Chapter 3, entitled, Basic IRB Review。  
Articles :“U-M Doc Broke Research Rules”, The Detroit News, by Justin Gillis。  
“A Hospital’s Conflict of Interest” Washington Post, by Sarah A. Webster。
3. IRB Clinical Research Committee A Meeting on August 7, 2002，會議中審核 24 項臨床試驗計畫案。
4. IRB Clinical Research Committee B Meeting on August 12, 2002，會議中審核 20 項臨床試驗計畫案。

### 三、心得

為何美國藥師在整個醫療團隊能有如此高的地位？有臨床藥師、專科藥師參與醫療服務之行列使得病患之用藥安全更加有保障並減少不必要之醫療資源浪費。單純的調劑作業由技術員代勞，而藥師擔負更重要之臨床服務工作。

當然，美國藥學教育制度造就了學有專精的藥師，加上兩年的住院藥師訓練加強臨床工作經驗，建立了專科藥師，成為醫療團隊不可缺乏之成員。病患除了到醫院看病，需要時也找藥師提供藥品諮詢及偵測特殊用藥之療效及安全性。醫師甚至授權給藥師開立處方和調整用藥劑量，醫療人員之間彼此合作提昇了醫療服務品質。我國藥師因缺乏特殊訓練，各界對其重視程度遠落後於美國。

職非常感謝此次能赴美實習及觀摩，雖然只停留7週，但收穫良多，由其對臨床試驗用藥管理，藥師之職責及其所扮演的角色有相當之瞭解及認知。願與同仁分享此次經驗，並在目前之工作崗位上能有所貢獻，發揮所學，讓臨床試驗水準及研究用藥管理絲毫不遜於美國。



#### 四、建議

- (一) 編制臨床試驗用藥專屬藥師負責管理全院研究用藥，能參與試驗計畫書之審查，成為人體試驗委員會的成員。
- (二) 規劃更寬敞的臨床試驗用藥專用儲存空間，適當之藥架、冷藏及冷凍櫃且設有門禁，只允許相關負責人員進出。
- (三) 推動全面電腦化臨床試驗用藥開方及給藥作業流程，詳記任何訪視或電話聯繫事宜以利日後之追蹤查詢。
- (四) 可參考美國臨床試驗用藥管理收費標準，依工作量適當的調整目前本院之藥品管理費。
- (五) 加強教育所有參與臨床試驗的藥師及病房護理人員使得完全瞭解進行之研究用藥。
- (六) 希望院方能全力支持臨床藥學推展工作，編制一定比例之臨床藥師，提高整體醫療服務品質。
- (七) 增加藥師臨床藥學訓練，提供進修機會。
- (八) 評估各護理站引用電腦化藥車儲備住院病患常用藥品，減輕調劑工作，讓更多藥師能參與臨床服務。
- (九) 全靜脈營養輸注液可考慮以電腦化調配機配製，以利作業，並減少操作過程污染機會。
- (十) 住院病患口服水劑以單一劑量小杯包裝供應，可防止大瓶裝提供所產生的浪費與污染。

## 五、「美國藥事作業見習心得」演講內容

職回國後已於 10 月 1 日在本院藥劑部研討會中報告此次赴美見習心得，並將於 12 月 21 日在”醫院評鑑制度之變革與藥事作業標準研討會”中演講「美國 University of California, Davis Medical Center 藥事作業見習心得」，講議內容如下：

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美國 UC DAVIS MEDICAL CENTER  
見習報告

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報告人：林 成 新

國立成功大學醫學院附設醫院藥劑部

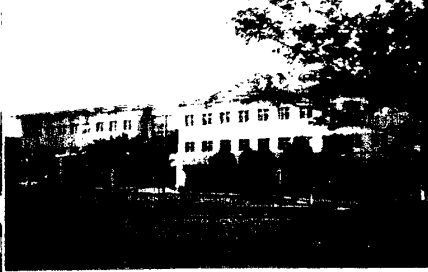
中華民國九十一年十月一日

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University of California,  
Davis Medical Center

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1

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## Scope of Pharmaceutical Services

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- ✦ Pharmacy Administration
- ✦ 8<sup>th</sup> Floor Satellite Pharmacy Service
- ✦ 2<sup>nd</sup> Floor Satellite Pharmacy Service
- ✦ Central IV Area (CIVA)
- ✦ Central Unit Dose Area (CUDA)
- ✦ Nutrition Support Service
- ✦ Investigational Drug Service
- ✦ Pharmacy Purchasing/Stores
- ✦ Primary Care Center Pharmacy
- ✦ Ambulatory Care Center Pharmacy
- ✦ Cancer Center Pharmacy
- ✦ Clinical Pharmacology Consult Service
- ✦ Infectious Disease Service
- ✦ Anticoagulation Monitoring Service
- ✦ Pain Management Service
- ✦ Medication Safety Service
- ✦ Managed Care Pharmacy Service
- ✦ Floor-Based Pharmacy Service

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## Investigational Drug Service

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1986 (5-10 active protocols)

~ till today

Active protocols : 162

Drug available

commercially : 64

IDS staff : 1.5 RPh

+ 1 technician



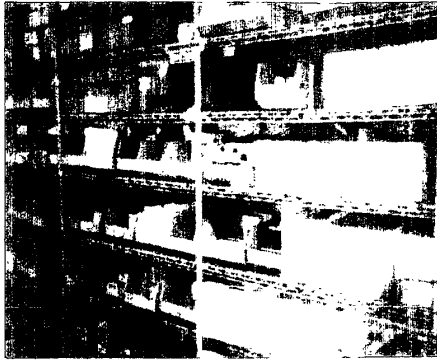
3

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# Investigational Drug Service

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## Storage of Investigational Drugs



## Refrigerated Investigational Drugs



4

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# Investigational Drug Service

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All investigational drugs used at UCDMC shall be appropriately stored, labeled, dispensed by the Pharmaceutical Services Department.



**IRB Committee**

**Trial setup**

**Stock control and dispensing**

**Trial administration**

**Audit (Sponsor, FDA)**

5

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## Role of Pharmacist

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### **IRB Committee**

- **Member of IRB, voting.**
- **Review study protocol, propose changes.**

### **Trial setup**

- **Receive a copy of the protocol at the earliest opportunity.**
- **Prepare investigational drug data sheet.**
- **Educate pharmacy staff and medical nursing about the protocol and dispensing requirements.**

6

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## Role of Pharmacist

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### **Stock control and dispensing**

- **Store trial drug supplies in secured area.**
- **Keep track of trial drug stock levels.**
- **Keep accurate dispensing records.**
- **Allow only appropriate staff to prescribe trial drugs.**
- **Ensure correct label of drugs.**
- **Prescription reviews, dispensing, checking and patient education.**
- **Return all unused material to the sponsoring company or destroyed in accordance with the sponsors instructions.**

7

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# Investigational Drug Service

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## Trial administration

- Keep randomization code for blinding purposes and emergencies.
- Accurately account for returned medicines to help the investigator to monitor patient compliance.

## Audit

- Maintain close working relationship with trial monitors from the sponsoring company.
- FDA audit.

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# Investigational Drug Service

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## Study Activity Check List

### Protocol File

- Study Protocol
- Investigator brochure
- FDA Form 1572
- Material Safety Data Sheet

### Study Initiation

- Master Drug Accountability Log
- Date of first drug shipment
- Storage: Room temp. Refrigerate
- Data base entry updated
- Prescription FAX form completed

### Satellite Binder

- Pharmacist Instructions
- Pharmacy Staff Training Log
- Drug Accountability Record
- Drug information, copy of protocol
- Nursing Assessment Questionnaire

### Study Closed

- Study Drug returned
- Randomization codes returned
- Formulary codes disabled
- Data base (status) updated

9





# Investigational Drug Service

## Fax Transmission of Prescription

UC DAVIS MEDICAL CENTER  
2315 Stockton Blvd  
Sacramento, CA 95817

Name: \_\_\_\_\_  
Med Record #: \_\_\_\_\_

### FAX TRANSMISSION

To: Investigational Drug Service Pharmacist From: Puro/Cit Care  
Fax: (916) 733-7048 Sent by: \_\_\_\_\_  
Phone: (916) 733-4333 Date: \_\_\_\_\_  
Date filled: \_\_\_\_\_ Date: \_\_\_\_\_  
ICB Protocol #: 98-2508 Phone #: \_\_\_\_\_  
RPh Initials: \_\_\_\_\_ Fax #: \_\_\_\_\_

Address & mailing instructions and/or comments: \_\_\_\_\_

### RX

Patient Initials: _____	ARFLO in COPD
PI Randomization #: _____	
Check the prescriptions needed:	
<input type="checkbox"/> "Run-In" Phase #20 bubble/bottle _____ bottles	
Sig: Take 1 into you BID immediately after a meal	
Return all unused medication and empty vials at next visit.	
<input type="checkbox"/> Ventolin Inhaler #1	
Sig: I.D. Bring Inhaler with you to each clinic visit.	
<input type="checkbox"/> Arthro 10mg or Placebo #20 bubble/bottle _____ bottles	
Sig: Take 1 into you BID immediately after a meal	
Return all unused medication and empty vials at next visit.	
No refills	
Signature _____	M.D. (Signature required)
	Andrew Chan, MD

# Investigational Drug Service

## Pharmacist Instructions

PHARMACIST INSTRUCTIONS: VIOXX™ is a generic  
A Double-Blind, Placebo-Controlled, Randomized Trial of VIOXX™  
as a Post-Operative Analgesic in Patients Undergoing Abdominal Gynecological Surgery  
ICB #: 98-2280 Expiration Date: 08/23/01 PI: Barry W. Weay, MD

Study Coordinator: Paul Beck Phone: 4-7088 Pager: 752-6482

Patients are randomized to Vioxx or placebo. 1 g po BID at days starting 2 hrs pre-op. Do not use on MS PCA for 24 hours post-op; then may take LOXIB 7.5/500 as needed (200mg/500mg) if all 5 doses of Vioxx have not been taken by the discharge date. The remaining are sent home with the patient. DO NOT give take-home Rx for Lorazepam if the investigator may order.

- The study coordinator will fax the signed consent into an order to 8 Rx.
- Randomize the patient by filling in the next open line on the enrollment log. This assigns the patient to either an treatment group (Vioxx or placebo).
  - All patients will probably be hysterectomy patients.
  - If a subject is to have a hysterectomy, call the study coordinator and/or ICB because randomization will be different.
- Doses of study drug are sent to the ICB at room temperature. They are in a tin labeled "VIOXX".
  - Doses are numbered by patient number.
  - Each box contains 6 bottles, 1 tablet per bottle.
  - Bottles are numbered Day 1 - Day 5.
  - Take the appropriate box, leave it close for ICB.
- Enter the order: VIOXX and dispense 1 tablet per day (keep the empty bottle in the box).
  - Day 1: The first dose is given 2 hours pre-op with 4-6 cc water.
  - Day 2: Give second dose 24 hours after the first dose. If pt is unable to take the study drug, continue PCA until to give the Vioxx/placebo within 4 hours.
  - Days 3 - 5: Give study drug at approx. 8 am.
- Accountability Records for Vioxx/placebo are in the study binder.
  - Sign out each daily dose.
  - 4 patients per case.
- For the first 24 hours post-op, patients will have PCA morphine, and then they may take Lorazepam 7.5/500 as needed by the study.

ICB Pharmacist Instructions Page 2 of 2

# Investigational Drug Service

## Pharmacy Training Log

### PHARMACY TRAINING LOG\*

*N-acetylcysteine in Acute Liver Failure*

PI: L. Rossaro, MD IRB #: 99-4231 Exp: 6/17/03

All individuals dispensing or managing the inventory of study drug must record their initials, printed name, and signature below.

1.	Initials	Name	Signature	Date
2.	Initials	Name	Signature	Date
3.	Initials	Name	Signature	Date
4.	Initials	Name	Signature	Date
5.	Initials	Name	Signature	Date
6.	Initials	Name	Signature	Date
7.	Initials	Name	Signature	Date
8.	Initials	Name	Signature	Date
9.	Initials	Name	Signature	Date
10.	Initials	Name	Signature	Date

\*Pharmacists responsible for dispensing study drug must fully understand the requirements as specified in the protocol.

14

# Investigational Drug Service

## Nursing Assessment Questions

### NURSING ASSESSMENT QUESTIONS

The "APOLLO" Trial: EFCS08

Name \_\_\_\_\_ RN Nursing Unit \_\_\_\_\_ Date/Time \_\_\_\_\_  
(Please return completed quiz to the Pharmacy)

- What is one name of this investigational drug?
  - Enoxaparin
  - Fondaparinux
  - Pondemir
- What is the indication for the use of this investigational drug?
  - Prevention of post-operative ileus and bowel dysfunction
  - Prevention & treatment of thromboembolic disease
  - Acute hemorrhagic stroke
- What are the proper routes of administration (select all that apply)?
  - Enteropercutaneous tablet
  - Deep I.M. "Z-track"
  - Deep I.M. alternating sites
  - IV injection via central line
- Side effects that may be seen include
  - Nausea & vomiting
  - Disabling
  - Headache or dizziness
  - All of the above
- Thrombocytopenia can occur with the administration of this study drug.
  - True
  - False
- Use with caution in patients with severe or moderate renal impairment as these patients may show delayed elimination of the study drug.
  - True
  - False
- According to the study protocol, the following drugs should not be taken with this study drug.
  - Warfarin
  - Warfarin
  - Cocaine
  - A and B
  - All of the above

Answer 1.B, 2.C, 3.C, 4.B, 5.A, 6.A, 7.D

Have completed this quiz in the back of the study drug.

15

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## Investigational Drug Service

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### Investigational Drug Service Fee Structure

**Study Initiation Fee :** Charged the first year of the study

Minimum US \$ 1,000

**Annual Fee :** According to anticipated annual workload

10 hours or less and low use of resources US \$ 500

10 ~ 20 hours and average use of resources US \$ 1,000

over 20 hours and high use of resources US \$ 1,500

**Individualized Fee :** Extremely complex or resource consuming studies

**Charges waived :** National Cancer Institute

16

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## A 2001 Survey for Investigational Drug Services

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### UHC Pharmacy Research & Education Committee

#### Purpose

- To provide an update on the Investigational Drug Service activities in US academic health centers.

#### Results

- Having a dedicated position for IDS (87%).
- Pharmacy department have dedicated space and facilities for the IDS (89%).
- Pharmacy satisfaction with institutional support for IDS (67%).
- Charging a fee for providing IDS (96%).
- Fees are intended to cover IDS salary expense(84%), however it does so in only 29%.

17

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## A 2001 Survey for Investigational Drug Services

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**UHC Pharmacy Research & Education Committee**

### Types of IDS Activities

- Drug storage (96%).
- Drug preparation/delivery (93%).
- Performing randomization (93%).
- Developing procedures with investigators (89%).
- Preparing placebos (85%).
- Developing drug information sheets (76%).
- Consulting on study designs (72%).
- Serving as member of the IRB (72%).
- Serving as a teaching/training site (65%).
- Developing consent forms (24%).
- Independent reviewer of clinical trials (22%).

18

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## A 2001 Survey for Investigational Drug Services

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**UHC Pharmacy Research & Education Committee**

### Key Findings

- Progression and increase in IDS activities compared to previous surveys.
- 65% pharmacy departments participated in the review of institutional clinical trials.
- 29% pharmacy departments have computerized "record-keeping".
- Pharmacy representation on IRBs is high (91%), and 72% attendance rate at meetings.
- Pharmacist full-time equivalents dedicated to IDS were 1 FTE-62%, 2~3 FTE-22%, 4~5 FTE-7%, 0 FTE-9%.
- Most institutions stated more than 100 protocols under IDS management.

19

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## Ambulatory Care Center Pharmacy

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- Dispense medications & supplies written by a UCDMC Physician.
- About 300 prescriptions/day.
- 1 Supervisor, 2 Pharmacists, 2 Technicians and 3 Clerks.



20

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## Ambulatory Care Center Pharmacy

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### ACC Pharmacy Counter



### ■ Prescription Filling Procedure

Pharmacy Clerk Receiving Prescriptions / ID card for Refill



Order Entry (Drug Name) by Pharmacy Clerk / Pharmacist



Drug Interactions Warnings reviewed by Pharmacist



National Drug Code (NDC) Label printed



Scanning Prescription & Drug Code Label



21

# Ambulatory Care Center Pharmacy

## ACC Pharmacy Work Desk



## ■ Prescription Filling Procedure

Technician receiving Computer Drug Label (NDC Label)

Automatic Baker Cell  
Dispenser/  
Baker Cassette

Drug on shelves  
counted by Lester  
tablet counter

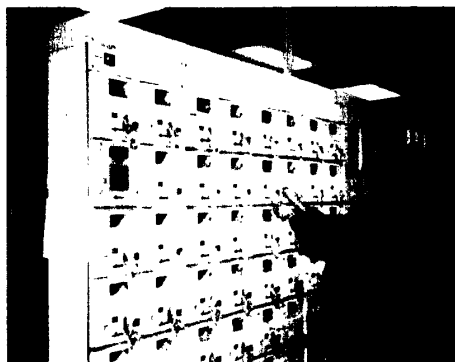
Label the medication container. Sign on Password

Place in box No. shown on computer screen

22

# Ambulatory Care Center Pharmacy

## Automatic Dispenser ( Baker Cell )



## ■ Prescription Filling Procedure

Pharmacist Checking

Sign-on Password

Sign Initial on Medication Container

Place on shelf in alphabetical order

23

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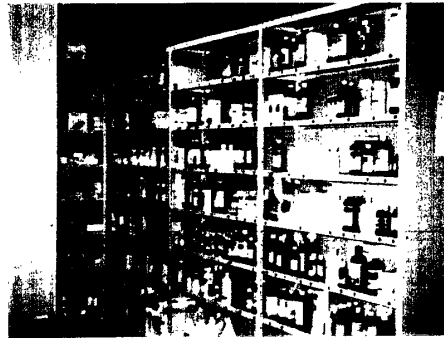
# Ambulatory Care Center Pharmacy

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**ACC Pharmacy Drug Shelf**



**Oral Solutions**



24

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# Ambulatory Care Center Pharmacy

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■ **Pharmacy Computer System** (Technician's screen)

**Baker Cell**  
**Cell : 50**



NDC Code:  
Drug Name:

Quantity :  
Quantity Filled :

Status : Done

**Shelf**  
**W**



NDC Code:  
Drug Name:

Quantity :  
Quantity Filled :

Status : Done

25

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# Ambulatory Care Center Pharmacy

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## ■ Pharmacy Computer System (Pharmacist's screen)



LEBARRON  
AMBULATORY CARE CENTER  
Ambulatory Care Center Pharmacy  
1000 W. 10th Street, Suite 100  
Lawrence, KS 66044  
Phone: (785) 842-1234

Patient Name: \_\_\_\_\_ Date: \_\_\_\_\_  
Address: \_\_\_\_\_  
City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Drug Name	Strength	Quantity	Refill

Pharmacist: \_\_\_\_\_  
NDC Code: \_\_\_\_\_  
Rx ID: \_\_\_\_\_  
# Days: \_\_\_\_\_  
Quantity: \_\_\_\_\_  
Refill: \_\_\_\_\_

NDC Code:                      P't Name:                      Rx ID :  
Drug :                              Doctor :                        # Days :  
Generic Name :                Sig. :                            Quantity :  
Dosage Form :                    Refill :  
Shape :  
Color :            Strength :    Drug Name :                NDC :  
Imprint :  
Manufacturer :

26

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# Ambulatory Care Center Pharmacy

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## ■ Patient Consultation

■ A pharmacist shall provide oral consultation to patient or patient's agent :

- a. Upon request.
- b. Whenever the pharmacist deems it warranted in exercise of his/her professional judgement.
- c. Whenever the prescription drug has not previously been dispensed to a patient, or
- d. Not previously dispensed to a patient in the same dosage form, strength or with the same written directions.

27



## Ambulatory Care Center Pharmacy

### E Labels



28

## Primary Care Center Pharmacy

- Fill prescriptions for outpatients, General Medicine Clinics and employees.
- 400 ~ 500 prescriptions/day.
- 1 Supervisor, 4~5 Pharmacists, 4~5 Technicians and 4 Clerks.



P

29

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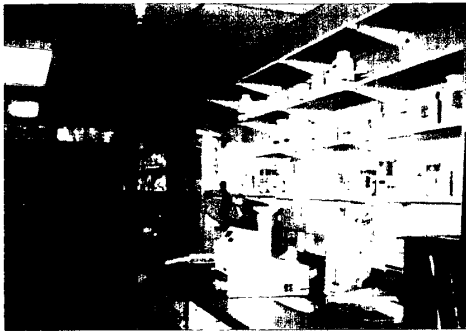
# Primary Care Center Pharmacy

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**PCC Pharmacy Counter**



**PCC Pharmacy Work Desk**



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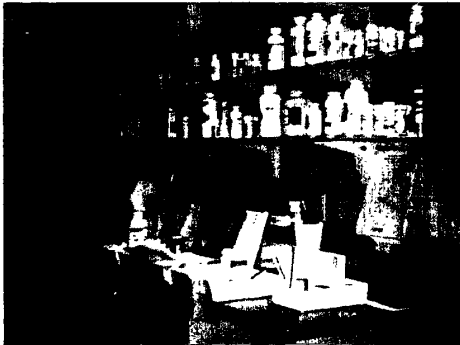
# Primary Care Center Pharmacy

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**Medication Dispensing**



**Pharmacist Checking**

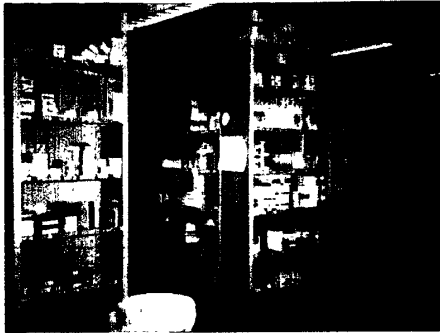


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## Primary Care Center Pharmacy

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**Drug Shelf**



**Unpicked-up Drugs**



32

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## Central Unit Dose Area (CUDA)

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- Working hours : 7:30 ~ 18:00, 7 days/week.
- Replenishes Pyxis machines (Regular/Daily Filling List) and provides patients' 24-hr non-IV admixture medications.
- 5 technicians responsible, pharmacist checking.



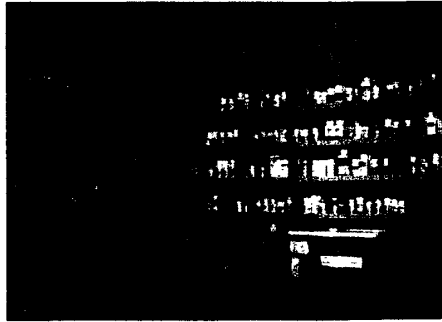
33

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## Central Unit Dose Area (CUDA)

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- In-house unit dose packaging



- Provides Medication on the Regular/Daily Filling List



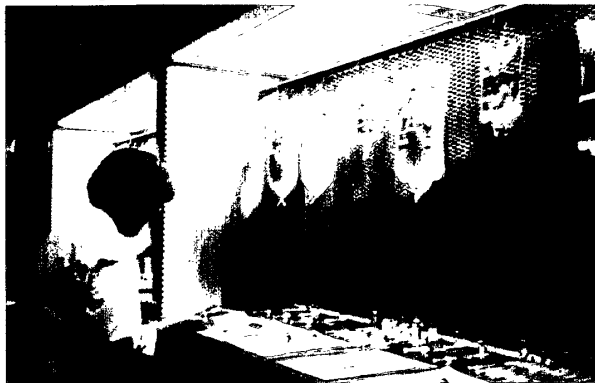
34

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## Central IV Area (CIVA)

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- Working hours : 7:30 ~ 18:00, 7 days/week.
- Prepares and distributes TPN solutions, hospital-wide batch IV admixtures and special sterile preparations.
- 5 technicians responsible ( 1 technician supervisor), pharmacist checking.



35

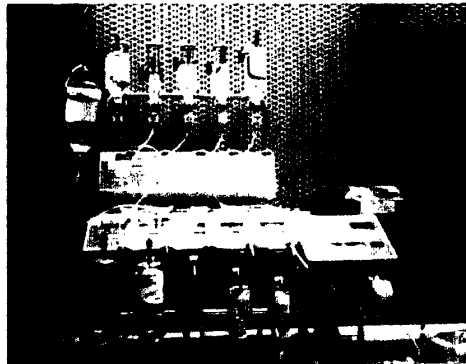
## Central IV Area (CIVA)

■ Prepares TPN solutions



■ Automatic micro-admixture

(K+ Acetate, MTE, Zinc, MgSO<sub>4</sub>,  
Cal. Gluconate, NaCl, KCl, .....)



36

## Central IV Area (CIVA)

■ Prepares IV admixtures



■ IV admixture labels

Name : \_\_\_\_\_ ID NO. \_\_\_\_\_ Bedside NO. \_\_\_\_\_

Nacl 0.9%                    250ml  
Erythromycin LA    500mg  
Expires \_\_\_\_\_  
Rate : 250mls/hr        Infuse over 60mins

RX NO. \_\_\_\_\_ Expires 08/09/02    Dr \_\_\_\_\_  
08/07/02                    Prep \_\_\_\_\_    RPH \_\_\_\_\_

Name \_\_\_\_\_ ID NO \_\_\_\_\_ Bedside NO \_\_\_\_\_

D5/0.9%Nacl                    1000ml  
Potassium Cl (Potassium)    20meq (10ml)  
Expires \_\_\_\_\_  
Rate : 100mls/hr        Infuse over 10hrs6mins

RX NO \_\_\_\_\_ Expires 08/09/02    Dr \_\_\_\_\_  
08/07/02                    Prep \_\_\_\_\_    RPH \_\_\_\_\_

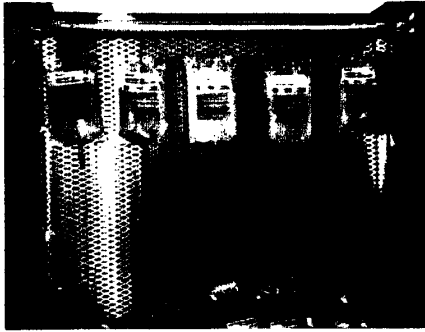
37

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## Central IV Area (CIVA)

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### ■ Thawing Vancomycin HCl



1g/200ml bag in Horizontal Flow Hood which creates immaculate atmosphere.

Store at or below -20°C. Thaw at room temperature 25°C or under refrigerators 5°C.

### ■ Thawing Frozen IVPBs

Cefazolin 1g, Cefotaxime 1g, Ceftazidime 1g, Ceftizoxime 1, 2g, Cefuroxime 750mg, Nafcillin 1,2g, Penicillin 2MU, Vancomycin 1g.



38

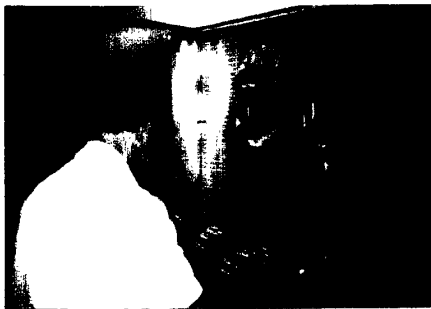
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## Central IV Area (CIVA)

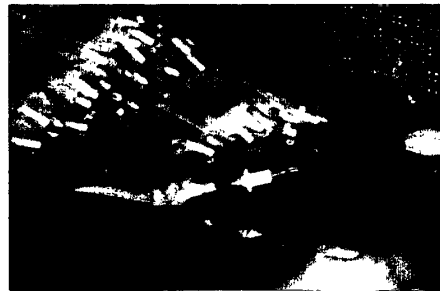
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### ■ Preparing Morphine Drip

100mg in 100ml Normal Saline



### ■ Dilution in 50ml 0.9% NaCl Using a Repeater Pump



39

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## Satellite Pharmacy

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- Serves 528 beds ( 8<sup>th</sup> & 2<sup>nd</sup> floor pharmacy).
- Prepare as needed, first dose unit-of-use medication & aseptically prepared IV admixtures.
- Profiles interface with Pyxis Profiling Medstations System located in every inpatient area.

### 8<sup>th</sup> Floor (Main Inpatient Pharmacy)

- 24hr-pharmacy, 7 days/week.
- Provides specialized expertise in Oncology and Pediatric.
- 4 pharmacists in operating team, 2 clinical for each shift, 2 technicians on the deliver run, 1 IV & 1 chemo technician and 1 supervisor.

### 2<sup>nd</sup> Floor (Inpatient Pharmacy)

- Provide services to the critical care areas (SICU, MICU, Metabolic ICU, neurosurgical ICU, burn unit and ER).
- Working hours : 7:00 ~19:00.

40

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## Satellite Pharmacy

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### ■ Profile Entering



### ■ Drug Shelf



### ■ Preparing Aseptical IV Admixtures



### ■ Technician Drug Filling



41

## Satellite Pharmacy

Nursing/Pharmacy Communication	
Patient name:	Issue (check all that apply)
(1) Code Sheet Request Patient Weight: _____ (2) Medication, Dose, Route, Sig	<input type="checkbox"/> Pyxis Med not loaded & not in cassette
	<input type="checkbox"/> Pyxis Med not available
	<input type="checkbox"/> Med not on Patient Profile
	<input type="checkbox"/> Empty Pocket
	<input type="checkbox"/> Med Greyed Out
	<input type="checkbox"/> Not in Cassette
	<input type="checkbox"/> Refill Requested
	<input type="checkbox"/> IV's not available
	<input type="checkbox"/> Floor stock requested
	<input type="checkbox"/> MD contacted - action pending
	<input type="checkbox"/> Needs MD Reorder
	<input type="checkbox"/> Please re-fax orders
(3) Comments:	

Date/time: \_\_\_\_\_ R N \_\_\_\_\_ Date/time: \_\_\_\_\_ R Ph \_\_\_\_\_  
 FAX to Pharmacy @ 2nd floor: 4-6135 or 8th floor: 3-4118  
 FAX 1X, then phone if not there after next hourly run (cut-off time, 5 mins. before hour)  
71483-299 (1/01)

42

## Satellite Pharmacy

■ **Daily monitoring with completion of monitoring form**

- ✚ **Warfarin, Therapeutic Heparin**
- ✚ **Aminoglycosides, initial dosing and workup**
- ✚ **Aminoglycosides, daily monitoring – toxicity**
- ✚ **Amphotericin B**
- ✚ **Ganciclovir**
- ✚ **Antibiotics Therapy > 3 drugs ( except TB, AIDS & neutropenic)**
- ✚ **Cyclosporin**

43



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## Clinical Problem Resolution

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- Inpatient pharmacists shall consult with specialty pharmacists when patient management is extraordinary in-depth consultation
  - ✚ Infectious Disease Pharmacist ~ 1
  - ✚ Anticoagulation/Pharmacokinetics Pharmacists ~ 3
  - ✚ Clinical Pharmacology Consult Service Pharmacists ~ 5
  - ✚ Investigational Drug Service Pharmacist ~ 1
  - ✚ Pain Service/Operating Room Pharmacists ~ 1
  - ✚ Nutrition (TPN) Pharmacists ~ 2
  - ✚ Pediatric, HIV-Pediatric Pharmacists ~ 5
  - ✚ Oncology Pharmacists ~ 5

44

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## Clinical Consult Service

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- 5 Clinical Pharmacists in service ( including 1 coordinator of the P&T Committee).
- Responsibilities :
  1. Develop guidelines for selected high use and/or expensive medications.
  2. Monitors adherence to guidelines.
  3. Consults with physicians in the management of patients with drug related problems.
  4. Evaluate new drugs requested and present at the P&T Committee.

45

# Pharmaceutical Formulary

- **Hospital Formulary is to provide members of the UC Davis Medical Staff with a current listing of drugs and biologicals available for inpatient use.**
- **The outpatient pharmacies are able to fill prescriptions on an open formulary basis. Only one brand of generically equivalent pharmaceuticals will be stocked based on system-wide contracts. Other pharmaceuticals will be stocked based on demand.**
- **Any medical staff member or the Chief of Pharmaceutical Service may initiate a request for the addition of a medication to the formulary for inpatient use.**

46

# Formulary Addition Request

**PHARMACY AND THERAPEUTICS COMMITTEE  
FORMULARY ADDITION REQUEST FOR HOSPITAL PHARMACEUTICALS**

1. Complete or describe name of drug: Brand name(s) and manufacturer(s) \_\_\_\_\_
2. Dosage form(s) and strength(s) requested \_\_\_\_\_
3. In what situations should this agent be considered a first-line drug? \_\_\_\_\_
4. In what situations would this agent be considered a second-line drug? \_\_\_\_\_
5. Suggested restrictions on use: \_\_\_\_\_
6. Reason why this drug is superior to drug listed in the Formulary (see additional sheets if necessary): \_\_\_\_\_
7. Which drug listed in the Formulary is similar to this agent in action? \_\_\_\_\_
8. Anticipated number of patients or UCDCMC who will be treated with this drug \_\_\_\_\_
9. Are you currently conducting research or bioassay trials with the manufacturer of this product? Check one: Yes/No \_\_\_\_\_
- 9.a. If yes, please indicate nature and amount: \_\_\_\_\_
10. Please list other names or gifts received from the manufacturer of this product during the past 12 months (but those over \$200 only): \_\_\_\_\_
11. Please list any financial interest you may have in the manufacturer of this product (stock, shares, investments, etc.): \_\_\_\_\_

Requested by: \_\_\_\_\_ M.D. Date: \_\_\_\_\_  
(Must be an attending physician, please print)

Signature: \_\_\_\_\_  
 Address: \_\_\_\_\_  
 Institution: \_\_\_\_\_

A. Complete above information. (Must be complete to process request.)

B. Attach documentation to support this request (i) letter explaining reason for the request with pertinent drug usage statistics and (2) published papers, drug studies, bioassay data, etc. (if applicable, etc.)

C. Submit to the Director of Pharmaceutical Services (RMP 591), ext. 6-3388.

D. This request is required for pharmaceuticals requested for **REPLACEMENT THE CHEM.**

E. All medications requested for addition to the UCDCMC Inpatient Formulary will be evaluated by the Department of Pharmaceutical Services. This independent evaluation process may take up to four weeks. After the evaluation is completed, the P&T Committee will discuss this request at the next available meeting.

P&T-Addition

47



# Pharmacy Drug Shortages

Pharmacy Drug Shortages  
as of 7/28/2002

Page 6 of 7

Drug	Dosage Form	Strength	Date Short	Estimated Release Date	Status Level	Comments
<b>Drugs Now Available</b>						
Drug	Dosage Form	Strength	Date Received			Comments
Bupivacaine Hcl Sterile Pak	AMP	0.5%, 30ml	6/24/2002			Limited stock available at Cardinal.
Ceftriaxone Sodium	SDV	1g	5/8/2002			Limited supply available from Cardinal.
Cisracurium Besylate Nimbex	SDV 5ml	2mg/ml	6/20/2002			Limited stock available at Cardinal.
Cisracurium Besylate Nimbex	MDV 10ml	2mg/ml	6/20/2002			Limited stock available at Cardinal.
Doxorubicin Hcl	SDPF	2mg/ml, 25ml	6/28/2002			Limited supply available
Erythromycin Lactobionate	PWWL	1g & 500mg	4/18/2002			Limited supply available
Factor VIII Recomb Helixate	Vial	5mg/ml, 10ml	6/20/2002			Available, No Longer on Allocation
Folic Acid	MDV	5mg/ml, 10ml	6/28/2002			Limited supply available
Heparin Sodium Porcine, Hep	SDV	100u/ml, 2ml	4/13/2002			Limited supply available at Cardinal
Lock PF 100u						
Lidocaine Hcl Viscous	5ml	2%, 100ml	7/5/2002			Limited supply available of the 100ml.
Misoprostol (Cytotec)	Tablets	100mg & 200mg	6/20/2002			Limited stock available at Cardinal.
Polymerin B Sulfate	SDV	500mu	6/20/2002			Limited stock available at Cardinal.
Rocuronium Bromide	MDV	10mg/ml, 5ml	6/5/2002			Limited supply available
Vasopressin	SDV	20u/ml, 1ml, & 5ml	6/30/2002			Limited supply available
<b>Discontinued Items</b>						
Drug	Dosage Form	Strength	Date Discontinued			Comments
Ampicillin	U/D Caps	All Strengths	7/19/2001	None		Only bc's available, repackaging

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OR DUPLICATE ANY INFORMATION

Pharmacy & Medical Group

50

# Incident Reporting System

- ◆ **Welcome to UCDHS Incident Reporting System**  
*<http://incident.ucdmc.ucdavis.edu/hirs/jsp/index.jsp>*
- ◆ **Pharmacists, nursing staff & health care providers**
- ◆ **DUE pharmacist reviews & categorizes the incidents**
- **Your contact information**
- **Department**
- **Locations and time pertinent to the incident**
- **Category : medication related events, medication devices.....**
- **Sub Category : adverse drug reaction, medication errors/delays.....**
  - Type of Error : extra dose, wrong dose, wrong drug, wrong dosage form...
  - Medication ordered :....
  - Medication given :....
  - Outcome : potential error, error no harm, harm
  - Contributing Factors : staffing insufficient, workload increase....
- **Result of reaction : antidote administered, hospitalization/prolonged, death....**
- **Physician , Pharmacy notified?**
- **Report to FDA (Medwatch)?**

51

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## Recognition and Reward Program

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- **Who's Eligible** : All pharmacy staff.
- **Types of Awards** : \$10 gift certificates to \$5,000 CASH !  
Up to \$60,000 will be available for awards.
- **Categories of Awards** :
  - Service** : Outstanding service provided to patients.
  - Financial** : Achieve significant cost savings for the hospital.
  - Safety** : Ideas that potentially reduce on-the-job accidents or significantly decrease medication errors.
  - Teaching** : Excellence in teaching patients, pharmacy, medical staff and nursing.
  - Research/Publishing** : Professional merit to the department and hospital.
  - Department Goals** : Meeting departmental goals set by supervisors.
- **Who decides who gets awards and how much ?**  
The Recognition and Rewards Committee will meet on a monthly basis.

52

*Thank You  
for Listening*



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