Marc Mitchell

Centralised Aseptic service 1995
Suspension of Licence September 1997
Reasons: Skills shortage, Finite capacity, over responsive, No capital, Forgotten!

CE commissioned report
Approved aseptic service tender
Interim arrangements
External company managed Tender exercise.
Tender process

Civa suspended
Adult/children & NNU PN - Cheltenham/Fresenius
70% Chemotherapy - Baxter M.Vernon
Remainder - Inhouse short dated, trials, plumbing
Resurgence of inhouse unit August 99
Intratec- NNU PN
Standard bags - adults

Project Board
PQQ
Invitation to Tender
Rate contractors
Service specification
Adjudicate preferred supplier
• Cost/capacity/quality
Implementation Board

September 97 Aseptic service - Manufacturing licence suspended
January 98 Review of Aseptic service
April 98 Decision to Outsource through tendering exercise
July 98 ASU project board
August 99 Preferred Bidder
**Outcome - Tendering process**
- Tender exercise resulted in only one bidder.
- Discussion with commissioners for additional costs. Budget £250K
- Interim arrangements- Fraying
- Trust agreed Baxter bid with proviso to agree operation and financial contract

**Issues during Contract preparation period**
- Demotivated staff
- Legal aspects
- Clinical trials exclusion
- Options for Site of building and type
- Planning permission
- TUPE
- Service specification
- Christie -warning

**IMPLEMENTATION ISSUES**
- TRANSITION PERIOD
  - July 2- postponed to 28th July
  - Completed 4th November 2001
  - Contract to 3rd Nov 2009
  - Technology/staffing issues
  - ASU Closed 2 February
  - Staff deployment
  - Drug transference
Baxter Service set up 2001

- MHRA LICENSE
- PRODUCT CHANGES-TPN/chemotherapy
  - Stability, waivers, devices
- SCREENING BY TRUST PHARMACISTS
- TPN - imposing change of practice by contractor
- BENCHMARKING
- FINANCIAL INFORMATION / MONITORING ACTIVITY

Contract key

- Experienced Compounding Manager
- Communication channels agreed
- Financial model - UTE/Capacity
- mg billing but with oncost
- Protect procurement function
- Dispensed product delivered to ward
- Protection from waste for speedy delivery of products
- Responds to crises, BP agreement, same system
- No financial penalty for poor performance
- Tupe agreed
- Stability work - corporate support
- On site purpose built unit
- Royalty payments for Non Oxford work
- Any consumable to make included in Management fee

Interface changes

- Chemotherapy ordering (On hold, screening standard, preordering, prescription format)
- Delivery - portering and tracking
- Legality of Ordering PN
- Documentation
- PN formula and giving sets
- Prefilled chemotherapy

- Process for confirming/Dose reduction
- Out of hours support
- Financial accounting
- Monitoring performance/activity
- Introduction of new products
- Weekend work
- Spillage kits/extra vasation kits
- stability
**PERFORMANCE OF SERVICE**

Communication Cascade - Baxter service users meeting
- Divisional Pharmacist/Compounding Manager
- Chief Pharmacist/Regional Manager
- Annual Division - Baxter CEO

Performance
- KPI reports
- Audit
- Incident reports - CAPA

- **POOR PERFORMANCE 2003**
  - One incident of cascade
  - Incorrect Equipment choice
  - Poor management support

**Developments**

- **CLINICAL TRIALS**
  - Lengthy negotiation of variation note
  - Confidentiality issue

- **COURIER/TRANSPORTATION - TRACKING SYSTEM**

- **ON HOLD LIST**

- **CHEMOTHERAPY WASTE/DISPOSABLE EXTRAVASATION/SPILLAGE KITS**

- **ON CALL**

- **DOCUMENTATION**
  - Risk minimization – Development of chemocare

**Interim changes**

- Experienced Compounding Manager and Regional Manager 2003
- Delay in developing finance systems
  - Plan developed
  - Delivery, credit, product price 2002
- Baxter staffing issues causing no routine Sunday opening 2004
- Aria Chemotherapy 2007
- Clinical Trials Legislation 2005
- Change of equipment for PN 2004

**Interim assessment for Outsourcing**

- Lack of choice for potential suppliers
- Financial agreement beneficial for Trust
- Purpose built unit on Churchill site
- Contract details lengthy and costly
- Transition from inhouse to new service – 6 months
- Poor management and strategy initially
- New management team – effective service
- Baxter – new equipment
- Clinical Trials – All eggs in one basket

**Interim issues**

- Royalty payments
- Licence inspection/review by third party
- Benchmarking exercise
- High cost drug - whole vial charge
- Clinical trials and gene therapy
- Heat wave - constriction of service
- Baxter consolidates potential future
- New Facility - no extra cost
Their current facility has a Specials license (MHRA) and IMP (PA) licensed for certain clinical trials. Have ability to extend contract by 12 months if Trust notify Baxter before 1st October 2008. (Negiotiation terms of extension) Legal process under European law to retender Trust/Baxter responsible for Exit Management Plan.

Pricing Model
Management fee based on UTE activity £

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Exit Management Plan
- Baxter to provide necessary information to allow tender issue
- TUPE requirement
- Will allow access to Aseptic service facility
- Information transfer-free
- Ability to purchase equipment
- Proportion of service costs

The Tender

Framework
- Based on EU legislation
- Based on equal treatment, non-discrimination, transparency, mutual recognition and proportionality
- Aim secure the most efficient use of public money.
- Pharmacy increasingly tangled for products and services

Key aspects of tendering
- Project team must include Procurement, Finance and Clinical representation.
- Education of Procurement law and process including time lines.
- Service specification
- Provide relevant information to bidders
- Communication and clarification
- Judgement parameters

Aseptic Services
- Service commencement
- Delivery of products directly to ward
- Provision of Chemotherapy / COSHH requirements.
- Advance Ordering – See annual activity and forecast
- Financial and capacity benefits from Dose banding
- Electronic Interface
- Opening hours and out of hour support
- Weekend Service
- Labelling
- Short Expiry Drugs Turnaround Time
- Intrathecal chemotherapy
- Suitable stability
- Procurement of medicines and associated products
- Finance reports
Quality and Governance requirements

- MCA compliance for manufacture, QA, delivery and supply including compliance with chemicals during transport.
- Adequate stock control systems that prevent out of stock incidents.
- Compliance with health and safety and COSHH regulations.
- Safe and effective disposal of clinical waste.
- Availability of staff by telephone or in person during normal working hours including weekends and an out of hours service communication link.
- Stability data and medical information together with COSHH data and extravasations information.
- Arrangements for maintaining production and delivery turnarounds.

Mechanism to capture and record near miss and out of limit incidents

- Clinical and technical training programmes for all staff.
- Compliance with National guidance for intrathecal chemotherapy.
- Required to meet Manual of Cancer Standards.
- All prescriptions will be screened for suitability by a Trust Clinical Pharmacist before they are requested.
- Trust expect easy access to organisations manufacturing facilities for inspections and audits—please outline whether there would be any restrictions to this access.
- Develop and maintain Capacity and contingency plans.

Strategy for Tender

- Trust Win 1st
- Outsource again - Service model (Not product model)
- Electronic prescribing interface
- Value for money
- Patient safety: Tracking via bar code technology
- Continued Quality
- Waste reduction
- NPSA alert 20: expansion of product portfolio
- Research and audit
- Dose banding saving

Tender process after PQQ Invitation to Tender (ITT)

- Structure of the ITT
- The ITT consisted of the following documents:
- Volume 2 - Lot 1 Specification for Chemotherapy Service
- Volume 3 - Lot 1 Evaluation Criteria and Response Requirements for Chemotherapy Service
- Volume 4 - Lot 2 Specification for Total Parenteral Nutrition
- Volume 5 - Lot 2 Evaluation Criteria Response Requirements for Total Parenteral Nutrition
- Volume 6 - Additional Information

Outcome

- One final bidder: incumbent service provider.
- Post tender negotiation around finance
- Clinical Trials taken inhouse (old Baxter unit)

Current arrangement

- June 2011: New Contract 5+++3 yr ext
- Service type tender – weaker negotiation standing.
- Similar set up except Clinical trials
- Different costing Model
- Cost pressure
  - Restrict weekends
  - Standardise PN
  - NPSA alert 20: unaffordable
  - Lack of interest for Dose banding
Future

- Regional Aseptic arrangement/Managed
- Local Hub - High value/Limited shelf life
- Product specification (Chemo/Std PN)
- Delivery direct to patient from supplier
- Homecare or Satellite (Vat saving)
- Pharmacy staff near patient (Prepacks, Robotics for aseptics)