CHI Learning & Development System (CHILD)

Project Title

Contract Manufacturing of Sildenafil Suspension for Paediatric Patients

Project Lead and Members

Project lead: Chow Hwee Yin

Project members: Jamie Stephanie, Lim Kae Shin

Organisation(s) Involved

SingHealth, KK Women's and Children's Hospital

Project Period

Start date: Dec 2017

Completed date: Jun 2018

Aims

To explore the production of Sildenafil suspension on a larger scale with the aim to

reduce cost to hospital and manpower time spent on compounding.

Lessons Learnt

The new Sildenafil Suspension was rolled out hospital-wide in January 2018 and was

well-received. However, the shelf-life was shorter compared to the previous

preparation. Further stability testing was explored with manufacturer. In June 2018,

the shelf-life was further extended to 70 days. Pharmacy also embarked on a home-

delivery service to improve patient convenience and reduce waiting times at

Outpatient Pharmacy. Pharmacy is currently reviewing all extemporaneous

preparations to explore if this initiative can be extended to other labour-intensive and

high-cost products.

Project Category

Clinical Improvement, Productivity



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Keywords

KK Women's and Children's Hospital, Clinical Improvement, Productivity, Pharmacy, Extemporaneous Preparation, Sildenafil Suspension, New Formulation, Paediatric Pulmonary Hypertension, Cost Saving, Reduce Manpower, Vendor Engagement, Contract Manufacturing, Stability Testing, Shelf Life

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Introduction

Sildenafil is used in the treatment of paediatric pulmonary hypertension at KK Women's and Children's Hospital. Administration to paediatric patients is a challenge as there are no registered liquid formulations available in Singapore . Pharmacy has compounding a suspension extemporaneously to meet this requirement since 2007. An average of 12,000mL is prepared each month with 75 hours of manpower spent.

Aim

We identified a need to explore the production of Sildenafil suspension on a larger scale with the aim to:

- Reduce cost to hospital
- Reduce manpower time spent on compounding

Methods

Vendor engagement

- local manufacturer with Good Manufacturing Practice certification
- Establish contract manufacturing agreement

Formula development

- Collaborate with manufacturer to develop suitable formula for Sildenafil suspension
- Conduct sourcing, evaluation, and purchase of raw materials

Costing

 Work out costing for production twice a month

Product

finalization

- Conduct further testing on assay content and stability of formulation
- Final product ready for production in Dec 2017

Results

Sildenafil Suspension **Formulated**

- Shelf Life: 60 days
- Storage at 2 8°C



Significant Cost Savings

- New formulation \$0.43/mL cheaper than previous extemporaneous preparation
- 61.4% price drop

Manpower Time Savings

- 74.5 man hours saved per month
- 99.3% decrease

\$146,510 OVERALL ANNUAL COST SAVINGS!



Time Savings

Discussion

The new Sildenafil Suspension was rolled out hospital-wide in January 2018 and was well-received. However the shelf-life was shorter compared to the previous preparation. Further stability testing was explored with manufacturer. In June 2018, the shelf life was further extended to 70 days.

Pharmacy also embarked on a home-delivery service to improve patient convenience and reduce waiting times at Outpatient Pharmacy. Patients no longer have to return to Pharmacy every 2 months before their suspension expires.

Conclusion

The contract manufacturing in collaboration with a local manufacturer is effective in reducing cost and manpower time spent by Pharmacy.

Pharmacy is currently reviewing all extemporaneous preparations to explore if this initiative can be extended to other labour-intensive and high-cost products.