P29 **TO EVALUATE A PROTOCOL FOR PROMPT MIGRATION FROM AN UNLICENSED TO A LICENSED PRODUCT USING THE NHS CHANGE MODEL IN A PAEDIATRIC CARDIOLOGY SETTING**

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The use of unlicensed medicines for infants and children is a well documented issue. A review in five hospitals showed over half of prescriptions were either unlicensed or off-label.[1] A marketing authorisation (also known as licensing) decision in medicine is based on a judgement that benefits outweigh the potential risks. Furthermore a licensed medication has been assessed for efficacy, safety and quality; has been manufactured to appropriate quality standards; and when placed on the market is accompanied by appropriate product information and labelling. Whilst there is no systematic evidence that children are disadvantaged by the high levels of unlicensed or off-label prescribing, it has been suggested that unlicensed and off-label drug use appear to be associated with medication errors in neonates and children and that medication errors causing moderate harm are significantly more likely to be associated with both unlicensed and off label than with licensed drugs.[2] Wherever possible, medicines prescribed for children should be licensed and used in accordance to licensed indications.[3] The NHS Change Model has been created to support the NHS to adopt a shared approach to leading change and transformation[4] and may offer an approach for migrating from unlicensed to licensed products.

Aim To migrate from an unlicensed Sildenafil product to a licensed equivalent in a paediatric cardiology setting at University Hospitals Southampton Foundation Trust, using a specially developed generic migration protocol.

Method A generic migration protocol was developed by mapping the NHS change model. The protocol was then used to migrate from an unlicensed to a licensed product.

Results The protocol introduced a systematic approach to migration to a licensed product and the task was accomplished

within an agreed time. The key benefits of the protocol are that it: (i) delineates responsibility for accomplishing the change task (ii) ensures implementation of change in time-bound manner (iii) ensures that changes are properly documented (iv) promotes a culture of continuous process of audit, and (v) increases awareness of the NHS change model.

Conclusion A clear generic protocol that is flexible and not prescriptive may offer a quick, safe and efficient way to migrate from an unlicensed to a licensed product in a paediatric setting. A further evaluation of the protocol across different user groups is required. It is hoped that more licensed products will become available for the paediatric population so the need for a clear method of change will become more important.

REFERENCES

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