Medicine wastage in a thromboprophylaxis protocol for ambulatory trauma patients

Introduction

With the NHS operating under continually tight budgets, efficiency savings are a vital part of ongoing financial management. This service evaluation investigates an area of potential resource wastage and discusses how this relates to current NHS strategies.

The NHS identified an estimated £30 billion shortfall in its budget and has drawn up plans to overturn this deficit by 2021 (Public health England 2014). Although the government recently pledged a funding increase of £20.5 billion to manage this deficit (Department of health and social care 2018), rising costs mean that revised spending strategies will still need to be implemented to capitalise on the benefit of the increased budget. One strategy driver highlighted in the NHS 10-point efficiency plan is maximising value from the £16 billion spent on drugs each year by the NHS by minimising unnecessary wastage (NHS England 2017a). While most of expenditure on drugs can be viewed as a necessity, a major study quantifying NHS prescribed medication wastage across all areas of healthcare estimated an annual cost of £300 million each year (Trueman et al 2010). It has been predicted that there is a 3% annual increase in number of prescriptions (Health and social care information centre 2016), which would suggest that this figure will have increased since these figures were published.

The government has introduced the Regional Medicines Optimisation Committees specifically to focus on whether efficiency savings can be made on a local level within existing protocols (NHS England 2017b), although at the time of writing there has yet to be information published on the effectiveness of this initiative. Individual healthcare Trusts have been tasked with reducing costs by reviewing any existing protocols to determine if any efficiency savings can be made. The authors own Trust introduced guidelines on the use of chemical thromboprophylaxis in 2016 for patients with lower leg injuries which required temporary immobilisation. Its basis was to manage the significant risk of venous thromboembolism (VTE), while acknowledging

the relatively low risk of harmful side effects such as bleeding associated with thromboprophylaxis treatment. These Trust guidelines standardise practice for this patient group but do not discuss potential cost changes associated with this protocol.

In the UK, the NHS is legally bound to support and fund any protocols recommended by the National Institute for Health and Clinical Excellence (Secretary of state for health 2013) within a period of three months. NICE review all new treatments in terms of both clinical and economic evidence, but while the thromboprophylaxis treatment will have been approved in terms of overall cost-effectiveness, there has been no analysis into the medication wastage associated with the protocol which could highlight areas of potential financial savings.

This study examines the thromboprophylaxis protocol at the authors own Trust, specifically reviewing the extent of medication wastage. The Royal College of Emergency Medicine (RCEM) has introduced guidelines on the management of this patient group, which underpins Trust policy in the UK (College of emergency medicine 2012). RCEM advise that patients should receive daily Clexane for each day that their limb remains immobilised, so the Trust uniformly provides 6-week's worth of medication at the time of treatment so ensure the patient does not leave with less than the required amount. There is a breadth of published evidence on the clinical benefits of this protocol (Nokes and Keenan 2009, Haque et al 2016, Horner et al 2020), but this topic has been selected due to the lack of existing data on the wastage aspect and the author suggests that improvements in this area could lead to significant efficiency savings.

Objectives

The primary aim of this audit is to evaluate wastage within the thromboprophylaxis protocol and ascertain if and how financial savings can be made, with the proviso that patient care is not compromised. Wastage will be defined as thromboprophylactic medication that has been provided to the patient for the management of their fracture but remains unused and subsequently destroyed at the end of treatment. The thromboprophylactic medication used within this protocol is Enoxaparin Sodium, known under the brand name Clexane.

The focussed objectives of this research can be identified as:

- To ascertain the financial cost to the Trust for each pre-loaded syringe of thromboprophylaxis medication.

- To review patient records over a given time to identify the quantity of thromboprophylaxis medication that was unused and thereby disposed of in each case.

- To calculate the total wastage over the duration of the audit and discuss how this may reflect on an annual financial saving

- To discuss potential amendments to service provision in both a local and national context that can minimise wastage and improve efficiency.

Design and methods

This section breaks down the decision-making process and the data gathering process into a logical sequence that makes the study theoretically reproducible for the reader.

A pilot study was carried out prior to undertaking this research to determine whether there was any likelihood that the study would reveal any significant wastage within the current protocol. This would determine if there was a potential need for change or improvement and serve as justification to proceed with this audit.

The results of this pilot showed significant wastage in medication with just over 30% of the prescribed Clexane being used as intended, with the remainder returned and destroyed. National policy states that any medication returned from patients should not be reused to avoid the risk that it has been stored incorrectly which can compromise medication effectiveness (Royal pharmaceutical society 2016). This means that unused medication can be interpreted directly as wastage of resources. As a result of these findings the full study proceeded to quantify the amount of wastage by using a much larger sample size and also to determine a financial value to this wastage.

This study analysed retrospective data for all patients meeting the eligibility criteria detailed below, over a six-month period to create a sample set of data which could be used to evaluate the aims and objectives. The author chose this method in preference to a prospective study to ensure that the data collection could be completed in sufficient time to allow analysis and review within the given timeframe. Using retrospective data also minimises the potential bias of clinical practice being

modified as the result of the study (Santos-Eggimann et al 1997). No patients were involved in the process and there was no impact on patient care. The study is deemed an audit as it reviews the performance of an initiative within a single Trust rather than researching the effects and impact of a clinical treatment across wider healthcare (Healthcare quality improvement partnership 2011). All data gathering was carried out by the author to ensure that a universal standard of information processing was used across all records and to avoid data collection bias.

This audit was focussed on the A&E department of the authors own NHS Trust. The study generated a comprehensive list of patients initiated on to the Clexane treatment pathway within a specified time and was estimated in advance to include 30-50 eligible patients. This number was based on estimates from the orthopaedic consultant who routinely manages these patients, considering the mean number of Clexane patients they would expect to observe over any random 6-month period.

Study design

This service evaluation was a solely quantitative study that drew data from the patient records relating to the usage and wastage of Clexane. Potential sources of bias within the study were minimised by consideration of the following factors:

- Use of retrospective data ensured that the study did not influence clinical practice
- All data collection was carried out by the author. This ensured uniformity in the application of inclusion and exclusion criteria
- Data was collected over a sufficient period to ensure that it was representative of ongoing practice
- The criteria used to select participants in the sample was stated precisely. These criteria were adhered to objectively throughout the study
- Any problems with the data collection process or unexpected findings were commented on as part of the results to ensure transparency

All information was stored securely to ensure patient confidentiality and information governance was adhered to always (McSherry and Pearce 2011). Patient data was encrypted before it was removed from the hospital grounds and was only published in the finished audit once it had been fully anonymised. Care was taken at the time of planning to ensure that ethical regulations were adhered to and patient care was not

compromised throughout. The study was carried out with the approval of the Trust research and development team.

Inclusion and exclusion criteria

The timeframe for eligibility to this study was patients who had their treatment initiated between 1st July 2017 to 31st December 2017 inclusive. It was considered that with the protocol launching in 2016 there may have been an initially reduced uptake on the treatment pathway, so a more current data set may provide a better indication of the usage of the treatment pathway. The data window would finish at the end of 2017 to allow enough time for the gathering and analysis of the information.

This research aims to include all patients who have sustained a lower leg fracture, and have had their risk of thrombosis managed by the initiation of Clexane therapy by the attending clinician. The following list highlights any patient groups that will be excluded from the final data set. Any data points that represent outlying values will be commented on individually but still included in the results.

- Patients with clinical management transferred outside of the Trust
- Patients admitted for open surgery. (Patients managed by closed reduction can still be included)
- Significant comorbidities or multiple injuries which impacts on treatment with routine chemical thromboprophylaxis.
- Insufficient data to review management

Collection of data

A list of potential target patients was generated by using specific indicators to refine the search within the time frame. All ineligible patients would then be excluded, with a reason noted for their omission and the remaining list would then be considered as the sample group. The outcomes for each of these patients would then be reviewed to determine the date on which the patient was remobilised and Clexane treatment was stopped. The number of doses of Clexane used was calculated on the assumption that one dose was used for each day of treatment, including the final day when the treatment was stopped. The number of unused Clexane doses was calculated by subtracting the number of used doses from the number of prescribed doses, which is set at 42 by the Trust policy.

Problems encountered

The main problems throughout the process involved the Trusts usage of paper records rather than using an electronic system database, as the Trust's archives had organisational flaws which meant that some records were misplaced or misfiled. In each case the file is no longer obtainable so is not able to be used for further reference. Missing records can be detrimental to patient care as there could potentially be important clinical information in these records which is consequently not acted upon. Although studies have shown that paper record systems can have some advantages over electronic databases, it is dependent on user diligence (Stausberg et al 2003) which in this case led to lost data. As this point can be considered a risk factor to patient safety a Datix would be completed to report this in a formal way and ensure that follow up measures would be taken at the next opportunity.

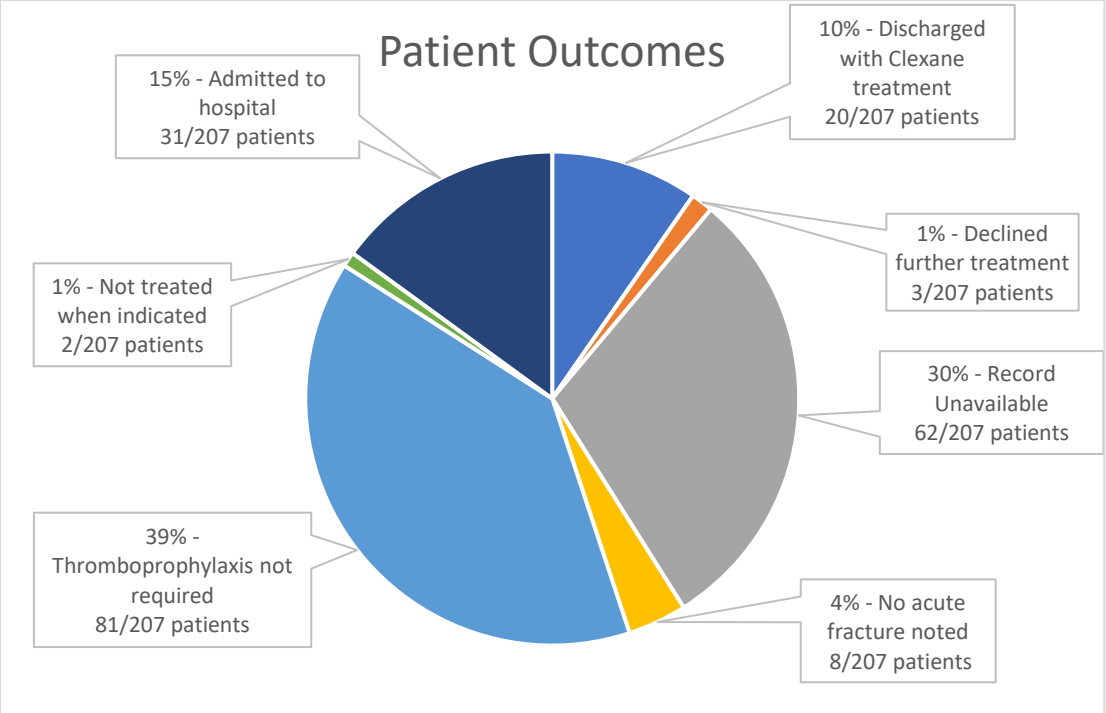
Identifying the target records for this research relies on the accurate coding of each case by the clinician at the time of entry. Any records that had the wrong coding entered by mistake would also be almost impossible to locate by a subject search like this due to the volume of patients that pass through the department.

There is no data available regarding patient compliance to medication, so any missed doses would not be detected. If this occurs, these cases will represent a higher level of wastage than recorded by the author. As this exact data is not available, this study will assume that one dose is taken on each day of treatment, but the author acknowledges that this leaves room for a small margin of discrepancy in the results.

Results, findings and outcomes

The initial phase of data gathering identified a list of 207 patients coded for a lower leg fracture within the time window. These cases were reviewed to determine whether the patient was treated under the thromboprophylaxis protocol. Graph 1 highlights the outcomes of each of these patient encounters providing an overview of the reasons why potentially suitable patients might not be treated under the thromboprophylaxis protocol.

Graph 1 – Interpretation of patient outcomes within study group



Of the data set of 207 patients with lower leg fractures, 20 of these were eligible for the audit and were discharged from hospital with the Clexane thromboprophylaxis protocol. Of these patients, 2 were omitted at this stage as they met the exclusion criteria. The remaining 18 cases are displayed in Table 2 along with any relevant case notes, with this list comprising the final study group for analysis. All patient indicators were removed to ensure no breach in confidentiality. The table includes the number of wasted doses calculated on the basis that each patient is provided with 42 doses of Clexane as per protocol and that a dose was used on each day while they were managing their own treatment in the community.

Table 2 – Review of wasted medication

#	Number of wasted doses (Syringes)	Relevant case notes
1	39	
2	37	
3	36	Commenced Clexane 3 days earlier due to injury while abroad. Further medication provided and referred to fracture clinic at first attendance with Trust
4	32	Commenced Clexane 5 days earlier due to injury while abroad. Further medication provided and referred to fracture clinic at first attendance with Trust
5	33	
6	31	

7	22	Commenced Clexane 3 days earlier due to injury while abroad. Further medication provided and referred to fracture clinic at first attendance with Trust
8	20	
9	33	
10	0	Advised by consultant after 27 days to remove rigid cast and stop Clexane. Patient rejected this so agreed to remain on the treatment protocol for a further two weeks
11	33	
12	8	Sustained injury 10 days prior to attendance. Clexane treatment commenced abroad, initial attendance was for further medication only; fracture management plan already in place
13	32	
14	34	
15	31	
16	22	Clexane treatment stopped at patient discretion against medical advice. Replaced with oral anticoagulants
17	3	
18	3	
Total	**449**	
Mean	**24.9**	

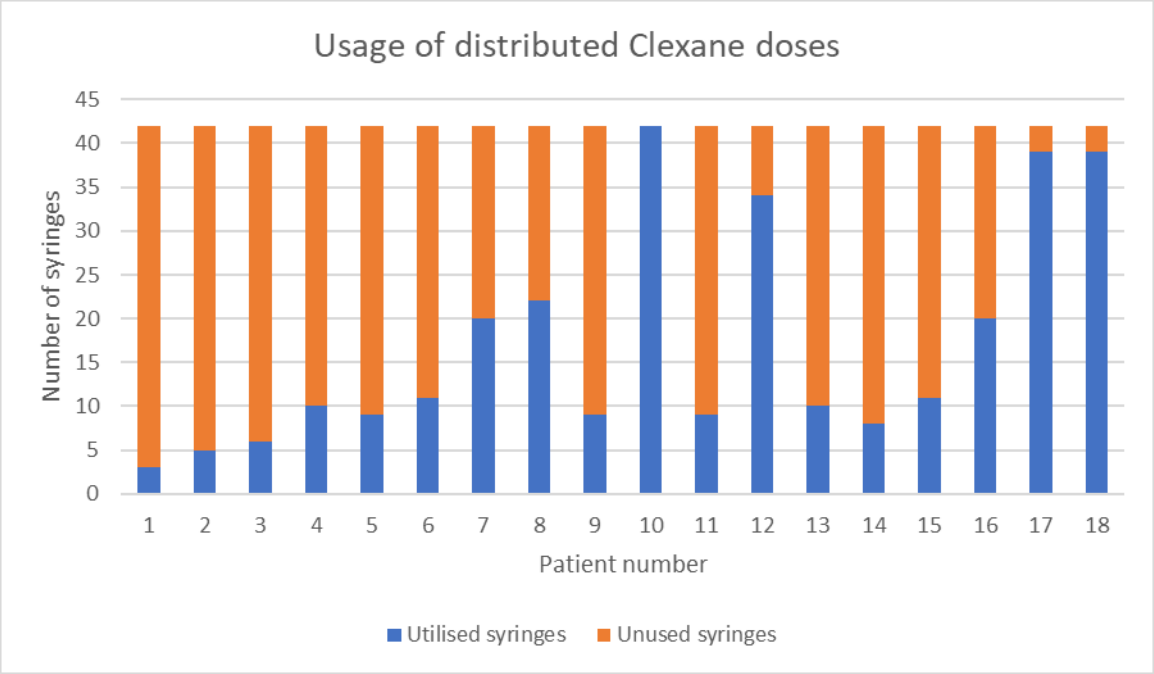
Additional findings showed that all but one of these consultations occur within 2 weeks of the initial attendance. There was limited information on the outlier result regarding why the patient was not followed up until day 30 other than that the management plan was initiated outside of the Trust.

Trust policy is that each patient is contacted directly on the next working day and the review of records showed that all but one case was contacted within 4 days of their initial attendance. This demonstrates that the cases are routinely reviewed at the earliest opportunity to allow maximum time to resolve any potential problems in clinical management.

The results show an overall degree of wastage for the patient group initiated onto the treatment program over the course of the study period. Of the 756 syringes were distributed cumulatively to the sample group, 449 of these doses remained unused representing 59% of medication units that must be returned and destroyed.

There are only 5 patients out of the sample of 18 that used at least half of their initial supply of medication as shown in graph 3.

Graph 3 – Medication wastage for each patient



Cost implications

Determining a cost value for the wasted doses proved difficult as the price of medication varies over time under the influence of supply and demand. Costing details for any given batch of medication is not readily available so for the purpose of the study a representative value was used.

The published cost per syringe when the protocol was launched was £9.77 (National Institute for Health and Care Excellence 2015) while publicly available costing data at the time of study showed a unit cost of £3.03 (National Institute for Health and Care Excellence 2018). This made the total cost of wastage for the duration of the study £4,386.73, or £1,360.47 depending on which price structure was used. These findings infer a 69% drop in costing since the protocol was launched.

Discussion

The data collected throughout the course of this project has been analysed and can be used as a sample of a wider population. In a protocol that has been widely accepted for its clinical benefits and the money it consequently saves the healthcare service, this service evaluation has identified an aspect of it that clearly demonstrates avoidable financial waste.

In a protocol such as this there will always be a degree of medication wastage as there must be a margin of tolerance to minimise the risk of missed doses. However, this study has identified the level of wasted medication at 59% of the amount initially distributed which the author would suggest is unacceptably high, especially if this

wastage is avoidable. Due to the lack of published financial information in this field it is likely that there is not much awareness of this situation, but the data shows that relevant savings that can be made if this wastage is reduced.

The difficulty obtaining accurate pricing is acknowledged as a minor weakness in the study, although efforts were made to use the most accurate representative values. While the findings highlight how the cost efficiency of a new medication protocol can improve dramatically during the initial period, it is difficult to accurately evaluate a service without clarity in the financial data. The cost of medication will be easier to determine in future as the cost of LMWH will become more stable the longer it has been on the market. A repeat of this audit at a future date would yield more accurate financial findings.

The author would state however that these values are likely to be highly indicative of the true amounts and are appropriate for the purposes of this study in an assessment of the financial wastage. The data in this project shows that the main factor in reducing financial wastage has been this fall in costs, rather than the numerical value of any wastage. While these costs do have potential to fall further, as studies show that after the launch phase of a new product on the market, follow-on drugs induce price competition (Mueller and Frenzel 2015). However, these prices would tend to level out as the Clexane product becomes well established and pricing becomes driven by market values (Stevenson et al 2017). However, while an accurate review of costs will enable a Trust to quantify the level of financial wastage, any wastage that can be considered avoidable can be targeted as a means of reducing costs which is currently a priority for any Trust.

<u>Proposed change to practice</u>

The study suggests that the main factor behind the medication wastage within this protocol is the over-dispensing of medication at the point of discharge, so this area could be targeted for potential efficiency savings. The author would suggest an initial supply of Clexane doses be provided for a period of two weeks rather than six. As RCEM guidelines requires treatment to continue for the duration of the limb immobilisation (College of emergency medicine 2012), further medication could either be given when they attend their fracture clinic review, or the patient could be provided with a dated prescription for further doses when they are first treated which can be redeemed at the pharmacy only if appropriate. As the patient is considered ambulatory on discharge it should be possible for them to attend a pharmacy in the

same manner that they are required to attend fracture clinic, but if there are extenuating circumstances why this is not possible the clinician can incorporate this into the management plan at their discretion to ensure there is no increased risk of doses being missed. Provided the patient has the theory and practicalities of the process explained to them clearly and is given the means carry out the process, the responsibility of implementation then lies with the patient. The author believes that these proposed changes would not represent an increased risk to patient health, with the healthcare provider still available in a supporting capacity if any problems with committing to the treatment arose. The Trust must be seen to conform to the national guidelines in this area to avoid potential litigation if any complications arise, but the author believes that these changes still operate within the framework of the published guidelines and do not represent a deviation from best clinical practice.

If the proposed reduction in medication was introduced before this service evaluation, the number of wasted doses would be reduced from 449 doses to 99 doses. As a percentage this sees the level of wastage fall from 59% to 13%. While there is no framework for determining what an acceptable level of wastage is, this represents a significant improvement in efficiency savings which would be appealing to any healthcare provider.

Using the costing figures from 2017 this would represent a financial saving of £1,060.50 over the six-month period that the research covered. Extrapolating this figure to give an annual cost would suggest estimated savings to the Trust of over £2,000. While the figure is not high in relation to NHS budgets, when it is considered across the entire healthcare system where there are 195 Clinical Commissioning Groups with most containing more than one acute treatment (NHS Clinical commissioners 2018), this amount is likely to be a considerable six figure sum that is wasted each year. Taking into account the many minor injury units and urgent care centres now utilising this treatment pathway as well, the author uses these values to project potential savings to the NHS of up to £500,000 per year. This figure is significant when considered in the context of the NHS efficiency strategies discussed earlier that look to minimise unnecessary wastage (NHS England 2017b). While most of this amount can be viewed as necessary expenditure, an estimated saving of 3-5% from this figure would represent an important positive move for cost effectiveness. If any improvements can be made at the authors own Trust on a pilot

basis, these advantages can then be utilised by other Trusts across the country to maximise the benefits.

The study also showed that barring mitigating circumstances, the Trust was effective in following up referrals efficiently, as patients were routinely contacted within 3 days of initial presentation, with a review in clinic within 2 weeks of presentation. Guidance published by the British Orthopaedic Association recommends that all referred patients referred should be seen in fracture clinic within 72 hours of initial presentation (British orthopaedic association 2014), meaning Clexane doses for 2 weeks would certainly provide the patient with enough medication. If there are any foreseeable reasons at the point of discharge that may prevent the patient being reviewed within these recommended timescales, it would be advisable to discharge with a greater amount of medication to reduce the risk of the patient running out of doses.

Conclusion

This audit has investigated the level of discarded medication within the thromboprophylaxis protocol and explored how changes can be made to minimise this wastage. By analysing patient data over a six-month period, the study has shown that 59% of the medication that is distributed to the patient at the point of treatment is unused and ultimately destroyed. While a degree of wastage is inevitable the author would suggest that this is higher than an acceptable level and would recommend measures to reduce this.

The primary recommendation of this study is to reduce the amount of Clexane distributed to the patient from 6-weeks' worth of medication to 2-weeks' worth of medication. The author anticipates this would have no significant detrimental effect on patient care or safety. The findings from this study suggest that implementing these proposed changes could reduce the amount of medication wastage to just 13% of the amount distributed. With a potential financial saving of up to £500,000 annually without any cost of implementing a change the benefits are clear, so the subject would warrant further consideration.

With limited existing research into medication wastage in these protocols, the author would advocate trialling the recommendations from this review at other Trusts in the UK to see if these findings could be reproduced. If improvements in efficiency and

financial performance can be confirmed, the author recommends implementation of these proposals in any comparable healthcare settings.

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