

East Midlands Academic Health Science Network

Evaluation of a new direct supply and pathway of paracetamol in Lincolnshire Care Homes

Executive Summary

Context

Traditionally, paracetamol is supplied to residents in Care Homes via GP prescriptions. It has been found that supply on prescription can result in a default position of paracetamol being supplied and administered regularly four times a day, rather than as required. There are many clinical circumstances in which paracetamol should be given regularly (for example in chronic osteoarthritis), but for other conditions (for example, colds, flu and headaches) it is more appropriate for it to be given as required.

A collective in Lincolnshire noticed a high trend of regular supply and initiated a pilot to supply paracetamol directly to homes (rather than on prescription), for administration to residents on an as required basis. They aimed to reduce the volume and cost of unnecessary paracetamol supply, to improve the pain control of residents in homes and to reduce their exposure to unnecessary medication and therefore side-effects, and to reduce the workload of GPs in prescription supply.

Intervention

The new supply pathway consisted of three features:

- GP review of residents on paracetamol for suitability to move from regular to as required
- Direct supply of paracetamol, purchased via a Wholesaler Dealer's Licence by the CCG, to care homes
- Development of a new Care Home Medicine Policy to support the new paracetamol pathway

A pilot of the new supply pathway was conducted in three nursing homes and one care home in Lincolnshire between December 2018 and August 2020. The pilot was initiated by Lincolnshire Care Association (LinCA) and was delivered in partnership with Lincolnshire CCG, the homes and local GP Practices.

They collected data on the number of residents on regular paracetamol prior to the pilot, the number that transferred on to the new supply and the number of paracetamol tablets given per month per home on an as required basis during the pilot.

Evaluation

The East Midlands Academic Health Sciences Network commissioned the School of Pharmacy at the University of Lincoln to evaluate the pilot. The evaluation consisted of three interlinking elements:

1. **Scoping visits and observations** – These were conducted in the four homes in the pilot, and one that was not in the pilot. Paracetamol administration procedures were observed and staff were interviewed about their experiences of using the new supply system.
2. **Data analysis** – Further investigation and analysis was conducted on the paracetamol data that had been collected during the pilot.
3. **Stakeholder consultation** - Four steering groups were held with representatives from EMAHSN, LinCA, UoL CCG, and lay representation. The process and findings from the pilot

were discussed to assess the value of the new method of paracetamol supply. This was supplemented with a further two interviews with stakeholders (one from LinCA and a lay representative). There was additional correspondence with a GP that contributed to the initiation of the project

Results

There was a significant reduction (99%) in both the volume and spend on paracetamol as a result of the new pathway/policies put in place and direct supply of paracetamol, as well the creation of new interactions and empowerment for both staff and residents which were well received.

During the pilot 15,576 paracetamol tablets were administered across the four homes at a cost of £263.23. This is in comparison to the calculations for the same number of residents for the same length of time as the pilot, based on each resident receiving regular administration of two tablets four times a day (224 a month each). Therefore, pre-pilot the equivalent figures are administration of 1,07,064 tablets at a cost of £38,652.69.

Volume and cost of paracetamol supply pre-pilot and pilot

	Pilot 'as required' / patient choice	Pre-pilot equivalent period (regular supply via prescription)
Number of residents	37	Calculations based on the pilot residents' number of 37
Number of paracetamol tablets	15,576	1,072,064
Cost of paracetamol (£)	264.79	38,915.92

The visits indicated that the new supply method was used safely and that residents' pain needs were reviewed. A particularly striking finding was that because the "as required route" required a conversation, this enabled better communication around pain and other aspects of care. Both staff and residents enjoyed the interaction and found it empowering. The extensive documentation supplied by LinCA in their Medicines Policy was a key feature in the success of the pilot, as was the effective partnership working between LinCA, the CCG, the NHS Trust, the GP Practices and the Homes.

The lay representative who conducted the scoping visits along with the researcher commented -

"Having spent time visiting those participating care homes taking part in the project, it was obvious that the patients regarded being asked if they required their paracetamol for pain relief as a positive contact"

Conclusion

Direct supply of paracetamol to Care Homes for as required administration can result in significant reductions in volume and cost, as well as creating an opportunity for better pain control and interaction between staff and residents. Key features to consider are the logistics of local supply, having protocols and implementation documentation for care home staff, the importance of GP review, the need for partnership working.

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FULL REPORT

1.0 Context

Traditionally, paracetamol is supplied to residents in Care Homes via GP prescriptions. It has been found that supply on prescription can result in a default position of paracetamol being supplied and administered regularly four times a day, rather than as required. There are many clinical circumstances in which paracetamol should be given regularly (for example in chronic osteoarthritis), but for other conditions (for example, colds, flu and headaches) it is more appropriate for it to be given as required (NHS 2020 & NICE 2020). Giving regular paracetamol in cases where as required would be more appropriate exposes residents to unnecessary medicines consumption with a greater risk of adverse effects. It also means that residents' pain levels are not frequently assessed to allow for appropriate escalation of de-escalation of treatment. In addition, it results in unnecessary prescribing and wastage of medicines (Lincolnshire PACE 2020).

A collective in Lincolnshire noticed a high trend of regular supply and initiated a pilot to supply paracetamol directly to homes (rather than on prescription), for administration to residents on an “as required” basis. They aimed to:

- reduce the volume and cost of unnecessary paracetamol supply
- improve the pain control of residents in homes
- reduce their exposure to unnecessary medication and therefore side-effects
- reduce the workload of GPs in prescription supply.

2.0 Intervention

The new supply pathway consisted of three features:

- GP review of residents on paracetamol for suitability to move from regular to as required
- Direct supply of paracetamol, purchased via a Wholesaler Dealer's Licence by the CCG, to care homes
- Development of a new Care Home Medicine Policy to support the new paracetamol pathway

The pilot of the new supply pathway was conducted in three nursing homes and one care home in Lincolnshire between December 2018 and August 2020. The pilot was initiated by Lincolnshire Care Association (LinCA) and was delivered in partnership with Lincolnshire CCG, the homes and local GP Practices.

LinCA developed a comprehensive Medicines Policy, which consisted of protocols for all aspects of the service. The Medicines Policy was distributed to the homes and all existing residents were reviewed by a GP at the beginning of the pilot to determine if they were suitable for moving to an “as required” paracetamol on the new pathway. Paracetamol in packs of 100 were purchased from the local NHS Trust and distributed to the participating homes.

During the pilot, data was collected on the number of residents on regular paracetamol prior to the pilot, the number that transferred on to the new supply and the number of paracetamol tablets given per month per home on an as required basis during the pilot.

The system of developing the pilot was named 'steps to success' and was published on the NICE website, under the section on quality matters case study (<https://qualitymatters.nice.org.uk/lincolnshire/index.html>).

3.0 Evaluation

The East Midlands Academic Health Sciences Network commissioned the School of Pharmacy at the University of Lincoln to evaluate the pilot.

The key questions underpinning the evaluation were:

- Did the new pathway reduce the volume and cost of paracetamol usage in the homes?
- Did the new pathway enable pain control to be tailored better to residents' needs?
- What were the more generalised benefits of the new pathway?
- Were there any disadvantages to the new pathway?
- What factors contributed to the success or limitations of the new pathway?
- What recommendations can be shared with others considering adopting a new medicines pathway for paracetamol?

In order to answer these question, the following three interlinking elements of enquiry were used:

- Scoping visits and observations** – These were conducted in the four homes in the pilot, and in one that had not been in the pilot. Paracetamol administration procedures were observed and staff were interviewed about their experiences of using the new supply system.
- Data analysis** – Further investigation and analysis was conducted on the paracetamol data that had been collected during the pilot.
- Stakeholder consultation** - Four steering groups were held with representatives from EMAHSN, LinCA, UoL and the CCG, plus contribution from a lay representative to the steering group and the scoping visits. The process and findings from the pilot were discussed at the steering groups to assess the value of the new method of paracetamol supply. This was supplemented with a further three interviews with stakeholders (two from LinCA and one GP).

Table 1: Details of the homes in the pilot

	Number of residents in home (capacity of home)	Mean number of residents accessing paracetamol on the new pathway, per month during the pilot	Type of home	Start Date of entering Pilot
Home 1	83	15	Nursing	December 2018
Home 2	26	5	Care	March 2019
Home 3	60	11	Nursing	December 2018

Home 4	46	6	Nursing	August 2019
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Further details of each of the investigations and their findings are detailed in the following sections.

4.0 Findings

4.1 Scoping visits and observations

Scoping visits and observations were conducted by in the four homes that had taken part in the pilot, and in another home that had not participated, which acted as a control. An EMAHSN Patient and Public Involvement (PPI) representative accompanied the researcher on two out of the five visits. The visit to home 1 was done on 02/10/19, followed by home 2 on 30/10/19, home 3 on 31/10/19 and home 4 on 12/11/19. These visits were done during the medicine rounds in each of the homes. The medicine rounds lasted between 40 minutes to 2 hours. All aspects of the medicines round, storage and documentation were observed, with particular attention to the preparation of paracetamol for administration, the interactions with each resident and administration and the documentation in charts and/ or residents' records.

The findings from the scoping visits centre around two main aspects of the new pathway: the written medicines policy and the observation of administration process for paracetamol under the new pathway. These aspects will be looked at in turn.

4.1.1 Medicines Policy

During the pilot LinCA supplied the homes with paracetamol in clearly labelled boxes, which were easily identifiable as being separate from the other medications in the home.

LinCA co-ordinated with each home to discuss the review process by GPs to determine which residents could safely move on to as required paracetamol. As part of the reviews GPs were asked to complete and sign a documented record of the review. This included a statement of assurance that any episodes of increasing pain would be escalated to the GP. A record was kept in individual residents' care plans.

LinCA produced and provided a comprehensive medicines policy for the care homes to follow. This covered all of the aspects of the new pathway from first admission of a resident through to the escalation of pain medication for a resident. These documents were key to giving the care homes a full understanding on all aspects of the paracetamol pathway. In many instances, homes produced their own written procedures which combined LinCA's documents with their own local context of the home.

Each aspect of the medicines policy for paracetamol was shown as a flowchart, for example Figure 1 shows the flowchart of considerations for administering as required medication, figure 2 shows setting up as required medicines on new resident's care plans and figure 3 gives guidelines for monitoring.

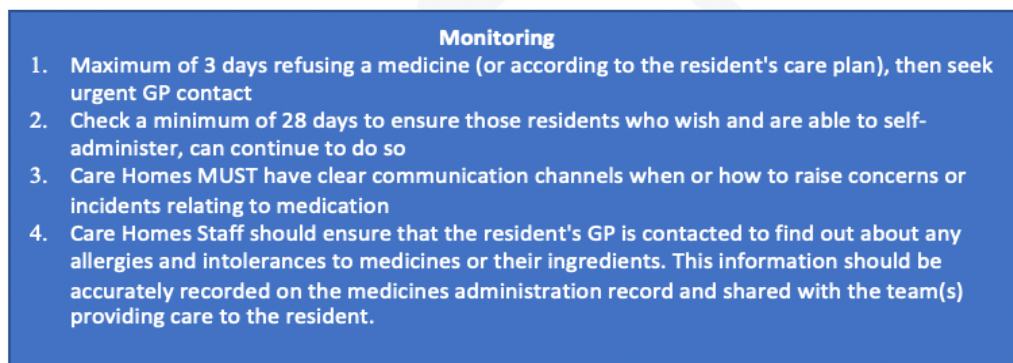
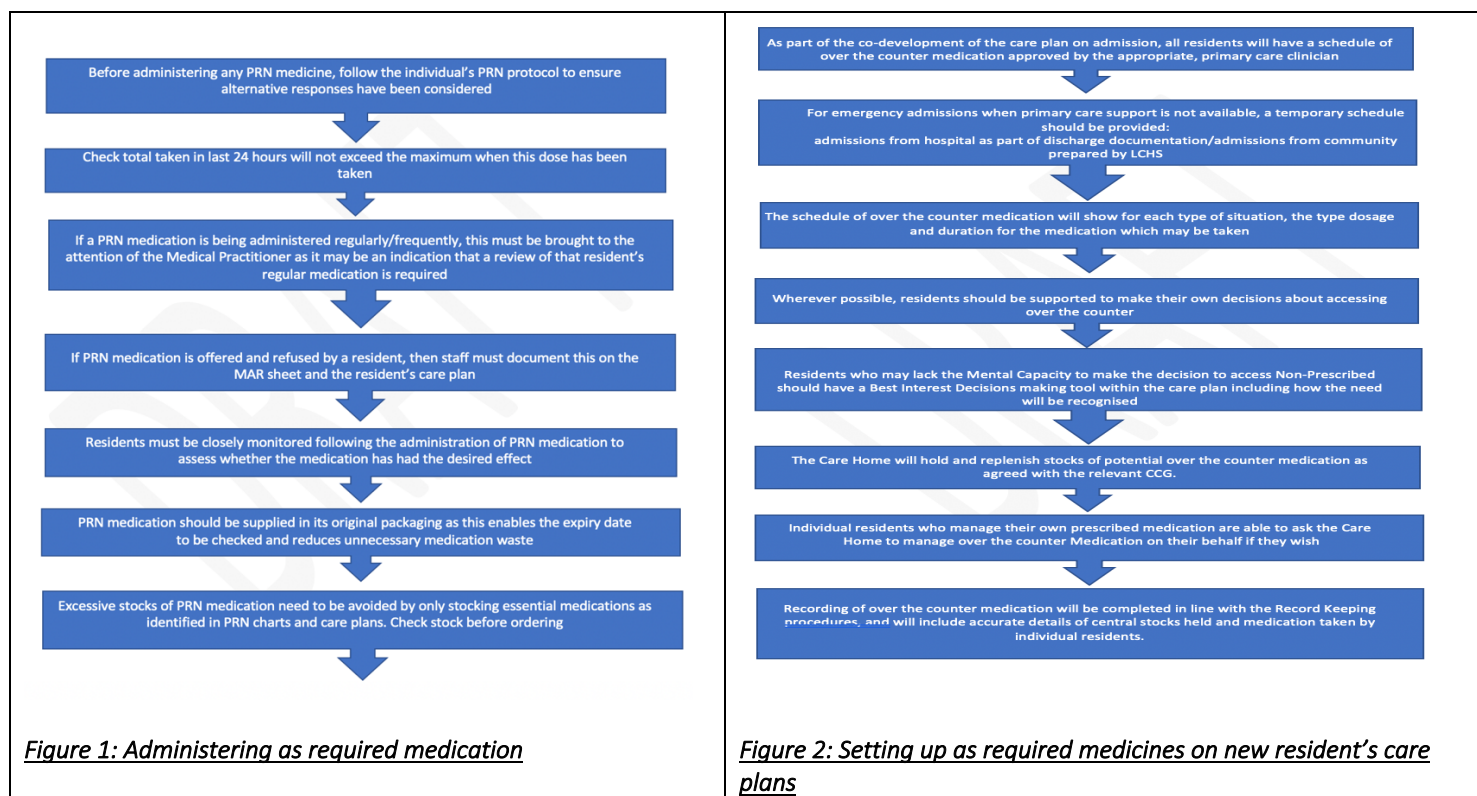


Figure 3: Guidelines for monitoring

Please note that the term OTC (Over the Counter) medicines is also used to describe “as required” medicines, and sometimes “homely remedies” is also used. However, under the remit of the new paracetamol pathway “as required” is the clearest description so as to distinguish from other remedies purchased by the home.

The range of LinCA WFD guidelines in the medicines policy included:

- Care Home to obtain review, written consent and approval from the GP for the resident to be supplied paracetamol as required.
- Care Home to monitor the amount of paracetamol administered to an individual on a weekly basis.
- Care Home to request a GP review for patients if their pain is not being adequately controlled and/or residents start needing paracetamol regularly.
- The responsibility for adherence to the Medicines Policy lies with the care homes.

- The Care Home is expected to send in a weekly audit to LinCA about the amount of paracetamol administered.
- Care home to liaise with LinCA when supply of paracetamol runs low, at an agreed amount, to enable stocks to be replenished
- Care Homes must have a system in place to ensure that the stock paracetamol supplied for use under the new pathway is not administered to patients on a regular prescribed basis. It should be clearly labelled and stored separately from the prescribed paracetamol.

LinCA also provided a list of responsibilities for GPs:

- The GP should assess all new residents on admission, and specify whether they should receive paracetamol on the as required pathway, or regularly on prescription.
- This initial review should be recorded with written approval and consent.
- The GP should respond to requests from the Care Home for on-going reviews of residents' pain control
- The final responsibility for authorising paracetamol for a resident remains with the GP.

The Medicines Policy formed the basis of the agreement between LinCA and the homes and it gave clear lines of responsibility and accountability.

"We are very stringent in informing all homes of what their responsibilities are, especially following the NICE communication which outline the difference between Homely Remedies and medication which is now classed as over the counter."

To summarise, LinCA played a key role in developing a comprehensive Medicines Policy of flowcharts and guidelines which covered all aspects of the medicines administration and review process. This policy acted as a framework for the pilot and laid out the responsibilities of LinCA, the homes and GPs.

4.1.2 Observation of administration processes

The homes in the pilot were observed to be following the new medicines process and policy, with one exception. In home 1 the member of staff conducting the medicines round removed paracetamol from the packaging before asking the resident if he or she needed paracetamol, which resulted in wastage. In all other regards the policy was being followed in all of the homes that were evaluated. This meant that residents' pain needs were assessed on each medicines round and only paracetamol that was needed was administered. It should be noted however, that all of these homes had been rated as good or above by the CQC and therefore good practice may be expected with or without the medicines policy. This principle is demonstrated by the home that was included in this evaluation, but had not been part of the pilot. Despite not having received the LinCA Medicines Policy and training, this home had well-structured procedures for paracetamol use and administration. This home had produced their own charts, structures and online system for monitoring and tracking medication, as well as all other procedures required by the home. This indicates that for this one home, procedures similar to those given by LinCA during the pilot were already being done internally by them, although the supply of paracetamol to the home would not have been the same. This home was one of the best rated by CQC in the region, so this could have influenced the observations in terms of procedures.

Observation of the medicines rounds in the homes from the pilot showed that the LinCA Medicines Policy had been integrated in to their existing policies and procedures to the extent that staff were not necessarily aware of this being something new. It had become “the way it is done” and staff had less appreciation of the rationale or benefits of using this process.

Staff were able to articulate how they recognised that a resident was in pain and how they would request a review to escalate pain control. It was observed that staff generally built up a good rapport with residents and were aware of their behaviours and needs in regard to pain and symptom control. A striking finding from the observations and interviews with staff was that the new paracetamol pathway and process appeared to be empowering for both staff and residents. It appeared to give them more control and dignity. Asking about paracetamol sparked other conversations and allowed for other conditions, such as depression, to be identified. It was apparent that staff knew their residents well and were in tune with their needs through observation and communication.

“Being given the control is very empowering and makes you feel like your job is even more worthwhile”
- quote from member of staff about the autonomy of asking before administering paracetamol

The lay representative who conducted the scoping visits along with the researcher commented -

“Having spent time visiting those participating care homes taking part in the project, it was obvious that the patients regarded being asked if they required their paracetamol for pain relief as a positive contact”

The staff appeared to enjoy the interactions with residents during the medicines round, as it allowed them to give more responsive and personalised care. It also enabled residents to have a greater role in managing their own medication and needs.

To summarise at this point, the observations showed that within each home procedures were in place to ensure that no patient or resident would be left in pain. The system therefore appeared to be safe and beneficial for residents. The LinCA policies had become integrated in to the existing practices of the home. The home that had not been in the pilot had developed their own policies and systems and had adopted a similar administration process for paracetamol. It was noted that a key part of the success of the project was the written Medicines Policy. Staff were aware of the “large folder” containing the policy and referred to it, even if they were less aware of the rationale behind the development of the policy.

5.0 Evaluation of data collected during the pilot

LinCA collected data from the pilot, which ran from December 2018 to August 2020. Data was collected on the number of residents on regular paracetamol per home prior to the pilot and then the number of residents obtaining as required paracetamol per month of the pilot, and the actual number of tablets administered. These data have been analysed further for the purposes of this evaluation. To note original data was not collected on the number of residents that received regular prescribed paracetamol during the pilot (although antidotally the homes reported this also significantly reduced) so the savings in these calculations have been conservatively based only on the number of tablets administered and the supply costs during the pilot of the 37 residents.

The results show that there was a significant reduction (99%) in the volume and spend on paracetamol as a result of the new pathway/policies put in place and direct supply of paracetamol.

Table 2: Volume and cost of paracetamol supply pre-pilot and pilot

	Pilot 'as required' / patient choice	Pre-pilot equivalent period (regular supply via prescription)
Number of residents	37	Calculations based on the pilot residents' number of 37
Number of paracetamol tablets	15,576	1,072,064
Cost of paracetamol (£)	264.79	38,915.92

This new route of paracetamol supply reduced costs because of the reduction in volume, and because the new route of supply was inherently cheaper irrespective of the reductions in volume. The cost of supplying a box of 100 tablets in the pilot was £1.70 compared to a cost of £3.63 if supplied as a pack of 100 on prescription.

These cost figures are based on the costs of supply to LinCA for supply by United Lincolnshire Hospitals NHS Trust (ULHT) (see Table 3), and the usual costs of supply via prescription at Drug Tariff prices, plus dispensing fee (see Table 3).

Table 3: Table showing cost of paracetamol purchased by LinCA.

Cost per order of 1000 tablets	£16.00
Supply fee per order	£3.88
Total	£16.88
Cost per tablet	1.69 pence
Cost per 100 tablets	£1.69

Table 4: Usual costs of paracetamol via prescription

Amount of paracetamol provided (pack sizes)	Cost of paracetamol on NHS (drug tariff)	Community pharmacy dispensing fee	Total cost for NHS
100	£2.38	£1.26	£3.64
32	£0.76p	£1.26	£2.02

Based on pack sizes of 100, the cost per tablet is 3.64 pence.

In summary, during the pilot 15,576 paracetamol tablets were administered across the four homes at a cost of £263.23. This is in comparison to the calculations for the same number of residents for the same length of time as the pilot, based on each resident receiving regular administration of two tablets four times a day (224 a month each). Therefore, pre-pilot the equivalent figures are administration of 1,07,064 tablets at a cost of £38,652.69.

6.0 Stakeholder consultation.

Throughout this evaluation, there was communication between all stakeholder groups including EMAHSN, University of Lincoln, LinCA, a lay representative and all of the care homes involved. Additional interviews were held with a LinCA stakeholder and with the lay representative. There was communication with a GP about the original vision of the project.

6.1 Stakeholder steering groups

Four stakeholder steering groups were held during the evaluation:

- An initial steering meeting was held at one of the homes in the pilot, on 02/10/19, to give an overview of paracetamol usage, pain management and the effectiveness of the pilot. This meeting involved the Chair of the Lincolnshire Care Association, the Lead Change Manager of Operational Efficiency in Lincolnshire STP, a Consultant Pharmacist in medicines optimisations at EMAHSN, The Head of School of Pharmacy Lincoln, a patient representative from EMAHSN PPI senate member and a research associate from the University of Lincoln School of Pharmacy.
- A second meeting was held to feedback on progress after the initial scoping visits to all 4 homes on 04/11/19. There was a decision at this meeting to add another home into the project that was not in the pilot, in order to act as a control. Dates were selected for a future interview with a LinCA stakeholder (05/12/19) as well as a discussion about the results and observations with feedback and findings from the patient representative.
- The next steering group was held on 17/12/19, with a discussion about progress and looking at preliminary data that had been collated by LinCA. The plan was set for the next stages with original data collection, and a meeting with LinCA stakeholders on 17/01/19 to discuss how the pilot was set up, whether there were any reservations, and how the homes were selected. This interview opened up another avenue for interviews with a GP who had been involved in the initial start-up process of the pilot, while also giving the perspective from a GP's side.
- A final steering group meeting was held on 24/02/20 (audio recorded) to confirm the findings, summarise the report structure and finalise the end dates. This meeting had another stakeholder attend from LinCA, who had not previously attended, who was able to give a detailed insight and more data that may be available to use for the report in terms of structures, procedures and confirmation (i.e. GP signatures for residents etc).

The main conclusions from the stakeholder meetings were that, there were many stakeholders to take into consideration, and therefore effective and extensive communication is vital for introducing a new system of medicines administration. There had been good communication in this pilot and all stakeholders were very positive about the new route of administration.

6.2 Stakeholder interviews

Two stakeholder interviews were conducted: one with a LinCA member, one with a patient representative. In addition, there was e-mail correspondence with the GP that had contributed to the initiation of the project.

- The LinCA Stakeholder interview was done the 05.12.19, lasting 2 hours and was audio recorded. The initial aims for the pilot, the rationale for initiating the pilot and her thoughts on the impact were discussed. She said that the best outcome for this pilot would be that there is *'recognition that there is a need for something in-between homely remedies and prescription/over the counter medication, with a visible communication line between all areas involved'*. The partnership

between different healthcare professionals working together for more patient centred care appeared to be the best end goal for the pilot, with a better data sharing process and management practice, with the eventual hopes of leading it into home care.

- In the interview with the patient representative she was asked about her views on the patient representation side of the project, in terms of safety and assurance that if rolled out, there would be no adverse effects or harm in the way of the patient or residents. She responded *'It appears to me to be a good project that ought to be rolled out across the country, as an improvement on simply giving out prescribed medication for pain relief whether or not the patient needed it at that time or not. Giving decision making back to the patient (where and when the patient was able to) can only be seen as giving some control of their own lives back to that patient'*.
- On 01/03/19, a GP was questioned about the project. He had been part of the pilot start up process, and was also able to provide a more information on how this process may affect GP's. he said that *'the project idea came about when a care manager told me that they were handing out up to 1000 pills a day, and I was having to sign multiple scripts (prescriptions)'*. This then led to a discussion on how to better manage this. He also commented on the fact that *'often, these are products that can be bought by the patient'*, therefore this is a solution that will be providing care homes with basic medications e.g. paracetamol, rather than having them on prescriptions. It can also be noted that any new residents/patients would not have to delay the administration of paracetamol should they require it, as it would just mean a GP is able to sign them off as having homely remedy paracetamol, with the knowledge that should they need it on a more regular basis, they are then able to get a prescription. This changes the need for multiple different prescription signatures from the same GP. He therefore initiated discussions with LinCA to take the idea forward.

'Providing care homes with basic medications i.e. paracetamol, without prescription. It's safer, quicker and more cost effective, whilst saving GP time'

In addition, a quote was obtained from a care home manager:

"The level of wastage for paracetamol prescribed has reduced, this must be a huge saving on a national level if it is managed in this manner in all registered care homes. It also opens up ways for the same management of medication going forward"

To summarise, the perspectives of the different stakeholder groups were as follows:

- Priorities for LinCA in this pilot were to be able to get recognition for a service between 'as required' and prescription medications. They also noted that they wished it to give access to a safe way for people/patients to have access to pain relief that is based more on their own decisions.
- Perspectives for the patient representative were to ensure that the patients/residents involved were being safely treated throughout the pilot, as well as whether the care home staff were confident in their ability to provide that care in this new way for their patients/residents.
- Perspectives for EMAHSM were to ensure the pilot ran smoothly, with hopes to have it effectively rolled out. EMASHN also need to ensure this pilot is able to be easily disseminated without holdbacks or safety issues for the medicine's management.

- The perspective of GP was simply to ensure safety. From LinCA's stringent guidelines, through to the actual receiving and giving of the tablets, it was the GP's responsibility to be able to ensure this process was safe and correct.

7.0 Summary of findings and recommendations

This evaluation sought to answer the following questions:

- Did the new pathway reduce the volume and cost of paracetamol usage in the homes?
- Did the new pathway enable pain control to be tailored better to residents' needs?
- What were the more generalised benefits of the new pathway?
- Were there any disadvantages to the new pathway?
- What factors contributed to the success or limitations of the new pathway?
- What recommendations can be shared with others considering adopting a new medicines pathway for paracetamol?

In answer to these questions, the new pathway reduced the volume and cost of paracetamol usage by 99%. It also enabled residents to be more empowered and involved in their medicines' usage. Both staff and residents valued the increased interaction during the medicines round. Staff reported that pain control was tailored better to residents' needs and there was evidence of a pain escalation protocol in the Medicines Policy. The pathway created partnership working between the NHS Trust, GPs, the CCG, LinCA and the homes. There were very few observable disadvantages to the new pathway. Factors that contributed to success were the implementation of the clear and comprehensive Medicines Policy and close partnership working. In addition, all of the homes in the pilot were already of a high standard. They effectively incorporated the Medicines Policy in to their own protocols so that it became standard practice. A potential limitation is the need for regular training of staff, particularly for new staff. It should also be noted that the home that was not in the pilot had developed their own as required paracetamol process. The advantage of using a collective standardised approach is the support that was offered and use of the Medicines Policy, rather than having to develop individual policies. This approach could be adopted effectively by others. Consideration should be given to developing a Medicines Policy, working effectively with key partners including GPs, the route and logistics of local supply arrangements.

Conclusion

Direct supply of paracetamol to Care Homes for as required administration can result in significant reductions in volume and cost, as well as creating an opportunity for better pain control and interaction between staff and residents. Key features to consider are the logistics of local supply, having protocols and implementation documentation for care home staff, the importance of GP review, the need for effective partnership working.

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