

The four or more medicines (FOMM) support service: results from an evaluation of a new community pharmacy service aimed at over-65s

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Abstract

Objective Inappropriate prescribing and nonadherence have a significant impact on hospital admissions and patient quality of life. The English government has identified that community pharmacy could make a significant contribution to reducing nonadherence and improving the quality of prescribing, reducing both hospital admissions and medicines wastage. The objective of this study is to evaluate a community pharmacy service aimed at patients over the age of 65 years prescribed four or more medicines.

Methods Patients were invited to participate in the service by the community pharmacy team. The pharmacist held regular consultations with the patient and discussed risk of falls, pain management, adherence and general health. They also reviewed the patient's medication using STOPP/START criteria. Data were analysed for the first 6 months of participation in the service.

Key findings Six hundred twenty patients were recruited with 441 (71.1%) completing the 6-month study period. Pharmacists made 142 recommendations to prescribers in 110 patients largely centred on potentially inappropriate prescribing of NSAIDs, PPIs or duplication of therapy. At follow-up, there was a significant decrease in the total number of falls (mean -0.116 (-0.217 – 0.014)) experienced and a significant increase in medicine adherence (mean difference in Morisky Measure of Adherence Scale-8: 0.513 (0.337 – 0.689)) and quality of life. Cost per quality-adjusted life year estimates ranged from £11 885 to £32 466 depending on the assumptions made.

Conclusion By focussing on patients over the age of 65 years with four or more medicines, community pharmacists can improve medicine adherence and patient quality of life.

Introduction

Almost 17.5 million people in the UK are believed to have a long-term condition, the majority of whom will be prescribed medication.^[1] Fifty-seven per cent of all prescriptions dispensed in the UK in 2003 were for people over the age of 60 with more than one-fifth of them prescribed five or more medicines.^[2] A Scottish study highlighted that the number of regular medicines is strongly associated with unplanned hospital admissions.^[3] Some 35% of medicine-related admissions to hospital have been attributed to inappropriate prescribing^[2] costing the National Health Service (NHS) an

estimated £750 million annually.^[4] Additionally, as many as 30% of medicine-related hospital admissions occur as a result of nonadherence to medication,^[2] which has been estimated to be as high as 30–50% in patients with long-term conditions.^[5] Consequently, evidence suggests that the return on medicines investment is not optimised and could be improved by enhancing the quality of prescribing and increasing patient adherence.

The English government believes that community pharmacists can contribute to supporting patient adherence and

improving prescribing quality potentially resulting in reduced hospital admissions.^[6] Evidence suggests pharmacists can reduce inappropriate prescribing and adverse events, encourage appropriate use of medicines by patients and realise savings within the drugs' budget.^[7–10]

Medicine use reviews are delivered as one-off interventions to patients prescribed medicines, mainly for long-term conditions^[11] and were introduced to reduce nonadherence. There is currently limited, robust evidence demonstrating the value of community pharmacy interventions particularly with reference to health economic outcomes,^[12] and this is in line with many other interventions to improve nonadherence.^[13] It has recently been suggested that longer-term behavioural-type interventions, where a relationship between the healthcare professional and patient is developed and used to influence change, may be more effective.^[14]

Tools such as STOPP/START and the Beers' criteria have been developed to reduce inappropriate prescribing in a systematic manner.^[15,16] Effective implementation of such tools should ensure that prescribing is rationalised, adverse events such as falls which lead to hospitalisation are minimised and that patient quality of life is improved by limiting the use of medicines known to cause sedation and confusion. Used by pharmacists working in care homes to some effect,^[4] they have not been widely utilised within the community pharmacy setting.

Inappropriate prescribing, monitoring and adherence (particularly in the case of psychotropic medication) are all contributing factors to the risk of falls experienced by this group of patients. People over the age of 65 are more likely to fall than any group in society with 30% estimated to fall at least once per year.^[17] The National Institute of Health and Care Excellence has recommended that a patient at risk of falls should undergo a multifactorial risk assessment to identify areas that could be addressed to reduce their risk of falling.^[9] Targeting inappropriate psychotropic and cardiovascular medication as part of a review along with appropriate information regarding falls prevention has been shown to help reduce the number of falls in older people.^[18–20]

Appropriate pain management is another area of concern for this group of patients and is thought to affect many patients over the age of 65 years.^[21] It has been shown that in patients with other co-morbidities, improving pain management may lead to improved outcomes for other conditions as well as quality of life.^[22]

The aim of this paper is to describe the effect of an holistic community pharmacy-based service with patients over the age of 65 years old and prescribed four or more medicines (FOMM) which has been designed to improve both patient adherence and prescribing quality using systematic tools to standardise the intervention.

Methods

Nottingham NHS Research Ethics Committee deemed this project a service evaluation, and therefore, formal ethical approval was not required. The University of East Anglia's research ethics committee confirmed this. The FOMM service was delivered from September 2012 to June 2013 and located in Boots UK, Co-operative, Lloyds and Rowlands pharmacies working together to design and implement at their own cost.

Final service design was based on interventions which had the opportunity to have the greatest impact on unplanned hospitalisations, patient quality of life and that which a community pharmacist could provide without significant re-training. These were poly-pharmacy, nonadherence, falls risk and pain management, and had been determined from patient need, best clinical practice, discussions with NHS clinical leads for older people and operational experience.

Patients were invited to participate in the service via the pharmacy or another healthcare professional (e.g. a general practitioner (GP) could give the patient a leaflet that explained the service) if they were over 65 years old and taking FOMM. Prior to meeting with the patient, the pharmacist conducted an assessment of their medication using their pharmacy medication record (PMR) and STOPP/START criteria. At the initial consultation, the pharmacist discussed this assessment with the patient and agreed what action should be taken in relation to contacting the GP. A patient record was used as part of the service to direct the consultation together with collecting the required data for evaluation including all elements listed below.

For this service, a sub-set of the STOPP/START^[23] criteria was used that were appropriate for interventions made by community pharmacists. Twenty-four of 65 (36.9%) of the STOPP criteria and two of 22 of the START criteria were used for this study. These were the criteria that community pharmacists could sensibly assess without access to the patient's medical notes. These criteria were listed on the patient's personal service record (designed to record relevant information for the study and separate to the PMR) in order that the pharmacist could assess their medication regime in an efficient manner. If a particular criterion was present, then the pharmacist ticked the box, and this prompted them to make a recommendation to the GP.

They then asked specific questions relating to falls risk, pain management and adherence, where appropriate. In terms of falls risk, the pharmacist assessed the patient's medication in a similar way to that of the STOPP/START criteria. The patient record prompted the pharmacist to highlight medicines that had an increased risk of causing falls. The pharmacist then devoted a period of time during the initial consultation to the discussion of falls risk. This included previous history of falls and other factors that might affect their

risk. If necessary, the pharmacist then made recommendations to the patient about how to mitigate any risks including advice on avoiding slips, trips and hazards, alcohol awareness, and exercise advice. If the patient was identified as being at risk of falls, then this was revisited and reviewed with them on a regular basis. The number of falls (self-reported) between each review was recorded along with details regarding whether it was self-treated or required medical attention.

The pharmacist assessed pain medication and their pain score using scales recommended by the British Pain Society and the British Geriatrics Society,^[24] and, if necessary, then provided follow-up advice to the patient and referred to the GP as appropriate. Pain scores (scoring 1 (no pain) to 10 (worst pain imaginable)) and the effect it was having on their daily activities (scoring 1 (not at all) to 10 (completely)) were recorded. Finally, adherence was assessed at every appointment using the Morisky Measure of Adherence Scale (MMAS-8),^[24] and if appropriate, the pharmacist suggested strategies to improve their medicine taking behaviour.

Where appropriate and throughout the entire intervention, the pharmacist discussed, and referred to, any public health interventions that might be useful to the patient (e.g. smoking cessation, weight management or medicine use review). The pharmacist discussed the STOPP/START assessment with the patient's GP if necessary. Patients then met with the pharmacist on a regular basis depending on when they collected their repeat medication or they felt a need. The pharmacists made a decision in conjunction with the patient regarding which sub-set of interventions was appropriate and which they were happy to receive (e.g. adherence, falls and/or pain management).

This service was implemented in 25 community pharmacies in the Aston, Leigh and Wigan areas of England. These areas were chosen because they contained a similar number of pharmacies from the four participating companies, and they have a large population of older people. All the pharmacies belonging to the four multiples within the localities were included in the project. This included a range of locations, and small and large pharmacies. The service was later rolled out to other pharmacies within the locality (independents, supermarkets). Data were not collected from this latter group. Pharmacists were trained via distance learning and face to face, which included how to use the various different tools and assessments. Training was then cascaded to other pharmacy members.

To estimate the levels of health-related quality of life, participants were asked to complete the EQ-5D-5L^[25] at baseline and at subsequent quarterly visits. Responses, which describe the level of problems (ranging from no problems to unable to do) with regard to mobility, self-care, usual activities, pain and anxiety/depression, were converted into a utility score (a scale where death is equal to 0 and full health 1) using a mapping approach based on the three-level version.^[26]

Table 1 Unit costs attached to different items of resource use, with associated source

Item	Estimated unit cost (£)
Pharmacist (nonpatient contact time)*	50.00
Pharmacist (patient contact time)*	63.00
Healthcare assistant (cost per hour of employment)	12.50
GP visit*	43.00
Hospital admission (cost per day) [†]	254.00
Day case (weighted average of all procedures) [†]	680.70
A&E visit (not admitted cost)*	112.00
Hospital specialist consultation***	139.00
Out of hours contact with GP/nurse [#]	53.58

A&E, accident and emergency; GP, general practitioner. *Taken from Curtis.^[27] [†]Taken from the National Schedule of Reference Costs.^[28] [#]Estimate based on a GP home visit lasting 11.4 min.^[27] ***Assumed to equate to weighted average of all out-patient procedures, taken from Curtis.^[27]

Pharmacist time was estimated after discussion with participating pharmacists at the end of the evaluation period. Levels of resource use associated with the intervention (training, patient contacts (where initial monthly and quarterly reviews were available)) and associated service materials were recorded. Participants were also asked at (1) baseline (recall period: previous 6 months) and (2) every subsequent visit (recall period: since their last visit) to report the number of the following items of other NHS resource use that were received:

- GP visits
- Hospital admissions (and total number of days admitted, if applicable)
- Accident and emergency (A&E) visits
- Hospital specialist consultation
- Out of hours contact with GP/nurse

Table 1 details the costs assigned to each of these items and were estimated at 2011/2012 financial year levels.

All data for analysis were collected as part of service provision. Pharmacists were encouraged to use this data to structure the consultation with the patient. No additional data, purely for the purposes of the evaluation, were collected from patients.

Data analysis

To be included in the final analysis cohort, each patient was required to meet the following criteria (where appropriate):

1. To have baseline data measured.
2. For the falls, pain and resource parameter analysis, to have at least one follow-up consultation within 6 months \pm 30 days to ensure that similar time horizons were being compared pre and postintervention (i.e. baseline versus follow-up). (Data collected during visits beyond this time period were not included within the data analysis.)

3. For adherence, patients for whom six monthly follow-up consultations were available were included; providing the sixth follow-up consultation fell within ± 30 days from baseline
4. For quality of life and in line with the complete case analysis approach,^[29] patients were only included if they had at least one follow-up visit at 6 months ± 30 days where they reported levels of resource use (if an EQ-5D score, was not also reported on this date, then the nearest follow-up EQ-5D score to this date was used).

For the main analysis, once mean values had been derived for each parameter before and after the pharmacy service intervention, mean differences and associated confidence intervals (CIs) were generated. The underlying assumption was that the sampling distributions of the mean estimates were normally distributed (though the distributions of many of the parameters were skewed). The assumption of a normal sampling distribution was made by applying the central limit theorem which requires that samples in question should have $n > 30$ patients. CIs associated with the estimate of mean change which did not cross zero were deemed to be statistically significant. No further analysis was performed.

The total cost of the intervention was estimated by summing the cost of the component parts (consultation, training and service material costs). Total other NHS costs were estimated by summing the costs associated with the aforementioned self-report items of resource use. Total NHS costs were estimated by summing the intervention and total other NHS costs. Mean costs over the 6-month preintervention period and the 6-month follow-up period were subsequently estimated. The difference between these two variables provided an estimate of the change in cost associated with the intervention.

The area under the curve method^[30] was used to estimate the change in quality adjusted life year (QALY) score between baseline and follow-up (the EQ-5D score was assumed to change linearly).

If the mean estimated change in cost associated with the intervention was positive along with the mean estimated QALY change, then the incremental cost per QALY gain (incremental cost-effectiveness ratio (ICER)) was calculated (mean change in cost/mean QALY change).^[31] Any calculated ICER would be compared with a cost-effectiveness threshold (λ) range of £20 000–30 000 per QALY.^[31] Based on the cost-effectiveness acceptability curve (CEAC),^[32] we also report the estimated probability of the intervention being cost-effective at the λ values of £20 000 and £30 000 per QALY. A further 12-month ICER was also calculated, where the 12-month QALY change was estimated based on the assumption that the EQ-5D score remained constant between the 6-month follow-up and 1 year; it was also assumed that no further costs were incurred beyond the 6-month point.

Results

Six hundred twenty patients were enrolled in the service (range 3–51 patients per pharmacy) and underwent an initial assessment; 179 (28.9%) patients withdrew from the service during the course of the evaluation period. The age distribution and number of medicines prescribed were approximately the same between those that completed the service and those that withdrew. The most common reasons that were stated for withdrawal were 'lack of time' (17.9%), 'patient did not want to be bothered again' (12.8%), 'patient had become housebound' (9.5%) and they felt they 'no longer needed the service' (6.1%). Of those initially registered, 51.0% were male, and the mean (standard deviation) age was 73.9 (6.03). Patients registered for the service had a median (IQ) number of conditions of 3 (2–4), and were taking a median (IQ) 7 (5–9) medicines. Of these, the most common conditions were cardiovascular, chronic pain, musculoskeletal and CHD.

Four hundred ninety-eight patients (80.3%) received the STOPP/START assessment as part of their initial consultation with the pharmacist. This resulted in 142 recommendations being made across 110 (22.1%) patients. Table 2 illustrates the type of recommendation made as a result of the STOPP/START portion of the intervention. Of those 142 recommendations, 35 (24.6%) were for an NSAID that had been prescribed for longer than 3 months, 28 (19.7%) where a proton pump inhibitor had been prescribed at maximum therapeutic dosage for greater than 8 weeks, 25 (17.6%) cases of duplication of therapy (six where the patient had been prescribed more than one opioid) and 22 (15.5%) cases of patients prescribed either an opioid or calcium channel blocker with a tricyclic antidepressant. No data were collected on implementation rate by the medical practice.

Table 3 provides the results for falls, pain and adherence scores. There was a significant reduction (mean 0.116 (95% CI, -0.217 to -0.014)) in the total number of falls. However, there was no significant difference between baseline and follow-up in the number of self-treated falls and those that were medically treated. Pain scores over the course of the evaluation period appeared to increase (nonsignificantly); however, the effect of pain on day-to-day activities reduced

Table 2 STOPP/START recommendations

Measure	Total
STOPP dose	5 (3.5%)
STOPP duration	70 (49.3%)
STOPP cautions	33 (23.2%)
STOPP duplication	25 (17.6%)
STOPP other	1 (0.7%)
START all	8 (5.6%)
Total	142

Table 3 Falls, pain scores and adherence

Parameter	<i>n</i>	Measure	Baseline	Follow-up	Difference (95% CI)	Significant
Falls – total	303	Mean (SD)	0.251 (0.88)	0.135 (0.41)	–0.116 (–0.217 to –0.014)	Y
Falls – medical	303	Mean (SD)	0.092 (0.39)	0.053 (0.24)	–0.040 (–0.089 to 0.010)	N
Falls – self-treat	303	Mean (SD)	0.158 (0.76)	0.083 (0.32)	–0.076 (–0.159 to 0.007)	N
Pain score	264	Mean (SD)	3.561 (2.85)	3.682 (2.45)	0.121 (–0.084 to 0.327)	N
Day-to-day activity	264	Mean (SD)	3.061 (2.87)	3.038 (2.40)	–0.023 (–0.233 to 0.187)	N
Adherence	115	Mean (SD)	7.348 (1.06)	7.861 (0.48)	0.513 (0.337 to 0.689)	Y

Pain score, max score = 10 indicating worst pain imaginable; day-to-day activity, max score = 10 indicating complete interference with day-to-day activities; adherence score, max score = 8 indicating highly adherent.

Table 4 Intervention costs

Component part	Resources costed (unit cost), participant costing	Mean cost (£ per participant)
Training (receipt)	Precourse distance learning (16 pharmacist hours) plus training course (2 h for pharmacist trainer and 8 h for pharmacists trained) plus cascade training (1 h for pharmacists and 3 h for health care assistants) (pharmacists £50 per hour*, health care assistant £12.50 per hour), divided across all <i>n</i> = 620 participants	2.24
Initial consultation	25-min patient contact time with pharmacist (£63 per hour*), <i>n</i> = 620 participants attended	26.25
Monthly review	10-min patient contact time with pharmacist (£63 per hour*), <i>n</i> = 1426 occurred in sample of 531	28.20
Quarterly review	11-min patient contact time with pharmacist (£63 per hour*), <i>n</i> = 1401 occurred in sample of 531	41.56
Equipment	Four sets of service materials (@£75.00 each), divided across all <i>n</i> = 620 participants	0.48
Total		98.72

*Taken from Curtis.^[27] Estimated within study costs.

Table 5 Per participant mean (range) levels of resource use and associated costs (*n* = 339 responders)

Item	Levels of resource use			Mean cost (£)		
	Preintervention	6-month follow-up	Difference	Preintervention (£)	6-month follow-up (£)	Difference (£)
GP visits	1.65	2.04	0.39	70.91	87.65	16.74
Number of hospital admissions	0.04	0.14	0.09	–	–	–
Total number of days in hospital	0.17	0.29	0.12	49.54	90.85	41.31
A&E visit	0.07	0.07	–0.00	7.93	7.60	–0.33
Hospital specialist consultation	0.36	0.72	0.37	49.61	100.46	50.84
Out of hours contact	0.03	0.05	0.02	1.42	2.43	1.11
Total other NHS costs				179.41	289.08	109.67
Intervention costs				0.00	109.67	109.67
Total NHS costs				179.41	398.76	219.35

over that same time frame. Adherence to medication improved progressively over the course of the evaluation period, with a significantly higher mean MMAS-8 score at the end of the study.

A description of the resource use associated with the component parts of the intervention is given in Table 4, where the cost of the intervention was estimated to be £98.72 per participant. A total of 339 (54.6%) participants had at least one follow-up visit at 6 months ± 30 days. The levels of resource use reported by these participants are summarised in Table 5, where it can be seen that these are generally higher in the 6-month follow-up period compared with preintervention.

Overall, the mean (per participant) total other NHS costs were higher in the 6-month follow-up period compared with that preintervention (see Table 5), as was the total NHS cost (when the intervention cost was included). The mean change in total NHS cost associated with the intervention was estimated to be £219.35 (95% CI, £167.91 to £273.19).

At the 6-month follow-up point, 249/339 (73.5%) patients had the EQ-5D score performed on the same day as the resource use data were recorded. The mean baseline, interim (3-month) and 6-month follow-up EQ-5D scores were 0.733, 0.745 and 0.758, respectively. This equates to a mean change in EQ-5D score of 0.025 (95% CI, 0.007 to 0.042) and an

estimated change in QALY of 0.007 at 6-month follow-up (95% CI, 0.001 to 0.012). The 6-month ICER was estimated to be £32 466.03 (£219.35/0.007), slightly outside the often quoted value for money threshold of £30 000 per QALY.^[31] Based on the CEAC, at £20 000 per QALY, the probability of being cost-effective was 13.8%, compared with 43.5% at £30 000 per QALY. Based on the 12-month QALY gain, the ICER would be estimated to be £11 885.18 (£219.35/0.018), with probabilities of 81.0% and 90.5%, respectively.

Discussion

This service evaluation has demonstrated that in patients prescribed FOMM, a community pharmacist intervention is associated with positive outcomes in patients over the age of 65 years. A significant reduction in the total number of reported falls together with a significant improvement in adherence to medicines and quality of life was seen. It also demonstrated that the service had the potential to be cost-effective (if the 6-month gains were maintained at 12 months at no further cost).

The strengths of this independently evaluated project were that it recruited a large number of patients and providers and therefore is likely to be generalisable. The intervention used standardised and validated tools to assess prescribing, adherence and quality of life and formed the basis for the consultations with patients in a naturalistic setting. This appears to have been beneficial as the service managed to retain a large number of patients for the duration of the intervention.

The main criticism of this project is that it is a before-and-after analysis, and from this, we cannot rule out the possibility that any improvement was due to external influences. It must also be assumed that some proportion of the patients would have been actively reviewed by their GP in the same time period. An attrition rate of just over a quarter of participants requires further research to better understand why patients chose to not continue with a service being provided by their regular pharmacist. A further limitation of this study was that it was not powered to detect significant differences in outcomes at the outset. A post-hoc power calculation was also not conducted.

This evaluation needed to report back in a timely fashion to inform pharmacy service development. As such, no follow-up data were collected after the end of the 6-month evaluation period, and as such, no inferences can be made about the long-term effect of such a service and whether the interaction with the pharmacist needs to continue on a regular basis to maintain its effect on the outcomes measured.

Adherence was characterised using a self-report method which may be less reliable than other forms of adherence measurement (e.g. prescription refill data^[33]), and the act of completing the questionnaire may have had an effect on this

result. However, this would have been the case at both baseline and follow-up, and the size of the effect seen is large, and therefore, it would seem prudent to assume that much of what was seen was as a result of the intervention. As patients are also free to obtain their medicines from any pharmacy, we could not be confident that refill data, based on a single pharmacy patient medication record, would be robust enough to be a measure of adherence. In this context, adherence was only used to explain any improvements in clinical outcomes. Another limitation is that data regarding the implementation rate of recommendations made to the GP were not characterised. Again, for this evaluation, this was only used to explain any improvements in clinical outcomes.

The findings from this evaluation appear to support the suggestion that community pharmacists can achieve the same outcomes as pharmacists working in care homes, with respect to a reduction in the number of falls after medication review.^[34] This may largely be due to the review of medication using a standardised tool which identified a number of cases where inappropriate therapy could have been linked to the increased likelihood of falling (e.g. duplication of opioid analgesics or tricyclic antidepressants prescribed with an opioid).

In the short term, this intervention may have resulted in an increase in referrals to the GP to alter medications as a result of the STOPP/START criteria. However, if this service was conducted by a supplementary prescribing pharmacist, working within a clinical management plan cost savings may be realised. This collaborative approach between the medical practice and community pharmacy may be preferred by patients where services are seen to be an extension of the usual care from their GP rather than as an independent add-on.^[35]

This service included an average of 7.2 consultations between patients and their pharmacist (based on those in the final analysis), and this appears to have been useful at reducing nonadherence. With a positive relationship with healthcare professionals a predictor of improved adherence,^[36] this may explain this finding. While evidence suggests that reducing nonadherence improves patient outcomes,^[37] no effect on hospitalisation or pain control was seen. This may be again due to the relatively short time period for follow-up in this study, and perhaps data from 12 months may have provided a more complete picture. The appropriate use of medicines and increased adherence this service may also have had an impact on reducing medicines wastage although data on this were not captured. Quality of life appeared to increase as a result of this intervention; however, it cannot be determined which aspect of the service contributed to this increase.

The emphasis on polypharmacy, defined as taking FOMM,^[2,21] along with an approach that focuses on the patient rather than a specific guideline-driven disease state,

is something that has been recently advocated in the literature^[38,39] and is now the focus of a consultation into a revision to the current GP incentive scheme.^[40] Pharmacists who participated in this service have demonstrated that when provided with a service specification and protocol to follow, they can have a significant effect on patient care.

Conclusion

By providing a multidimensional, patient-focused intervention, pharmacists were able to demonstrate positive outcomes in relation to quality of life, adherence and risk reduction. This was a multiconsultation service that aimed to build a relationship with the patient. The intervention was estimated to be associated with a mean cost increase of £219.35 to the NHS and a mean QALY gain of 0.007. The intervention was shown to have the potential to be cost-effective if these increases can be maintained at no further cost, though due to the before and after nature of the analysis, these results should be treated with caution.

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Declarations

Conflict of interest

The Author(s) declare(s) that they have no conflicts of interest to disclose.

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MT and DW were involved in analysing the data and writing the publication; GB performed the health economics analysis and contributed to the writing of the paper. TT and CK are part of the CPF team who performed the study. They assisted with data analysis and writing of the report. All Authors state that they had complete access to the study data that support the publication.

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