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ORIGINAL REPORT

SPASTICITY MANAGEMENT WITH BOTULINUM TOXIN: DEVELOPMENT AND EVALUATION OF A TOOL FOR AUDIT

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Objective: **To develop and evaluate tools for the audit of spasticity management with botulinum toxin.**
Design: **Audit tools to assess the organisation of services and process of care were developed with a consensus process. The tools were piloted across 8 services using a retrospective case note audit. Inter-rater reliability was assessed, using percentage agreement and kappa scores. Clinicians involved in the pilot were surveyed and qualitative feedback was analysed.**
Results: **Eight services (100%) completed service Organisation tools and 7 (88%) returned process of Care tools. One hundred sets of clinical records were audited, with 34 used to assess inter-rater reliability. Eleven items on the process of care tool demonstrated a good degree of inter-rater agreement, but 6 require further development. In the qualitative analysis clinicians stated that the tools captured indicators of quality, and that they would use them again. They recommended that patient satisfaction was included as a measure of quality. The audit has been used practically in the pilot services to provide an impetus for quality improvement.**
Conclusions: **The majority of the audit questions showed a good level of reliability, and clinician feedback supports face validity but a larger scale evaluation is required.**

Key words: muscle spasticity; clinical audit; botulinum toxin.

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INTRODUCTION

There is an absence of data to indicate the prevalence of spasticity generally, but studies estimate that up to 40% of stroke survivors are affected (1), and up to 85% of people with multiple sclerosis (2). Currently it is recognised that optimal treatment should be multidisciplinary and includes physical interventions and medications such as botulinum toxin (3).

In January 2009, the Royal College of Physicians, UK published national guidelines for managing spasticity with botulinum toxin (4). The guidelines contain recommendations that cover the organisation of services, and the process of care. The original guidelines were published without tools to assess the extent of their implementation. The aim of this project was to use a structured process to develop and evaluate audit tools for this purpose.

METHODS

The UK Healthcare Quality Improvement Partnership (5) has developed a structured framework to ensure the quality of clinical audit. This framework includes a step wise process to agreeing standards with all stakeholders, and ensuring that data collection and analysis are reliable. The framework was adopted to ensure a robust approach to the development of these tools (Fig. 1).

The first step of the process was to agree the draft tools through a consensus process with clinicians and service users. Nine standards relating to service organisation and 17 related to process of care were drawn from the national guidelines (the remainder related to research recommendations). The standards and questions for their audit were sent to the lead clinicians of the 8 spasticity services in the region with a request for feedback. This indicated that all the clinicians agreed with the standards and felt the tools had face validity in measuring achievement against the standards. Service user views were ascertained via a broader project on patient and public involvement in spasticity services. Twenty-nine people, who had attended a local clinic, were asked to indicate areas of service provision that were important to them. Seventeen (59%) people responded, and highlighted the importance of having the opportunity to discuss prognosis and different treatments, and receiving information about self management and exercise (6). These comments gave further support to the standards and draft tools (Appendix I).

The service organisation tool included aspects of team working, training, access to equipment, and links with other services. The process of care tool was designed to audit clinical records and consisted of 17 items related to assessment, consent, goal-planning, treatment, information provision and aftercare. Audit questions were phrased so that answers were 'Yes' or 'No' depending on whether the standard

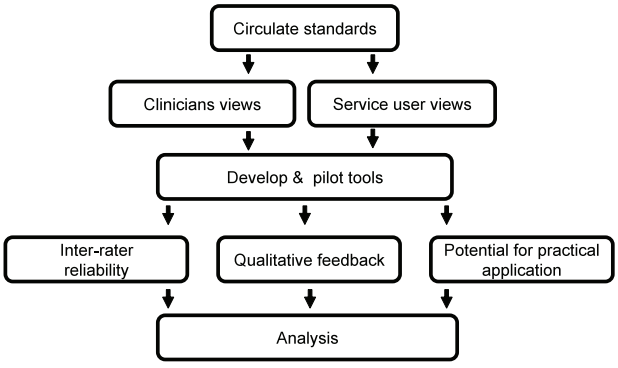

Fig. 1. Process of development and evaluation of tools.

Table I. *Questions to structure qualitative feedback*

• Did you agree with the standards used for the audit?
• Were the tools easy to complete?
• Do you feel that the tools captured indicators of quality in spasticity management with botulinum toxin? If not, what was missing?
• Was there anything else we should have included on the tools?
• Has the process been helpful?
• Would you use the audit again?
• Is there anything else you would like to feedback?

had been met, with a 'No, but' category to allow for situations when the standards may not apply. The draft process of care tool was tested with clinicians working in rehabilitation in the developing hospital, and findings were used to draft some written advice for completion of the tool, prior to a regional audit across the 8 centres. Each service was then asked to audit at least 15 sets of records and to audit 5 of these twice using different auditors, working independently.

Following return of the tools, the data were entered into an Excel spreadsheet and the agreement between auditors and kappa scores calculated for each audit item (7). Each clinician who had taken part in the audit received a questionnaire to ascertain qualitative feedback to the use of the tools with a mix of open and closed questions. The questions are shown in Table I. Written qualitative responses were entered into a framework and analysed (8).

RESULTS

All 8 services returned completed copies of the service organisation tool. Seven services completed process of care tools, with a total of 100 sets of case records audited. Four services used two independent auditors to assess a total of 34 sets of records.

Statistical analysis

The full results of the analysis are shown in Table II. Agreement between independent raters varied from 41% to 100% over the set of questions. Audit questions where there was a high level of agreement included recording of product, dose and dilution, agreeing goals, and planning long-term care. Areas where there was lower agreement included the recording of discussion of risks, follow up reviews, and information provision. Where pos-

Table II. *Summary of statistical analysis and decision making process*

Question	% agreement between raters	Kappa coefficient	Confidence interval	Kappa rating	Comments	Decision
Is there a record of patient and carer expectations?	70	0.02	0–0.53	Poor	Moderate agreement High variation	This question needs further development
Is there a record of consent	88	0.64	0.29–0.97	Good	High agreement High variation	Include in final draft
Did patient receive information on risks of treatment?	67	0.26	0–0.61	Fair	Moderate agreement High variation	This question needs further development
Is there a formal assessment of spasticity?	82	0.4	0–0.83	Fair	High agreement Moderate variation	Include in final draft
Is there a functional goal of treatment?	88	[b]	NA	[a]	High agreement Low variation	Include in final draft
Is an outcome measure completed?	100	1	1–1	Perfect	High agreement Moderate variation	Include in final draft
Is the product used recorded?	100	[b]	NA	[a]	High agreement No variation	Include in final draft
Is the dose given recorded?	100	[b]	NA	[a]	High agreement No variation	Include in final draft
Is dilution of dose recorded?	97	0.92	0.77–1	Very good	High agreement High variation	Include in final draft
Has a follow up treatment plan been identified?	88	0.54	0.12–0.96	Moderate	High agreement Moderate variation	Include in final draft
Was there a therapy review at 7–14 days post injection?	41	0.15	0–0.39	Poor	Low agreement High variation	This question needs further development
Was the patient reviewed at 4–6 weeks post injection?	61	0.39	0.13–0.64	Fair	Moderate agreement High variation	This question needs further development
Was the patient reviewed at 3–4 months to plan future treatment?	71	[b]	NA	[a]	Moderate agreement Low variation	Include in final draft
Is there an evaluation of goals?	85	0.41	0–0.87	Moderate	High agreement High variation	Include in final draft
Is there an evaluation of outcomes?	70	0.36	0.03–0.69	Fair	Moderate agreement High variation	This question needs further development
Was information given to support self management?	61	0.13	0–0.51	Poor	Moderate agreement High variation	This question needs further development
Is there a plan for future management?	88	0.29	0–0.94	[a]	High agreement Low variation	Include in final draft

[a]Example of kappa paradox.

[b]Kappa scores were unable to be calculated due to very low, or no variation, within the responses.

sible, kappa scores were calculated for each question. Generally, a kappa of +1.00 indicates perfect agreement, whereas a value of zero indicates agreement no better than chance (7).

There were 5 questions where kappa values could not be calculated as there was insufficient variance in the range of responses of auditors (this typically occurred when there was high agreement between raters but little variation across the 'Yes', 'No' or 'No, but' categories). Viera & Garrett (10) and Cicchetti & Feinstein (11) have highlighted this difficulty and suggest that interpretation of reliability results needs to take account of both percentage of rater agreement, and kappa scores, which was the approach taken in this case. An audit question was considered suitable for the final tool if the kappa statistic was classified as good, very good, or perfect. Questions were also accepted if the kappa value was fair or could not be calculated but the percentage agreement between raters was at least 70%, with moderate or low variation across the range of responses. Table II summarises these results. It should be noted that even when kappa values are high, confidence intervals are large, due to the relatively small sample size.

The analysis identified that 11 questions on the tool demonstrated a fair degree of agreement and reliability. Six of the questions were identified as requiring further work before they could be included in a final draft of the tools. These questions related to discussing patient expectations and risks, evaluating outcomes, giving information to support self management, and follow-ups. These areas are fairly subjective areas to grade with audit, and it is likely that more explicit written advice is needed to support the tools. The statistical analysis was supplemented by the review of qualitative feedback from clinicians.

Qualitative feedback

Eleven clinicians who had completed the audit tools were sent a follow-up questionnaire. Seven of them (64%) returned written comments and all of them indicated that they agreed with the standards used, had found the tools easy to complete and would use them again. All the clinicians indicated that they felt the tools captured indicators of quality, a statement that supports the face validity of the tools. 100% also expressed that they had found the process to be useful and gave comments to explain this:

> *'The process was useful as it has highlighted the need for standardised documentation and written information.'* Auditor 7

Four of the clinicians made comments about the need for feedback from patients or carers, as described in this example:

> *'I thought it captured the structure of the clinic but not really the quality from a patient or carers perspective.'* Auditor 1

One of the clinicians suggested that the audit tools needed to include a measure of patient or carer experience, but this may be difficult to achieve within an audit of records. An alternative may be for the audit tools to form one measure of quality assurance, but for this to also include a measure of patient and carer satisfaction. This could be particularly useful given the difficulty ensuring the reliability of responses to questions about some of the aspects of care involving discussion with patients such as expectations, risks of treatment, and information provision, and given that the service users surveyed highlighted the importance of these areas.

DISCUSSION

To the best of our knowledge, this has been the first project to develop and evaluate tools for audit of the national guidelines for spasticity management with botulinum toxin. The tools have been developed with input from both clinicians and service users, and have been piloted across all services within the Peninsula area. They not only provide a unique opportunity to observe care delivered at a regional level, but also allow individual providers to review their own performance in the local management of spasticity. Several of the clinics included in the pilot have used the data obtained to help evaluate and further develop services. One, for example, instigated a piece of work with service users and carers to develop written information to support self management after the audit highlighted the lack of this.

Limitations of the study

Although results have been generally positive, this pilot has been small and a larger scale test of the final draft tools will be necessary to gain assurance regarding validity and reliability.

Results from the statistical analysis demonstrated the paradox that can occur when calculating kappa scores on samples when there is a limited distribution of responses. A larger pilot may ameliorate this occurrence and produce more conclusive results, although, if the variation in responses remains low, kappa may not be a helpful method for statistical analysis.

Qualitative feedback was given by 64% of the clinicians involved and it could be argued that those who felt most positively are more likely to have responded. The qualitative questions that were sent to clinicians were few in number and mostly closed. The initial comments support the face validity of the tools but a greater depth of feedback could be achieved through either the use of a longer survey with more open questions, or a focus group.

In conclusion, the purpose of this project was to develop multi disciplinary audit tools for spasticity management with botulinum toxin. Draft tools were developed and piloted, using consensus techniques with input from clinicians and service users, and early piloting with a particular emphasis on reliability. Eleven of the questions on the draft tools showed a good level of reliability, and clinician feedback supports the face validity. The tools are able to be used practically as part of the audit cycle to improve quality. Six of the questions on the tools need further work to support their reliability, and a larger pilot of the tool is ultimately required. The process highlighted the need for service user feedback as well as clinical audit as a component of a quality account.

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REFERENCES

1. Leathley MJ, Gregson JM, Moore AP, Smith TL, Sharma AK, Watkins CL. Predicting spasticity after stroke in those surviving to 12 months. Clin Rehabil 2004; 18: 438–443.
2. Rizzo MA, Hadjimichael OC, Preiningerova J, Vollmer TL. Prevalence and treatment of spasticity reported by multiple sclerosis patients. Multiple Sclerosis 2004; 10: 589–585.
3. Intercollegiate Working Party for Stroke. National Clinical Guidelines for Stroke. London: Royal College of Physicians; 2008.
4. Royal College of Physicians. Spasticity in adults: Management using botulinum toxin: National Guidelines. London: RCP, 2009.
5. Healthcare Quality Improvement Partnership. Criteria and indicators of best practice in clinical audit. London: HQIP; 2009.
6. Allison R. Devon PCT Spasticity service users questionnaire results. Exeter: NHS Devon; 2010.
7. Altman D. Practical statistics for medical research. London: Chapman and Hall; 1991.
8. Lathlean, J. Qualitative analysis. In: Gerrish K, Lacey A, editors. The research process in nursing. Oxford: Blackwell Publishing; 2006, p. 417–433.
9. Viera AJ, Garrett JM. Understanding interobserver agreement: The kappa statistic. Family medicine 2005; 37: 360–363.
10. Cicchetti DV, Feinstein AR. High agreement but low kappa: II. Resolving the paradoxes. J Clinical Epidemiology 1990; 43: 551–558.

APPENDIX I. Management of spasticity with botulinum toxin (BTX)

Patient identifier:	Yes	No	No/But
Tool for audit of process of care. (To complete one per patient)			
1. Is there a record of patient and carer expectations?	☐	☐	
2. Is there a record of consent?	☐	☐	
3. Did patient receive information on risks of treatment?	☐	☐	
4. Is there a formal assessment of spasticity?	☐	☐	
5. Is there a functional goal of treatment?	☐	☐	
6. Is an outcome measure completed prior to treatment?	☐	☐	
7. Is the product used recorded?	☐	☐	
8. Is the dose given recorded?	☐	☐	
9. Is dilution of dose recorded?	☐	☐	
10. Has a follow up treatment plan been identified?	☐	☐	
11. Was there a therapy review at 7–14 days post injection?	☐	☐	
12. Was the patient reviewed at 4–6 weeks post injection?	☐	☐	
13. Was the patient reviewed at 3–4 months to plan future treatment?	☐	☐	
14. Is there an evaluation of goals?	☐	☐	
15. Is there an evaluation of outcomes?	☐	☐	
16. Was information given to support self management?	☐	☐	
17. Is there a plan for future management?	☐	☐	
Tool for audit of service organization. (To complete one per service identified)			
1. Is there a co-ordinated multidisciplinary team for managing spasticity?	☐	☐	
1a. If so, which professions typically attend clinics:			
2. Has the injecting clinician completed the following training requirements stipulated by the national guidelines (tick all that apply):	☐	☐	
a) Attendance on botulinum toxin training course (to include a formal certificate) approved by the relevant college.	☐	☐	
b) Observation of the assessment of and injection technique in at least 5 patients with arm and 5 patients with leg spasticity related problems.	☐	☐	
c) Ability to use the relevant equipment, e.g. electromyography (EMG), nerve stimulation or ultrasound.	☐	☐	
3. Has the injecting clinician(s) been involved in clinical professional development for this intervention in the past year?	☐	☐	
4. Does this clinic provide training to other clinicians to develop skills in assessment and management?	☐	☐	
5. If so, do new clinicians in training complete the following training requirements stipulated by the national guidelines (tick all that apply):	☐	☐	
a) Attendance on BT training course (to include a formal certificate) approved by the relevant college.	☐	☐	
b) Observation of the assessment of and injection technique in at least 5 patients with arm and 5 patients with leg spasticity related problems.	☐	☐	
c) Ability to use the relevant equipment eg EMG, nerve stimulation or ultrasound.	☐	☐	
6. Is there access to EMG/ muscle stimulation equipment if required?	☐	☐	
7. Does the service have pathways of care for those with very complex disability including referral to:	☐	☐	
a) Intrathecal baclofen service.	☐	☐	
b) Orthopaedic surgery.	☐	☐	
8. Does the service routinely provide written information to patients and carers on managing spasticity?	☐	☐	
9. If so, please indicate if this information is produced by the service or sourced externally.			