

Research Article

Reducing Complications from Community Non-Therapeutic Infant Male Circumcision Through the Introduction of a Quality Assurance Process

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ABSTRACT

Background: It is estimated that there are over 3,000 infant male circumcisions performed in the community in the Greater Manchester area each year. The present study evaluated the effectiveness of a quality assurance process for community providers of infant male circumcision performed in Greater Manchester, England in reducing complications.

Study design: Comparison of hospital admissions data before and after the introduction of the quality assurance process, and comparison of provider compliance with quality assurance standards in 2011 and 2017.

Methods: Records were retrieved for all males less than 12 months of age admitted to the region's main children's hospital in 2009 and 2016 (1 Jan – 31 Dec) following complications from circumcision. Compliance with quality standards was assessed by a multi-disciplinary panel annually.

Results: 27 male infants were admitted with complications from non-therapeutic circumcision in 2009, and 13 in 2016. Total number of bed days was 38 in 2009 and 25 in 2016. Bleeding occurred in 21 cases in 2009 (78%) and 12 in 2016 (92%). Infection was identified in four cases in 2009 (15%) and one in 2016 (8%). There was no significant difference in the distribution of complications between the two years (p=0.57). Median haemoglobin levels were significantly greater in 2016 compared to 2009 (9.85 g/dL vs 13.05 g/dL, p=0.01). In 2011, nine providers applied for quality assurance and four met the required standards. In 2017, eight providers applied for quality assurance and seven met the required standards.

Conclusions: The introduction of a voluntary quality assurance process was associated with improved compliance with standards of care and a reduced number of admissions to hospital for complications from infant male circumcision.

Key words: Health policies, Systems and management in high-income countries; Public health; Health service quality; Quality assurance; Quality improvement

How This Fits in with Quality in Primary Care

What do we know?

In the UK, the majority of non-therapeutic infant male circumcisions for religious or cultural reasons are performed by private providers in community settings. There have been reports of unsafe practices by some unregulated private providers.

What does this paper add?

Voluntary quality assurance is a feasible option to implement quality improvement for services outside clinical governance systems.

Introduction

Male circumcision is one of the most frequently performed surgical procedures across the world, with an estimated one third of men being circumcised [1]. Although there is some evidence of therapeutic benefit [2,3] it is predominantly performed in infancy for non-therapeutic reasons within the Jewish and Muslim faiths. The ethics of this practice are contentious and highly emotive and will not be addressed here [4-7].

Male circumcision generally has low reported complication rates; a systematic review of the procedure in childhood found a median complication rate of 1.5%, although there was significant variation with three of the 16 included studies reporting complication rates over 10% (range 0-16%) [8]. Older childhood age at circumcision, lack of operator experience and poor setting sterility appear to be indicators of increased risk of complication [9,10].

In the UK, non-therapeutic infant male circumcision for religious or cultural reasons is not generally provided by the NHS. The vast majority of these procedures are undertaken by private

providers in community settings. There have been reports of unsafe practices by some unregulated private providers [11,12].

In 2011, a quality assurance (QA) process was implemented for private providers of male infant circumcision operating in Greater Manchester. This sets out expected standards of care for the provision of non-therapeutic infant male circumcision for boys less than 12 months of age in the community. QA involves annual voluntary assessment of providers against the standards of care. The implementation of the QA process has been described previously [13].

The aim of this paper is to assess whether the introduction of this QA process has been associated with a decline in the number of hospital admissions due to complications from infant male circumcision procedures performed in the community.

Methods

Compliance with quality assurance standards

The Greater Manchester QA infant male circumcision panel assesses applications for quality assurance annually. The panel membership includes the following or a nominated deputy; Consultant in Public Health, Consultant Paediatric Surgeon, Safeguarding Representative, Community Health Professional. The panel considers evidence provided from each applicant in relation to the minimum standards of care for QA that are listed in Table 1.

Table 1: Greater Manchester Quality Assurance Standards for Non-therapeutic Community Male Infant Circumcision.

Quality Criteria	Minimum Standard
1. Training	Practitioners should attend specific training on performing circumcision using their chosen technique. This must include neonatal resuscitation, administration of local anaesthetic dorsal penile nerve block or ring, and performing some circumcisions under supervision.
2. Maintaining competence	Practitioners should perform a minimum of 20 circumcisions per year. Practitioners who have performed fewer than 20 circumcisions per year should undergo refresher training.
3. Settings	Circumcisions must be performed in a clinical area registered with the Care Quality Commission[+] for minor surgery with adequate infection control measures in place.
4. Consent	Consent is to be sought from both parents. Consent needs to be obtained and documented even by telephone from the second parent and witnessed. A consent policy needs to be kept in the records. There is an exception to this rule if there is only a single parent.
5. Pain relief	Local anaesthetic by dorsal penile nerve block or ring block should be used. These techniques reduce, but do not eliminate, the pain of circumcision, so treatment with systemic analgesics should also be used.
6. Post-procedure observation	The infant should be observed by the practitioner for at least 30 minutes after bleeding from the circumcision site has stopped.
7. After-care	The person who performed the circumcision is responsible for the post-operative care of the patient, and must ensure that the parents understand how to care for the wound and the infant following the procedure, and under what circumstances they should seek medical advice. This advice should be provided verbally and in writing. The person who performed the circumcision should be available to answer questions, or assess the infant in the week following the procedure. This information should be available in a range of languages.
8. Follow-up appointment	A routine follow-up appointment should be offered to local families about two weeks after the circumcision. If this is not a practical option, follow-up should be arranged with their GP.
9. Safeguarding training	Practitioners must have completed level three* safeguarding training.
10. Audit	The process and outcomes of the procedures performed should be subject to annual audit. The audit must include: •The results of any complications including detail about any referrals into secondary care. •Complaints received about the service should be recorded and reacted to appropriately. •A note about reflective practice.
11. Complaints	All providers should provide a written copy of their complaints procedure and provide information for parents on how to make a complaint.

[+] The requirement for registration of premises with the Care Quality Commission was added in 2013

* This requirement was changed from level two safeguarding training in 2014

The QA standards are updated annually in light of new recommendations from the Care Quality Commission, British Association of Paediatric Surgeons, Initiation Society, British Medical Association and General Medical Council, plus information about complications presenting to primary and secondary care.

The compliance of the applicants with each QA minimum standard was recorded and compared for 2011 and 2017.

Hospital admissions

There is one regional tertiary paediatric surgery centre situated in the region's main children's hospital, where all significant complications of circumcision should either present or be transferred to. This evaluation was performed by a retrospective analysis of patient records for infant boys admitted to the main regional children's hospital. Only males aged less than 12 months of age were included, reflecting the scope of the QA process which only assessed providers operating on boys less than 12 months of age. Only complications from non-therapeutic circumcisions performed in the community were included. Any complications secondary to therapeutic circumcision performed in hospital were excluded. Complications that were treated by other hospitals in the region, or minor complications treated in the emergency department and not resulting in admission, have not been measured in this evaluation.

The admitting hospital uses the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10) coding system for all patient admissions [14]. This does not, however, feature an exact fit for complications of circumcision. The most appropriate query was a diagnosis of T81 (complications of procedures, not elsewhere classified) combined with either Y83.6 (removal of other organ [partial] [total]) or Y83.4 (other reconstructive surgery) [15]. The query was run for the calendar years 2009 (1 January 2009 to 31 December 2009) and 2016 (1 January 2016 to 31 December 2016). These years were chosen as 2009 reflects the latest date prior to the planning and implementation of the QA process, and 2016 is the most current year for which full data is available.

The patient discharge summaries were screened to exclude patients that had not undergone non-therapeutic circumcision in the community. For eligible cases, full patient notes were examined to extract the following data; number of bed days, circumcision technique, circumcision provider, type of complication, outcome of complication and haemoglobin level. The data collection was conducted according to the principles of the Declaration of Helsinki.

Comparison of complication rates was not possible due to the absence of the required denominator, as no accurate record is available of the number of private community male infant circumcisions performed in the region. Therefore, analysis is focused on the comparison of absolute numbers between the two years of interest. Fisher's exact test was used to determine whether there was a significant difference in the distribution of complications and the distribution of outcomes between the two years. This was used rather than Chi-squared test due to the small numbers involved. A Mann-Whitney test was performed to determine whether there was a significant difference in the distribution of haemoglobin levels between the two years.

Results

Compliance with quality assurance standards

In 2011, nine providers applied for quality assurance and four met the required standards. Two providers failed to provide evidence that they were adequately trained in circumcision surgical technique and neonatal resuscitation. Two providers could not demonstrate that they performed enough procedures annually to maintain their competence. Four providers did not obtain dual consent from both parents before performing infant male circumcision. Three providers did not provide adequate after care advice to parents and five did not offer a follow-up appointment. Four providers had not completed level two safeguarding training. Four providers did not provide an audit of their outcomes, and three providers failed to provide a complaints procedure. In 2017, eight providers applied for quality assurance and seven met the required standards. One provider did not demonstrate that he performed enough procedures annually to maintain his competence at performing the procedure. This was the only standard that was not met by all applicants in 2017. Details of standards met by the applicants can be seen in Tables 2 and 3.

Table 2: Applicants compliance with quality assurance quality standards in 2011.

Provider ID/ Standard Criteria	Procedure training	Neo-natal Resus	Perform >20 per year	Premises registered with CQC⁺ for surgical procedures*	Dual consent	Local anaesthetic	Post-procedure analgesia advice	Post-procedure observation 30 minutes	After-care advice	Follow Up offered	Safe guarding training level 2	Audit	Complaints procedure available	QA-ed
QA2011-01	Y	Y	Y	N/A	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
QA2011-02	Y	Y	Y	N/A	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
QA2011-03	Y	Y	Y	N/A	Y	Y	Y	Y	Y	N	N	N	N	N
QA2011-04	Y	Y	Y	N/A	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
QA2011-05	N	N	Y	N/A	N	Y	Y	Y	Y	N	Y	N	Y	N
QA2011-06	N	N	N	N/A	N	Y	Y	Y	N	N	N	N	N	N
QA2011-07	Y	Y	Y	N/A	N	Y	Y	Y	N	N	N	N	Y	N
QA2011-08	Y	Y	N	N/A	N	Y	Y	Y	N	N	N	Y	N	N
QA2011-09	Y	Y	Y	N/A	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y

⁺ CQC= Care Quality Commission

*The requirement for registration was added to the quality assurance standards in 2013

Table 3: Applicants compliance with quality assurance quality standards in 2017.

Provider ID/ Standard Criteria	Procedure training	Neonatal Resus	Perform >20 per year	Premises registered with CQC+ for surgical procedures	Dual consent	Local anaesthetic	Post-procedure analgesia advice	Post-procedure observation 30 minutes	After-care advice	Follow-up offered	Safe guarding training level 3	Audit	Complaints procedure available	QA-ed
QA2017-01	Y	Y	y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
QA2017-02	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
QA2017-03	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
QA2017-04	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
QA2017-05	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
QA2017-06	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
QA2017-07	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N
QA2017-08	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y

+ CQC= Care Quality Commission

Hospital admissions

A total of 54 cases were identified by the initial coding query. After inspection of patient discharge summaries, 13 cases were excluded as complications of other procedures (such as repair of inguinal hernia or gastroschisis), and one case was excluded as it featured a hypospadia repair plus circumcision performed in the hospital setting. This left a total of 40 cases which met the study criteria.

Of these 40 admissions following community male infant circumcision, 27 were admitted in 2009 and 13 in 2016 (Figure 1). Recording of circumcision technique was incomplete for both years (21 of 27 in 2009 and 12 of 13 in 2016). However, all cases in which technique was recorded had used the Plastibell device. The provider of the infant male circumcision was only recorded in six cases in 2009; in four of these the provider participated in the 2011 QA process and two did not. The provider was recorded only twice in 2016; in both cases the provider was a participant in the QA process. The total number of bed days for all patients was 38 in 2009 and 25 in 2016 (Figure 1). The number of bed days per patient ranged from one to two in 2009 (average 1.4 days) and one to three in 2016 (average 1.9 days).

Types of complication

In line with the smaller number of admissions, the frequency of all categories of complications was lower in 2016 compared with 2009 (Figure 2). Bleeding was the most common complication in both years, occurring in 21 of the 27 admissions in 2009

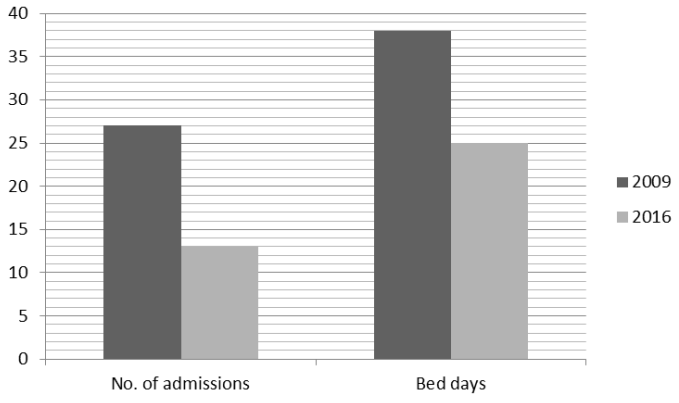

Figure 1: Number of admissions and bed days, 2009 and 2016.

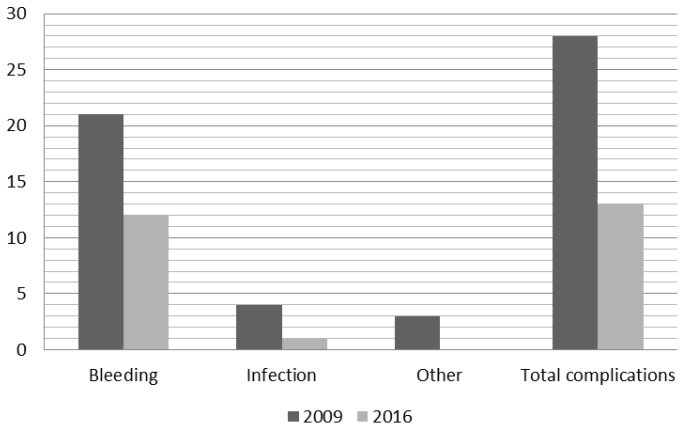

Figure 2: Frequencies of complication by type, 2009 and 2016. Treatment required by frequency, 2009 and 2016.

(78%) and 12 of the 13 admissions in 2016 (92%). Infection was identified in four cases in 2009 (15%) and one case in 2016 (8%). Other complications recorded in 2009 were: one case of tight phimosis, one case of swollen glans and one case of retained Plastibell. No other complications were recorded in 2016. The Fisher's exact test found no difference in the distribution of complications between the two years (p=0.57).

In both years, the most common treatment was observation; recorded for 11 of the 27 admissions in 2009 and five of the 13 admissions in 2016 (Figure 2). Conservative haemostasis was defined as bleeding requiring non-operative intervention; this included Dermabond topical skin adhesive or application of fresh dressings (Surgicel or Kaltostat were used). Conservative haemostasis was adequate for the treatment of bleeding in seven of the 2009 admissions and four of the 2016 admissions. Antibiotics were given only in cases diagnosed with infection; that is four cases in 2009 and one in 2016. Surgical revision under general anaesthesia was performed for surgical haemostasis (diathermy or ligation) and/or surgical completion of the circumcision. This was performed in five cases in 2009 and four cases in 2016. Seven patients needed to have a Plastibell device removed in 2009 and four in 2016. One of these incidences in 2009 was for a simple retained Plastibell, and the remainder were required for the management of bleeding or infection.

In 2009, 12 of the 27 patients (44%) had their haemoglobin measured and 10 of the 13 patients (77%) in 2016. Mean levels

of haemoglobin were 10.4 g/dL in 2009 and 12.8 g/dL in 2016. As the data was not normally distributed, a Mann-Whitney test was used to detect a difference in the distribution of haemoglobin levels between the two years. Median haemoglobin was 9.9 g/dL in 2009 and 13.1 g/dL in 2016. The test indicates that there is a statistically significant difference in median haemoglobin levels between patients in 2009 and 2016 (p=0.01).

Discussion and Conclusion

This evaluation of the impact of a QA process implemented since 2011 shows that there was improved compliance with quality standards among applicants in 2017 compared to 2011 and there were fewer admissions due to complications of community non-therapeutic infant male circumcision in 2016 compared to 2009. The most common complications were bleeding and infection. There was reduced frequency of all categories of complications. Most complications were treated conservatively. The most serious complications required surgical revision under general anaesthetic. It should be noted that although the number of surgical revisions performed did decrease this was only from five in 2009 to four in 2016, so it may be that the QA process has not altered the risk of serious complication. There was a statistically significant increase in median haemoglobin of admitted patients between 2009 and 2016, which may indicate post-circumcision bleeding is less severe, although not all patients had these levels measured.

Both healthcare professionals and parents recognise the risks of non-therapeutic male circumcision being performed by unregulated private practitioners [11,16,17]. This highlights the necessity for quality assurance of the procedure in the UK. Whether safe practice is best delivered through the NHS or other providers has been much debated [18-22]. In the UK a number of different models of care have been established to deliver a safe service. In Bradford, a NHS hospital-based service is delivered by volunteer nurses with access to consultant urologist supervision [23]. A nine-year service evaluation demonstrated an 11% complication rate and a 96% satisfaction from parents [24]. The most common complications were problems with the Plastibell ring (3.6%) bleeding (3%) and infection (1.5%). Other regions have established NHS community-based services with the aim of ensuring safe practice and minimising complication rates in response to concerns about unregulated private practice [17,25]. A decreased risk of complications is associated with performing the circumcision at a younger age, with evidence from in inpatient settings in USA finding complication rates of 0.2% for infants aged <1 month, 0.4% for infants aged <1 year, and 9% in children aged 1-9 years [26].

The Plastibell device was the only recorded technique used in this study. A recent large cross-sectional study found a complication rate of 1.1% in boys up to four months of age who underwent Plastibell circumcision under local anaesthetic in the hospital setting [15].

The implementation of the Greater Manchester QA process for private community providers of non-therapeutic infant male circumcision has been previously described [13]. The process was developed through engagement with the local providers, healthcare staff and community and faith groups, with the only cost being administration. In its inaugural year, 10 providers applied and four were granted QA status. By 2016 this had risen to nine providers with QA status.

The implementation of a voluntary quality assurance process in one region in North West England has been associated with a decrease in the number of paediatric surgical admissions of infant boys admitted following complications of circumcision in the community. From the results of this evaluation it is impossible to say whether the QA process has reduced the rate of complications from non-therapeutic male circumcision due to the lack of denominator data. However, the evaluation has demonstrated that the frequency of admissions has more than halved from pre- to post-implementation. Further evidence supporting a reduction in the complication rate is provided from the demographic data for the region. Census data from 2001 tells us that there were 8,621 boys aged zero to four years of Jewish or Muslim religion in Greater Manchester (therefore approximately 1,724 aged zero to twelve months) [27]. The most recent census from 2011 reports that this number has increased to 15,588 boys aged zero to four years (approximately 3,118 aged zero to twelve months) [28]. This represents an 81% increase over a decade. If we assume the rate of circumcisions has remained constant in these groups, we would therefore expect a corresponding increase in the number of circumcisions performed between 2009 and 2016.

Limitations of this Study

Although the number of admissions more than halved, the data sets are small. Only complications which were admitted to the paediatric surgery centre were included in this study. Although local policy dictates that any significant complication is transferred here, some cases may have been seen in other hospitals across the region. This evaluation does not include any information on the number of minor complications managed in the community or emergency department.

Additionally, data was collected retrospectively based upon identification from hospital coding. This is not as reliable as prospective data collection, as some cases may have been coded incorrectly.

Finally, any attempt to calculate a complication rate would require accurate recording of infant male circumcision in all patient records to provide a reliable denominator. Providers that participate in the QA process are required to keep records of the number of infant male circumcisions they perform and to inform the patient's GP of the procedure. However, this voluntary process may not cover all infant male circumcisions performed in the region and includes many patients that travel from outside the region. In future, recording the name of the community provider in hospital records would enable quality improvement feedback to individual providers and verification of their self-recorded outcome audits. This would allow more transparent monitoring of practitioner safety.

This comparison of admissions before and after the implementation of a QA process suggests that the frequency, and likely rate, of complications due to non-therapeutic infant

male circumcision has reduced. The setup of the QA process was low-cost and likely resulted in a cost-saving to the NHS. Other regions should consider how they monitor the safety of non-therapeutic infant male circumcision providers operating in the community, and whether the implementation of a QA process could meet the needs of their local population.

Acknowledgements

Thank you to all the professionals, parents and community groups that have been involved in the development and implementation of the Greater Manchester Infant Male Circumcision Quality Assurance Process. Particular thanks to Eleanor Roaf, Helen Gollins, Jess Guy, Bob Postlethwaite and Dr Basem Khalil.

Author contributions

JS carried out the research and drafted the manuscript. PW conceived the study, contributed to the design and coordination of the study, and edited the manuscript. AV and IS contributed to the design and coordination of the study and revised the manuscript critically. All authors read and approved the final manuscript.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Competing Interests

The authors have no interests to declare.

Ethical Approval

This service evaluation did not require ethical approval confirmed by the HRA criteria http://www.hra-decisiontools.org.uk/ethics/

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Submitted: September 25, 2019; Accepted: October 22, 2019; Published: October 29, 2019