Digital pen and paper technology is an effective way of capturing variance data when using arthroplasty clinical pathways

Patrick H Derhy, Karen A Bullingham and Andrew J Bryett

Abstract

The aim of this study was to test the effectiveness of digital pen and paper technology (DP&PT) to capture clinical pathway variance data in real time and at the point of care for patients on an arthroplasty pathway.

This study was conducted across multiple departments providing orthopaedic services in a public health care facility. Treating clinicians were required to record variance data on a predefined coded template, and these data were uploaded to a database for analysis and reporting. The information could be represented in a web-based user interface for immediate review.

User acceptance, length of stay (LOS), accuracy of data, and reliability of the DP&PT hardware were measured. User acceptance was high; LOS reduced; and the data and hardware were, respectively, found to be accurate and robust.

This technology provides a dependable, real-time solution to transform handwritten clinical data into a digital format. The data available will help inform clinicians of areas for clinical practice improvement, and provide ongoing monitoring of care processes for patients on a clinical pathway. Future studies should aim to assess if using this method to capture variance data is a more efficient and effective means of informing clinical decision making than retrospective review processes.

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THIS PAPER PROVIDES a case study of an investigation testing digital pen and paper technology (DP&PT) and its effectiveness in capturing real-time variance data for patients on an arthroplasty clinical pathway in a hospital setting.

Clinical pathway (CP) variance is defined as any deviation from the expected outcome for the diagnosis-related group for which the pathway applies. This variance capture is important, as analysis of variance from the stated path is a sophisticated means of providing quality control in health care delivery, and therefore patient care.[1] The reasons behind a variance occurring can be multifactorial. Therefore, to have an effective clinical pathway program, variance analysis must be included as a quality activity to measure the effectiveness of the pathway and the care processes delivered to a patient.

Yet health care organisations rarely collect variance data. In one study, only 4% of health care agencies with CPs implemented also had a process for analysing variance.[2] More recently, a local survey evaluated the uptake of clinical pathways and variance management in all Queensland public hospitals, revealing that of those hospitals using CPs, only 5% were able to complete variance analysis. The barriers to completing variance analysis in these hospitals were found to be multifaceted, including lack of human resources (commonly, Local Project Officer returned to normal duties), lack of clinical relevance in the code set (see Box 1), cumbersome manual processes for

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1 Variance codes

Patient related	Clinician related	Hospital related	Community related
1.1 Patient condition	2.1 Clinician decision	3.1 Bed availability	4.1 Community care booking
1.2 Patient choice	2.2 Clinician other	3.2 Equipment availability	4.2 Community care availability
1.3 Patient other		3.3 Service availability	4.3 Transport availability

capturing data, or lack of an electronic information system.

DP&PT is relatively new to health care, and evidence of its uptake is limited. However, application of this technology appears to deliver an efficient and effective means of capturing data in the clinical setting. DP&PT has been increasingly used in clinical settings as there is little change management or technical education required.[3] In several European health care facilities, improvements in real-time data capture in clinical environments using DP&PT have been observed, for example in emergency departments and cancer screening. These organisations have identified benefits for the quality of patient care and for the organisation. These are:

- Readily accessible critical patient information
- Improved data accuracy
- Highly accurate data entry resulting in the elimination of misdiagnosis
- High level of clinician acceptance as the process is intuitive and natural, therefore easy to use
- Eliminated need for clerical data entry assistance
- Improved billing processes.[4-8]

One comparative study of the application of this technology to collect mammography clinical trials data found that the digital pen was statistically equivalent to conventional pen and paper in initial data entry speed. Average verification time for digital pen-derived data was significantly less than secondary electronic data entry of paper forms (*P* value less than 0.001). Two trials have also been completed to compare the reliability of data capture between digital pen and scanner analysis. Overall users were satisfied with the technology, as it was easy to use. However, in that study, some digitalised data were missing due to lack of a standardised form. This, as well as software bugs, affected data validity and confidence.[9]

In order to address identified barriers and to improve the ability of a hospital to capture, report, and analyse variance data, a pilot study testing the effectiveness of DP&PT as a solution was undertaken.

Methods

The clinical setting chosen was an Orthopaedic Department at a Queensland health facility, which had recently implemented arthroplasty CPs. All patients attending the pre-admission clinic on a CP for hip and knee arthroplasty during the last 6 months of 2006 were included.

(Originally, a paper-based free-text page was developed for inclusion in the clinical pathway for clinicians to code and note problems, actions and outcomes as they arose during the course of treatment. An excel spreadsheet was developed for each clinical pathway which highlighted key areas for monitoring. Number of variances and types of variance were recorded during chart audits of the pathways. This was done retrospectively by the local project officer as part of the evaluation of clinical pathways during the district pilots. The spreadsheet incorporated some calculations allowing for reports and graph plotting. Evaluation of this spreadsheet was difficult as the assumption could be made that the pathway was of a sufficiently high standard that variances were not frequently reported. The success of this system was reliant on sufficient human resources to complete a retrospective audit chart, analysis and reporting.)

There was no impact on the delivery of patient care, as all patients eligible for admission on an arthroplasty CP (as the agreed standard of care for

this patient cohort) were included in the study during the 6-month trial. DP&PT uses 128-bit symmetric key encryption, which ensured patient confidentiality. Furthermore, only authorised personnel had access to the database. There was adherence to Queensland Health's policy regarding remote access dial-in and server management.

The project utilised PM+® Project Management methodology,[10] which included the development of a concept brief for securing funding and a project plan outlining the key performance indicators (KPIs), deliverables, and evaluation strategy. Clinician knowledge of CP and variance was assessed using a pre-pilot survey. Information gained from this survey was used to define the list of variances to be collected and to develop an education plan. End-user training requirements associated with the implementation of this technology were minimal. As the pen simply records pen strokes on paper there was little if any change to current documentation practices for the user. The only real change to pre-implementation practice was the requirement to dock the pen to facilitate data transfer. Due to the simplicity of the solution, most end users required only a single training session supported by a simple users guide. Training requiring less than 30 minutes to complete was delivered to small groups in the clinical setting.

The technology to support a variance management system incorporating DP&PT consists of three parts; the paper (variance form), the pen, and the database. The variance form, which acts as an interface between the pen and the database, is digitally printed with variance codes and associated checkboxes. The local steering committee provided the governance, and recommended the clinically relevant code set for inclusion in the design and development of the variance form. Following installation and testing of the technology, the generation and activation of unique variance forms for each patient included in the trial commenced in the pre-admission clinic. The activated form stayed in the patient's chart until admission. The form was included in the bedside documentation for ease of access.

The digital pen recognises, records, and stores pen strokes marked on the form. Installation of docking stations, to support the charging of the pen's battery and the download of data stored in the pen, occurred in various clinically relevant areas around the facility. These included preadmission, physiotherapy, occupational therapy, operating rooms (including recovery), ward areas, and doctors offices. When variance from expected clinical outcomes occurred, the form was marked using the digital pen. On docking the pen, the variance data stored in the memory were downloaded and transferred to an Oracle database. The clinician was able to access an electronic view of the form (in PDF format) and generate prospective analytical reports via the generation of predefined graphical representations of the data.

At the closure of the pilot, an audit of 270 charts was completed. Two investigators examined the data available in the database, and evaluated the accuracy and appropriateness of codes against the corresponding documentation in patients' charts. The investigators also measured the time taken to complete this audit for reference on time taken.

A post-pilot staff satisfaction survey looked to identify user acceptance and effectiveness of the DP&PT as a means to capture variance data at the point of care.

Areas evaluated by the survey included:

- Ease and regularity of pen use
- Reliability (dependability) of the pen
- Quality and design of the variance form
- Accessibility and usability of the form
- Relevance and completeness of the code set
- Representation of acquired data
- Provision of support for end-users
- Impact of the implementation on end-users
- End-user recommendation regarding continuation of the trial
- Areas for improvement, and
- Other potential applications of the technology.

Results

The study involved 270 patients who had a knee (154) or hip (116) arthroplasty during the last 26 weeks of 2006. The local clinical pathway steer-

2 Descriptive statistics of the study population

	All	Knee replacement	Hip replacement
Total patients	270	154	116
Period 1	130	69	61
Period 2	140	85	55
Mean age (SD) in years	67.7 (9.5)	65.7 (10.6)	69.2 (8.2)
Ratio male : female	0.85 : 1	0.73 : 1	1.04 : 1
Overall average length of stay (SD)	7.35 (4.67)	6.77 (3.28)	8.13 (5.97)
Period 1	7.90 (6.02)	7.00 (4.25)	8.92 (7.45)
Period 2	6.84 (2.82)	6.58 (2.20)	7.26 (3.55)
Total variances	1494	822	672
Postoperative complications	474	244	230
Risk/social factors	483	265	218
Comorbidities	299	180	119
Pathway	136	66	70
Preoperative delay	84	52	32
Discharge delay	18	15	3
Total variances (per patient)	1494 (2.77)	822 (2.80)	672 (2.73)
Period 1	682 (2.66)	323 (2.45)	359 (2.57)
Period 2	812 (2.86)	499 (3.08)	313 (2.89)
Total postoperative complications	474 (0.88)	244 (0.83)	230 (0.94)
Period 1	269 (1.05)	118 (0.89)	151 (1.22)
Period 2	205 (0.72)	126 (0.78)	79 (0.65)

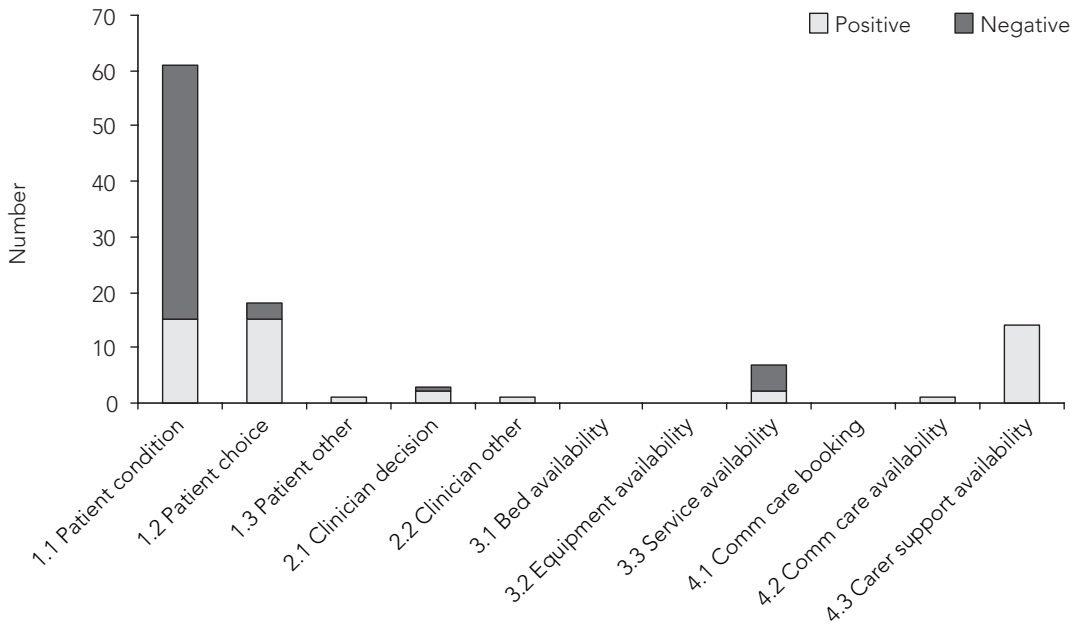
ing committee identified a list of 76 distinct variance codes, relevant to the arthroplasty for this study. Each code was related to one of the following six subgroups: pre-operative delay, pathway, general comorbidities, post-operative complication, discharge delay, and risk/social factor. During the survey period, the database received 1494 variances for these patients. Eighty percent of these variances were derived from 19 of the listed 76. A summary of the findings from the database is available in Box 2.

Pre-trial review of manual recording of variance data included the auditing of 20 patient charts; this represents 4% of all patients who receive a hip arthroplasty (around 500) each year. Box 3 shows that of 106 recorded variances, 58% of these related to patient condition. Seventy-five percent of the total "patient condition" code was recorded as a negative variance or adverse event for the patient. The chart audit took an average of 22 minutes per chart.

Forty multidisciplinary end-users participated in the post-trial survey (for determining user acceptance), a response rate of 67.5%. The following results were observed:

- 80% of end-users found the pen easy to use.
- 74% of users found the pen to be highly reliable (when poor reliability was identified as an issue, this was commonly associated with failure to ensure the pen was adequately charged).
- 80% of respondents were satisfied with the format and design of the variance form.
- 80% of responses indicated the form was easy to use and understand, but more than 30% of users indicated that the form was not always available

3 Count of variance categories



at the bedside (as other clinicians had removed the pathway folder and not replaced it).

- The code set utilised to develop the variance form was relevant to the patient condition in 74% of responses, though many codes were seldom or never utilised.
- Appropriate levels of support for end-users was provided in over 60% of cases, with a further 30% of respondents reporting they did not require further support beyond initial training.
- 85% of users felt this trial had not deleteriously impacted on their workload.
- 70% of respondents recommended continuation of the trial, and a further 11% were undecided.
- 89% of respondents supported the utilisation of this technology to capture variance data from other pathways.
- An identified key area for improvement was the ability for the application to interface with Patient Master Index data to avoid the necessity to manually input patient demographics onto the generated form, or, alternatively, to implement digital pens with barcode reading capability to allow the scanning of patient labels.
- Many end users commented on the wide scope of potential for this technology in a form- and documentation-driven environment, such as health care, particularly given recent advances in handwriting-recognition software allowing for very accurate conversion of handwriting into text supporting direct download to a back end system.

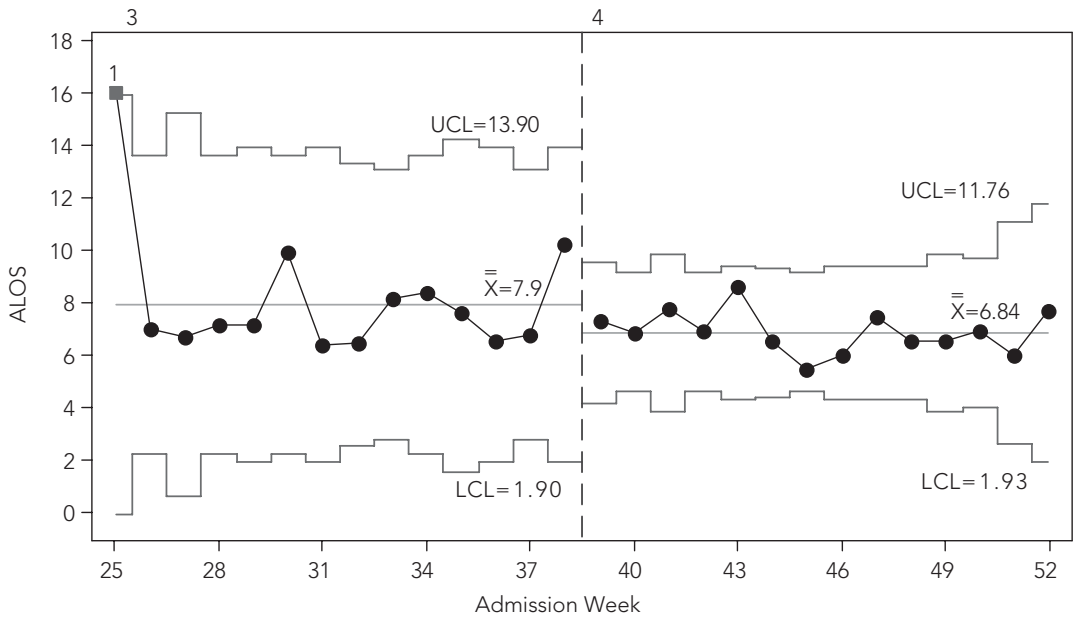
Discussion

Anoto (Anoto Group AB, Lund, Sweden) is the inventor and exclusive owner of the DP&P technology. To achieve the functionality of digitalised records and data extraction, there are five main elements consisting of:

- The patent-protected Anoto dot pattern;
- Paper and printing;
- The digital pen;
- Architecture; and
- Interfaces.

The digital pen has the ability to record every pen stroke through an infra-red camera that is fitted into the pen. The camera captures the images as drawings, sketches and alphanumeric

4 Xbar chart: average length of stay (ALOS) by admission week (*n* = 270)



UCL = upper confidence limit. LCL = lower confidence limit.

data. The pen stores that information in its memory. Transmission of these data can be via a docking station (USB) or via mobile phone using Bluetooth technology.

Anoto have some recommendations regarding the quality of paper, ink, and printers, however printing can be achieved through a variety of means:

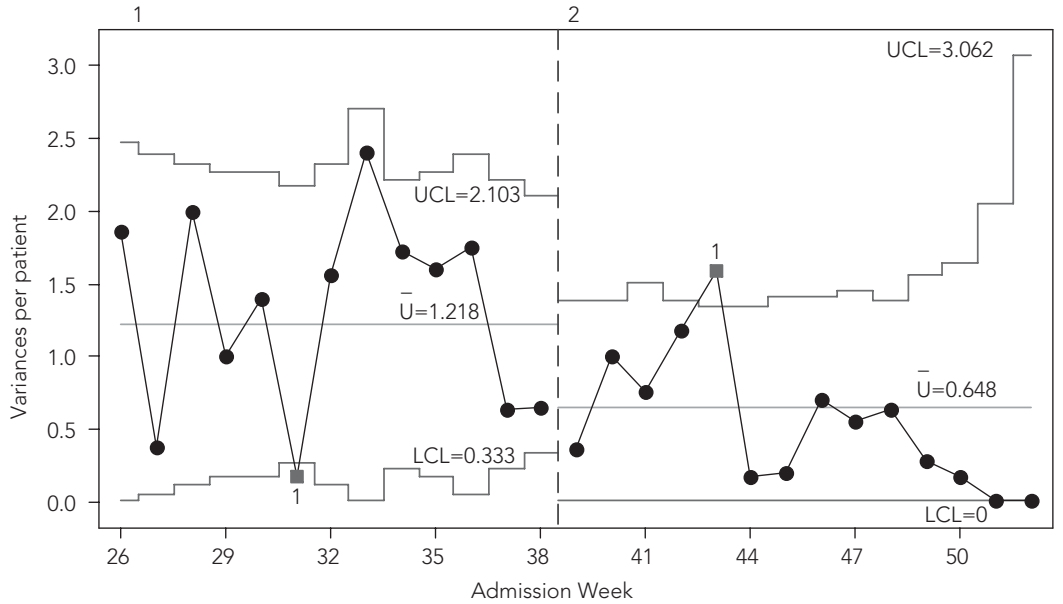
- Offset printers;
- Digital presses; or
- Office colour laser printers.

Ensuring the quality of the printing process translates into good data capture. The functionality of the form is based on the structure or placement of the dots in a pattern (matrix). The camera records the pen stroke exactly as the ink image left on the form.

The project required the development of new applications and services that enabled the deployment of the arthroplasty pathway variance solution. After testing, the Arthroplasty Clinical Pathway Variance form required some redesign for digital use. The new form was simpler and quicker to use. Data were accessible on designated PCs in the local network and directed to the server hosting the database.

The monitoring of variance using the DP&P technology may have contributed to more timely clinical intervention, decreasing complications and improving resource utilisation. The average length of stay in hospital was one of the indicators measured in order to test the impact of this technology (timely intervention shortening the length of stay [LOS] of the patient). An improvement was noted among the population of patients having arthroplasty interventions (Box 4). At the beginning of the study, the average LOS for knee arthroplasty was almost 8 days and had decreased to less than 7 days by the end of the period. More significantly, LOS among the hip replacement patients had decreased from 8.9 to 7.3 days. Not only the mean, but also the variation of the LOS decreased significantly. The factors attributed to this trend are likely to be complex. Whether the LOS outcomes are attributed to staff retraining, the use of CPs or a heightened awareness of variance capture as a result of using the digital

5 U chart: postoperative complications per patient — hip replacement



UCL = upper confidence limit. LCL = lower confidence limit.

pen, it is not an insignificant outcome to have achieved a measurable reduction in LOS, given that this was not the primary aim of the project. This would be worthy of further investigation.

To measure the decrease in complications, we defined the number of post-operative complications per patient as the second quality improvement indicator. As expected, the number of variances per patient increased during the survey period. However, the number of post-operative complications per patient decreased, significantly among the patients having a hip replacement (see Box 5).

Throughout the trial, dependability of the digital pen, and the associated hardware and software applications were monitored. The pens were robust and capable of taking the knocks associated with use in clinical settings. Transfer of data from the pen to the database was reliable and timely. The software application associated with the digital pen required regular re-installation at some workstations. This was potentially associated with the organisation's standard operating environment (SOE) and multiple users sharing individual workstations. To achieve desired functionality, various exemptions to aspects of the SOE were required and implemented. The technology then proved reliable and robust.

This technology has only been trialled at a single site for a limited purpose. No assessment of a multisite application has occurred. A wider implementation would be a logical next step in the process of assessing the efficacy of this technology to capture clinical data at the point of care.

Potential areas for use of DP&P technology[11] include:

- Mandatory data collection;
- Any clinical necessity to transfer data from a paper system to an electronic system;
- As an integral part of a variance management system;
- Prescription writing and recording;
- Patient journals (ie, symptom journals);
- Surveys (forms and open-ended questions);
- Field notes and transcription (ie, in qualitative studies);
- Graphic documentation (ie, pressure sores and skin lesions, fundal height, anatomical position, tumour staging, etc.);

- Rapid, emergent documentation (ie, "codes" and resuscitation flow sheet);
- As an intermediary technology to a "paperless" system, or as digital adaptation of "paper must" processes;
- Instances where a patient's handwriting/signature is required (ie, informed consents, living wills etc.).

Conclusion

This technology provides a dependable, real-time solution to transform handwritten clinical data into a digital format. The process of digitising these data forces encryption and therefore safeguards patient confidentiality. The data transfer easily into a database environment where they can be analysed to provide statistically relevant reports to inform clinical practice. Clinicians have readily accepted the technology, as limited training or change to practice is necessary. The production of timely, reliable variance data is required to ensure that improvements in the process of care occur consistently across departments at the point of care.

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Competing interests

The authors declare that they have no competing interests.

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