



Review

Effectiveness of barcoding for reducing patient specimen and laboratory testing identification errors: A Laboratory Medicine Best Practices systematic review and meta-analysis[☆]

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ABSTRACT

Objectives: This is the first systematic review of the effectiveness of barcoding practices for reducing patient specimen and laboratory testing identification errors.

Design and methods: The CDC-funded Laboratory Medicine Best Practices Initiative systematic review methods for quality improvement practices were used.

Results: A total of 17 observational studies reporting on barcoding systems are included in the body of evidence; 10 for patient specimens and 7 for point-of-care testing. All 17 studies favored barcoding, with meta-analysis mean odds ratios for barcoding systems of 4.39 (95% CI: 3.05–6.32) and for point-of-care testing of 5.93 (95% CI: 5.28–6.67).

Conclusions: Barcoding is effective for reducing patient specimen and laboratory testing identification errors in diverse hospital settings and is recommended as an evidence-based “best practice.” The overall strength of evidence rating is high and the effect size rating is substantial. Unpublished studies made an important contribution comprising almost half of the body of evidence.

Disclaimer: The findings and conclusions in this article are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention/the Agency for Toxic Substances and Disease Registry (CDC/ATSDR).

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Abbreviations: CDC, U.S. Centers for Disease Control and Prevention; CI, Confidence interval; ID, Identification; IOM, Institute of Medicine; LMBP, Laboratory Medicine Best Practices Initiative; QI, Quality improvement.

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Introduction

Reduction of medical errors has been a major national priority since the publication of the Institute of Medicine report *To Err is Human* [1]. Patient specimen and laboratory testing identification errors have been reported as the leading cause of laboratory errors [2]. Identification (ID) errors may result in patient harm and are completely preventable. Identifying effective strategies for reducing these errors has been identified as a research priority [3], but there are no systematic reviews available providing evidence of effectiveness for quality improvement practices. The purpose of this article is to provide a systematic review that evaluates whether barcoding practices are effective at reducing patient specimen and laboratory testing identification errors. The answer is provided by applying the CDC Laboratory Medicine Best Practices Initiative's (LMBP) systematic review methods for quality improvement practices and translating the results into evidence-based guidance [4].

Accurate identification of patients, their specimens and laboratory test results linked to them is essential in all healthcare settings for providing effective, safe, timely, efficient, equitable and patient-centered healthcare. Systems to monitor errors in patient specimen and laboratory testing identification are federally regulated [5], and accurate identification is a nationally recognized patient safety priority [6–11]. Although government, accreditation, patient safety, professional and industry organizations require laboratories to establish and follow policies and procedures to ensure accurate identification from specimen collection to result reporting, the guidance provided is largely based on expert opinion. Typical hospital clinical laboratories are responsible for thousands of tests daily, yet there is considerable uncertainty about how to reduce identification errors, and what quality improvement practices are effective [12]. ID error consequences include incorrect, delayed and/or lack of treatment which may cause injury, disability, death, longer lengths of stay, and higher healthcare costs, as well as other patient harm and diverted resources [13–15]. Accurate identification is particularly essential to the safe transfusion of blood products since ID errors put patients at risk for adverse outcomes from blood incompatibility [14].

Quality gap: patient specimen and laboratory testing identification errors

ID errors involve incorrect matching of patient, specimen and/or test information, all of which should be unequivocally linked to a correct patient identity throughout the entire testing process [7,13]. There are

many causes of ID errors, most of which are associated with human error and under the control of the laboratory [13]. ID errors lack a standardized definition¹ and systems for detecting, reporting, measuring and categorizing them and their consequences among laboratories and health care organizations. They are generally considered under-reported as the true frequency includes undetected errors [8,11]. As a consequence, reported ID error results can vary among organizations due to differences in measurement methods and how effective laboratory and clinical staff are in identifying errors [8,9], which makes it difficult to arrive at conclusions about the true size and variability of the ID error quality gap.

Reported ID error rates of 1% and less are common [3,10,16–20], yet are still considered a serious problem since any error has the potential for serious adverse patient consequences. The lowest rates are associated with transfusion medicine and are usually less than 0.1%, followed by the general pathology laboratory at closer to 1%, but as high as 10% [21–26], with even higher rates found in surgical pathology [8,13,27]. While errors rates at or very close to 0% have been documented, the upper end of the range could be as high as 50%. The highest rates [23,27] have been measured by a prospective, direct observation method using surgical specimen requisitions and container labeling with an extensive list of variables included in the ID error definition. Most detected errors do not harm patients since their detection results in the associated erroneous test reports typically not being released by the laboratory [8,9,28].

Methods

This evidence review followed the “A-6 Cycle” systematic review methods for evaluating quality improvement practices funded by the CDC's Laboratory Medicine Best Practices Initiative (LMBP) and reported in detail elsewhere [4]. This approach is derived from previously validated methods, and designed to transparently evaluate the results of studies of practice effectiveness to support evidence-based best practice recommendations. A review team conducts the systematic review and includes a review coordinator and staff trained to apply the LMBP methods. Guidance is provided by a multi-disciplinary expert panel including at least one LMBP Workgroup member and

¹ See Glossary for more detailed information on ID errors and associated terms.

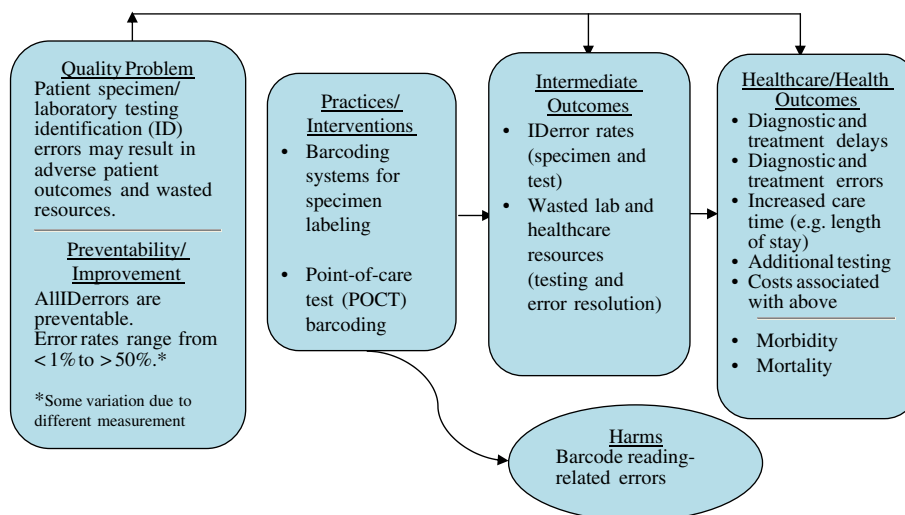


Fig. 1. LMBP QI analytic framework: patient specimen and laboratory testing identification errors.

individuals selected for their diverse perspectives as well as relevant expertise in the topic area, laboratory management, and evidence review methods.² The results are translated into an evidence-based best practice recommendation by the expert panel for approval by the LMBP Workgroup. These methods as applied in this evidence review of barcoding practices are presented below.

ASK: review question and analytic framework

The LMBP methods begin with the ASK step which frames at least one review question supported by an analytic framework and PICO elements (population, intervention/practice, comparator, outcome). The question answered by this evidence review is:

Are barcoding practices effective at reducing patient specimen and laboratory testing identification errors? This review question is addressed in the context of an analytic framework for the quality issue of patient specimen and laboratory testing identification errors (Fig. 1). The relevant PICO elements are:

- **Population:** all patients in healthcare settings using laboratory or point-of-care testing and their specimens requiring accurate identification for use in a healthcare context
- **Intervention:** barcoding practices defined as laboratory test barcoding systems using barcoded patient identification linked to specimen labels or point-of-care testing
- **Comparison practice/intervention:** non-barcoded identification systems for patients, specimens and laboratory tests
- **Outcome:** specimen and/or laboratory testing identification error rates are the primary and most direct outcome of interest.

The two barcoding practices being evaluated in this review are described below.

Barcoding systems

Electronic barcoding for identification of patients, specimens and laboratory testing is used to positively establish identification and link specimens and tests to a patient throughout the entire testing process including test ordering, specimen collection, analysis and test result reporting [13]. Barcode scanners are used to confirm patient identity. Other options include barcoded patient wristbands,

portable printers to generate labels at the bedside, and use of an interface with a computerized physician order entry (CPOE) system.

Point-of-care test barcoding systems

Automated patient specimen and laboratory testing identification system use bar-coded patient identification and bar code scanners with a testing device at or close to the patient. Testing devices can interface with laboratory information systems to receive and transmit patient identification and test result information. This practice may include barcoded patient wristbands.

ACQUIRE: search for practice effectiveness evidence

The search for studies of barcoding practice effectiveness to reduce patient specimen and laboratory testing ID errors included a systematic search of multiple electronic databases, hand searching of bibliographies from relevant information sources and their bibliographies, provision of references by as well as consultation with experts in the field including members of the expert panel (Appendix A). Additional evidence was obtained by solicitation of unpublished quality improvement studies resulting in submissions to the Laboratory Medicine Best Practices Initiative.³ The literature search strategy and terms were developed with the assistance of a research librarian and included a systematic search in August 2011 of three electronic databases (PubMed, Embase and CINAHL) for English language articles from 1995 to 2012 about human subjects. The search contained the following Medical Subject Headings: automatic data processing, blood transfusion, hospitals, laboratories, methods, patient identification systems, patients, and specimen handling as well as these keywords: barcode/bar-code/bar code, labeling errors, laboratory/ies, methods/strategy(ies) reduce patient specimen handling practice/identification errors, patient identification system errors, pharmaceutical, specimen, and transfusion.

APPRAISE: screen and evaluate evidence

The ACQUIRE step search results are reviewed by an initial screening of titles and abstracts using pre-specified inclusion criteria consistent with the ASK step, followed by a full-text review of all eligible effectiveness studies, involving abstracting, standardizing and evaluating study quality using the LMBP methods. Included studies are

² See Appendix A for the LMBP Patient Specimen Identification Expert Panel Members. LMBP Workgroup members are listed at: https://www.futurelabmedicine.org/about/lmbp_workgroup/.

³ More information on submission of unpublished studies to the Laboratory Medicine Best Practices Initiative is available at www.futurelabmedicine.org.

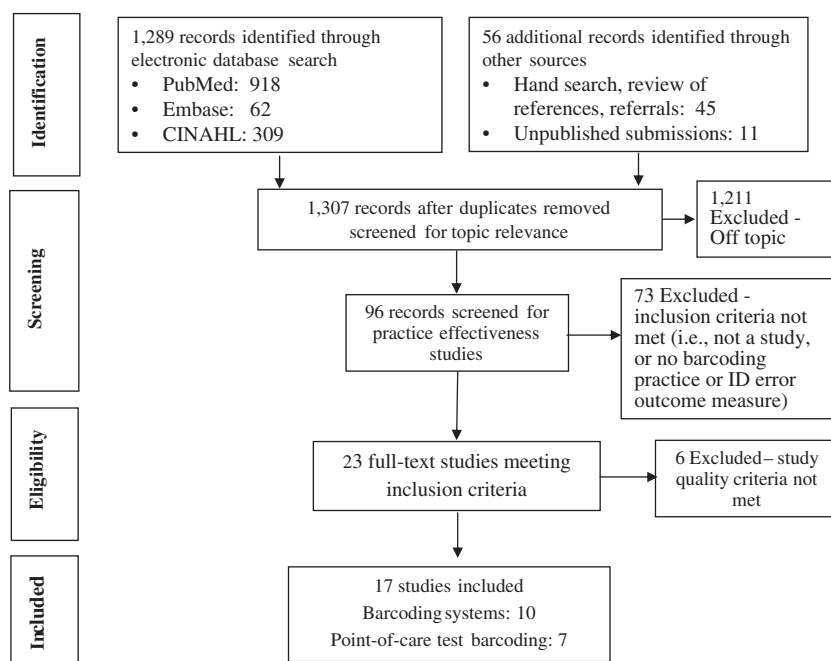


Fig. 2. Systematic review flow diagram.

considered to provide valid and useful information addressing the review question [29] with barcoding effectiveness findings that include at least one ID error outcome measure. To reduce subjectivity and the potential for bias, all screening, abstraction and evaluation are conducted by at least two independent reviewers, and all reviewer discrepancies are resolved through consensus. The effect size for each study was standardized using its reported data and results to calculate an odds ratio (OR)⁴ since the outcome of interest is dichotomous (i.e., correctly identified versus misidentified) and the findings for these practices are typically expressed in terms of rates or percentages. The OR compares the barcoding practice to a non-barcoding practice in terms of the relative odds of a successful outcome (i.e., the patient's specimen and/or test is correctly identified versus incorrectly identified). Each study is assigned one of three quality ratings (Good, Fair, Poor) and one of three effect size ratings (Substantial, Moderate or Minimal/none).⁵

ANALYZE: evidence review synthesis and results

The individual effectiveness study results from the APPRAISE step are aggregated into two practice-specific bodies of evidence (barcoding systems and POCT barcoding) and then analyzed to produce the systematic review practice effectiveness results for translation into evidence-based recommendations (Recommend, No recommendation for or against, Recommend against).

Both qualitative and quantitative analyses are used to assess effect size consistency and patterns of results across studies [30]. Qualitative analysis is used to rate the overall strength of the body of evidence for practice effectiveness (High, Moderate, Suggestive, or Insufficient). Criteria for these ratings are described in detail elsewhere [4,31]. The qualitative analysis synthesizes the individual studies to convey key study characteristics, results and evaluation findings summarized in a body of evidence table. A quantitative analysis is provided

using meta-analysis of the results from similar individual studies to estimate a weighted average effect size and confidence interval using a random-effects model⁶ with the results presented in a forest plot.

Evidence review synthesis and results

The ACQUIRE step procedures identified 1307 separate bibliographic records that were screened for eligibility to contribute evidence of the relation of barcoding with ID error outcomes. The APPRAISE step screening resulted in 1211 of these records being excluded as off-topic, and 73 being excluded for not meeting effectiveness study inclusion criteria (i.e., not a study, no barcoding practice, no ID error outcome measure) for a total of 23 full-text studies meeting the review inclusion criteria. A systematic review flow diagram in Fig. 2 provides a breakdown of the search results. Abstracted and standardized information as well as study quality ratings for the 23 eligible studies are provided in Appendix B containing evidence summary tables preceded by a Body of Evidence table for each practice. Bibliographic reference information for these studies is provided in Appendix C.

The full-text review and evaluation of the 23 eligible studies resulted in the exclusion of 6 studies due to "poor" study quality ratings which did not meet the minimum required LMBP study quality inclusion criteria (4 barcoding system studies: 3 published and 1 unpublished; 2 point-of-care test barcoding studies: 1 published and 1 unpublished). A total of 17 studies are included in this review as evidence of practice effectiveness (8 of which are unpublished submissions): 10 studies for barcoding systems (3 unpublished) and 7 studies for point-of-care test barcoding (5 unpublished). All included studies used observational before–after study designs.

⁴ See Glossary for more information on odds ratios.

⁵ The criteria for a Substantial effect size rating: $OR > 2.0$ and significantly different from $OR = 1.0$ at $p = 0.05$ (i.e., the lower limit of the 95% confidence interval is > 1.0).

⁶ Random-effects model assumes there is no common population effect size for the included studies and the studies' effect size variation follows a distribution with the studies representing a random sample. This is in contrast to the fixed-effects model which assumes a single population effect size for all studies and that observed differences reflect random variation.

Barcoding system practice effectiveness evidence

Of the 10 studies included in the barcoding system practice body of evidence, 7 were published and 3 were unpublished, and 6 were rated “Good” study quality and 4 were rated “Fair” with summarized information provided in Table 1. The earliest study time period was 1999–2000, and the starting date for 6 of the studies was 2005 or later, with 3 published in 2010. All study sample sizes were very

large while the number of identification errors was very small. In all studies both the barcoding and the non-barcoding comparison groups were considerably in excess of 1000 specimens. All but 2 studies exceeded 10,000 specimens for both groups, and 3 studies exceeded 100,000 specimens. All 10 included studies involved laboratory testing with identification of patient specimens using labels in U.S. hospital settings; 8 studies from clinical pathology laboratories and 2 from surgical/anatomic pathology laboratories (Zarbo 2009 and University

Table 1
Body of evidence summary table: barcoding systems.

Study (quality and effect size ratings)	Population/sample	Setting	Time period	Results (specimen ID error rates)
Bologna 2002 – Fair – Moderate	All phlebotomies Pre: 69,432 Post: 59,490	Valley Hospital, Ridgewood, NJ; >400 beds; 10 care centers	Pre: 1/1999–12/1999 Post: 1/2000–9/2000	Incorrect/incomplete specimen label (misidentified) rate: Pre: 0.017% (12/69,432) Post: 0.007% (4/59,490) OR=2.57 (CI: 0.83–7.97)
Brown 2010 – Good – Substantial	Inpatient blood specimens from 6 care units (3 med/surg., intermediate, psychiatry, and obstetrics) ^a Pre: 456,069 Post: 458,461	Howard County General Hospital, Columbia, MD: 227-bed, nonprofit acute care community hospital	Pre: 11/2005–10/2006 Post: 11/2006–10/2007	Specimen labeling error rate (per 10,000 specimens): Pre: 2.26 Post: 0.17 OR=12.95 (CI: 6.31–26.58)
Hayden 2009 – Good – Substantial	All tissue and body fluid test order events (accessions) Pre: 19,247/mo. (1 yr.) Post: 17,793/mo. (1 yr.)	St. Jude Children's Research Hospital, Memphis, TN Pediatric oncology hospital	Pre: 9/2003–8/2004 Post: 9/2005–8/2006	Mislabeled specimen rate: Pre: 0.032% Post: 0.005% OR=6.58 (CI: 5.26–8.22)
Hill 2010 – Good – Substantial	All emergency department specimens sent to any hospital laboratory Pre: 724,465 Post: 334,039	Johns Hopkins Hospital, Baltimore, MD; Academic medical center; Adult emergency department	Pre: 9/2004–4/2008 Post: 5/2008–9/2009	Specimen processing error rate (unlabeled, mislabeled, wrong patient specimen or requisition): Pre: 0.42% Post: 0.11% OR=3.67 (CI: 3.30–4.08)
Kileen 2005 – Good – Substantial	All emergency department patient specimens Pre: 22,243 Post: 22,574	UCSD Medical Center, San Diego, CA; Academic medical center; Emergency Dept.	Two 6 month periods for Pre and Post— no dates	PSID error rate per 1000 (misidentified, unlabeled, or mislabeled specimens): Pre: 2.56 [CI: 1.94–3.32] Post: 0.49 [CI: 0.24–0.87] OR=5.27 (CI: 2.76–10.05)
Morrison 2010 – Fair – Moderate	All inpatient phlebotomist blood draws Pre: 181,758 Post: 184,043	Brigham and Women's Hospital, Boston, MA; 777-bed Academic medical center	Pre: 10/2007–7/2008 Post: 9/2008–6/2009	Labeling error rate per 10,000 (unlabeled and mislabeled): Pre: 5.45 Post: 3.20 OR=1.70 (CI: 1.23–2.35)
Zarbo 2009 – Good – Substantial	All surgical cases/accessions (specimen containers) Pre: 2694 Post: 2877 Note: Other outcomes reported require more specimen processing ^b	Henry Ford Hospital, Detroit, MI Surgical pathology laboratory gross room	Two 3-week periods; Pre: 7/2006 Post: 8/2007	Surgical cases misidentification rate: Pre: 1.67% Post: 0.63% OR=2.68 (CI: 1.55–4.63)
<i>Unpublished</i>				
LBJ 2009 – Good – Moderate	LBJ 2009 – Good	LBJ 2009 – Good	LBJ 2009 – Good	LBJ 2009 – Good
Univ of WA ^c 2009 – Fair – Substantial	Univ of WA ^c 2009 – Fair	Univ of WA ^c 2009 – Fair	Univ of WA ^c 2009 – Fair	Univ of WA ^c 2009 – Fair
Unpub A 2009 – Fair – Substantial	Unpub A 2009 – Fair	Unpub A 2009 – Fair	Unpub A 2009 – Fair	Unpub A 2009 – Fair
Body of evidence ratings		# Studies by quality and effect size ratings		
		5 Good/substantial		
		2 Fair/substantial		
		1 Good/moderate		
		2 Fair/moderate		
Consistency		Yes		
Overall strength		High		

^a Number of blood samples not provided in published article; provided in direct e-mail communication received 7/12/2011 from Susan Neal-Lyman.

^b Additional measures: specimen parts, tissue cassettes, and histology slide labels.

^c Excluded from meta-analysis.

of Washington 2009). There was geographic and patient diversity across study settings which included inpatient, outpatient, emergency department and pediatric settings. All hospitals were relatively large, with the smallest exceeding 200 beds. Four studies relied exclusively on inpatient blood specimens and used bedside label printing (Brown 2010, Morrison 2010, LBJ 2009, Unpub A 2009), and two studies relied only on emergency department specimens (Hill 2010, Killeen 2005).

Body of evidence qualitative analysis

As summarized in Table 1, the evidence of practice effectiveness for reducing ID errors indicates a consistent improvement associated with barcoding systems compared to non-barcoding practices with a high strength of evidence in hospital settings. The odds ratio for 9 of the 10 barcoding system studies exceeded 2.0 (favoring barcoding), and the 95% confidence interval lower limit exceeded 1.0 for 8 of the 10 studies. The 3 study exceptions (Bologna 2002, Morrison 2010, and LBJ 2009) had the smallest numbers of ID errors in the barcoding and non-barcoding study groups ranging from 0 to 12 which corresponded to very large sample sizes; the smallest being about 25,000 and the rest substantially larger. The odds ratio estimates for all 10 included studies ranged from 1.7 to 147. The unpublished studies' odds ratios were consistent with those of the published studies with the exception of the uppermost unpublished study odds ratio of 147.

Meta-analysis

The forest plot in Fig. 3 presents the meta-analysis effect size results for barcoding systems. The odds ratio for each of the 9 included studies favors the barcoding system practice over the non-barcoding practice for improving identification error rates indicating a consistent and statistically significant effect. The overall summary effect mean odds ratio was 4.39 (95% CI: 3.05–6.32). The higher rated “Good” study quality subgroup summary effect size exceeded that of the lower rated “Fair” quality subgroup with an odds ratio of 5.14

versus 2.43. The lower limit of the confidence interval for both subgroups exceeded 1.0 at 3.41 for the 6 “Good” quality studies but only 1.1 for the 3 “Fair” studies. One of the ten barcoding system practice effectiveness studies was excluded from the meta-analysis (University of Washington 2009) as its ID error rate outcome measure (processed specimen cassettes/blocks rather than specimens in their original containers with labels) and results (OR=147; 95% CI: 55–391) were considered too heterogeneous relative to the other nine included studies.

Meta-analysis results for barcoding systems show significant statistical heterogeneity which is typical of random effects results. The I^2 statistic ranges from 0 to 100% and estimates the percent of variability in estimates attributable to between study differences. Studies rated “Good” showed somewhat less between-study variation (10.5%) relative to “Fair” studies (15.9%) which had larger estimated odds ratios. This modest attenuation of effect size from “Fair” studies contributes to modest between-study variation (24.8%) in the overall estimate.

Point-of-care test barcoding practice effectiveness evidence

Of the 7 studies included in the point-of-care barcoding practice effectiveness body of evidence, 2 were published and 5 were unpublished, and 5 were rated “Good” study quality and 2 were rated “Fair” with summarized information provided in Table 2. All of the included studies relied on U.S. hospital inpatient point-of-care glucose tests, with at least 4 studies also including emergency department patient tests. The earliest study time period began at the end of 2002, while the remaining studies began in 2006 or later, with 4 ending in 2011. Like the barcoding systems' practice effectiveness studies, the point-of-care test barcoding study sample sizes were typically very large with all barcoding and non-barcoding groups exceeding 10,000 tests with one exception (Rao 2005). Several studies had barcoding and/or comparison groups with substantially more than 100,000 tests. Four of the unpublished studies came from separate hospitals within one hospital system (Catholic Health System: Kenmore Mercy Hospital, Mercy Hospital of Buffalo,

Patient Specimen Identification: Bar Coding Systems

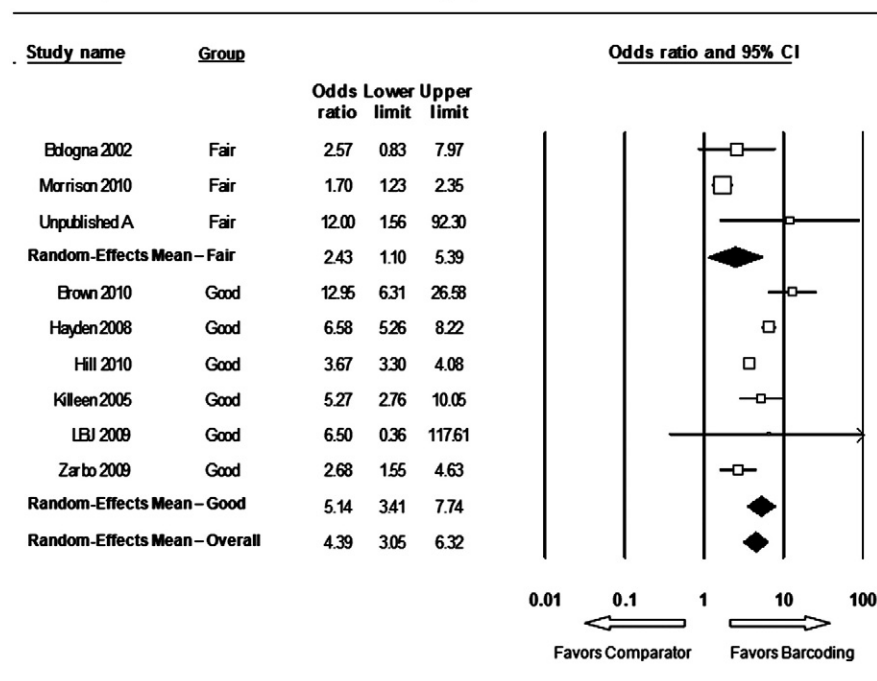


Fig. 3. Meta-analysis forest plot: barcoding systems. Each box represents the mean odds ratio for an individual study indicated to the far left, with the box size proportional to the study sample size. The endpoints of the lines on the left and right sides of the box represent the lower and upper limits, respectively, of the study odds ratio's 95% confidence interval, with the numerical values provided to the left. The bottom line represents the overall summary effect (or grand mean) for all the studies in the body of evidence along with its confidence interval. In addition, meta-analysis results were tabulated separately for two subgroups using the two study quality ratings “Fair” and “Good”.

Table 2

Body of evidence summary table: point-of-care test barcoding.

Study (quality and effect size ratings)	Population/sample	Setting	Time period	Results (specimen ID error rates)
Colard 2005 – Good – Substantial	All inpatient glucose POCT— approximately 12,000–15,000/mo. (no data provided for study sample)	Saint Luke's Hospital, Kansas City, MO; 629-bed tertiary care teaching hospital	11/2002–12/2003 Pre: 1 mo. (11/2002) Post: 9 mos. (4–12/2003)	Patient ID error rate (monthly) Pre: 9.4% Post: 0.7% OR=14.72 (CI: 13.47–16.08)
Rao 2005 – Fair – Moderate	Glucose POCTs for 35 inpatients No Barcoding: 304 Barcoding: 158	Massachusetts General Hospital, teaching hospital, >900 beds	No dates reported No barcoding: 2 mos. Barcoding: 1 mo.	Patient ID error rate No barcoding: 1.32% Barcoding: 0.00% OR=4.75 (CI: 0.25–88.73)
<i>Unpublished</i>				
Geisinger 2009 – Fair – Substantial	Glucose POCTs for all inpatients; ~18,000/mo.; Baseline sample size not reported (includes ~1/3 barcoding); Barcoding: 106,780	Geisinger Medical Center, Danville, PA; teaching hospital, >300 beds.	1/2004 and 1–6/2009 Baseline: 1 mo. (2004) Barcoding: 6 mos. (2009)	Patient ID Error rate Baseline: 2.9% Barcoding (full implementation): 0.5% OR=5.94 (CI: 5.26–6.71)
Kenmore Mercy 2011 – Good – Substantial	All hospital inpatient and Emergency Dept. POC glucose tests Pre: 79,437 Post: 184,491	Kenmore Mercy Hospital, Kenmore, NY; teaching hospital; 100–300 beds	1/2007–5/2011 Pre: 16 mos. Post: 37 mos.	Patient ID Error rate Pre : 2.16% Post: 0.57% OR=3.85 (CI: 3.56–4.16)
Mercy Buffalo 2011 – Good – Substantial	All hospital inpatient and Emergency Dept. POC glucose tests Pre: 249,667 Post: 517,744	Mercy Hospital of Buffalo, Buffalo, NY; teaching hospital, >300 beds	1/2007–5/2011 Pre: 17 mos. Post: 36 mos.	Patient ID error rate Pre : 2.24% Post: 0.44% OR=5.23 (CI: 4.98–5.50)
Sisters Buffalo 2011 – Good – Substantial	All hospital inpatient and Emergency Dept. POC glucose tests Pre: 120,718 Post: 259,787	Sisters of Charity Hospital, Buffalo, NY; teaching hospital; 100–300 beds	1/2007–5/2011 Pre: 17 mos. Post: 36 mos.	Patient ID error rate Pre : 1.56% Post: 0.42% OR=3.75 (CI: 3.48–4.04)
Sisters. St. Joseph 2011 – Good – Substantial	All hospital inpatient and Emergency Dept. POC glucose tests Pre: 44,932 Post: 182,150	Sisters of Charity Hospital St. Joseph's Campus, Cheektowaga, NY; teaching hospital; 100–300 beds	1/2007–5/2011 Pre: 11 mos. Post: 42 mos.	Patient ID error rate Pre : 3.22% Post: 0.54% OR=6.09 (CI: 5.61–6.60)
Body of evidence ratings		# Studies by quality and effect size ratings		
		5 Good/substantial		
		1 Fair/substantial		
		1 Fair/moderate		
Consistency		Yes		
Overall strength		High		

Sisters of Charity Hospital Buffalo and Sisters of Charity Hospital St. Joseph Campus). As a result, the body of evidence is not as geographically diverse as for barcoding systems, but the study settings may be reasonably representative of diverse hospitalized patient populations.

Body of evidence qualitative analysis

As summarized in Table 2, the evidence of practice effectiveness for reducing identification errors indicates a consistent and substantial improvement for point-of-care test barcoding compared to non-barcoding (manual entry) practices with a high strength of evidence for point-of-care glucose testing in hospital settings. The point-of-care barcoding practice odds ratio for all 7 of the included studies exceeded 2.0 (favoring the barcoding practice over non-barcoding practices), and the lower limit of the odds ratios' 95% confidence interval exceeded 1.0 for 6 of the 7 studies. The one study exception (Rao 2005) had the smallest numbers of errors (4 without barcoding; 0 with barcoding) and the smallest total sample size (462) of the included studies. The odds ratio estimates for all the included studies ranged from 3.76 to 14.72.

Meta-analysis

The forest plot in Fig. 4 presents the meta-analysis results for the point-of-care test barcoding practice. The overall summary effect mean odds ratio was 5.93 (95% CI: 5.28–6.67). The 5 higher rated

“Good” quality studies' subgroup summary effect size was similar: mean odds ratio of 5.83 (95% CI: 3.86–8.82). Of the 7 included studies, only one had an odds ratio 95% confidence interval lower limit less than 1.0 (Rao 2005), reflecting the very small number of identification errors in the study (4) as well as a relatively small sample size (462). These meta-analysis results show significant statistical heterogeneity as is typical of random effects results. Most of the point-of-care test barcoding meta-analysis results' statistical heterogeneity is attributable to within-study variance. The higher rated “Good” study quality subgroup showed modest between-study variation ($I^2=27.8\%$) while all between-study variation in the fair and overall results can be attributed to chance. At the aggregate level, results for “Fair” and “Good” studies are essentially indistinguishable and can be considered well represented by the overall mean estimate.

Discussion

Additional considerations

Applicability

Barcoding practices demonstrated effectiveness at reducing ID errors for patient specimen and laboratory testing identification is generalizable to most common hospital settings and patient populations, to clinical pathology laboratory testing, and potentially to surgical/

Patient Specimen Identification: Point-of-Care-Testing Bar Coding Systems

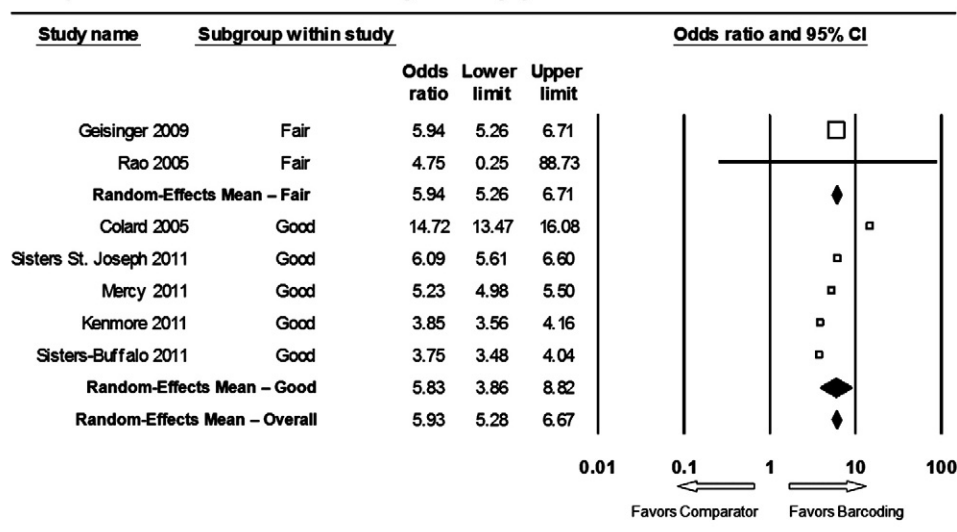


Fig. 4. Meta-analysis forest plot: point-of-care test barcoding.

anatomic pathology laboratory testing for which there was more limited evidence [28,32,33]. Although barcoding effectiveness studies for non-hospital settings and point-of-care testing other than glucose were not included in the body of evidence reviewed, barcoding may be similarly effective at reducing ID errors but no evidence was available to test this hypothesis. Cost, technological requirements and training may be barriers to adoption of barcoding in some non-hospital settings, as well as hospital settings; however this is not clearly supported. In relatively low volume testing settings, limited economies of scale for barcoding technology may present a cost barrier. Non-hospital settings generally do not rely on patient identification armbands typically used in hospital inpatient and emergency departments, but patients may have specimen container or test requisition form labels with identification information that can be barcoded.

Harms

Barcoding technology is not error free. ID errors associated with barcoding practices include those created by the patient identification barcodes themselves [34]. Barcode scanners may misread patient identification barcodes due to incompatibility between the barcode print area size or symbology on patient ID bands or specimen labels with scanner settings. In one study a small number of scanner misreads occurred due to the narrow wrist band curvature of pediatric patients [35]. Other sources of barcoding ID errors included labels being unreadable by a scanner due to label print quality problems, which may indicate a need for label printer maintenance, and degradation of the barcode on the patient ID band from being worn or written on. Studies and articles have also reported scanner failure attributable to low batteries [36]. Even when the scanner works properly, incorrect information such as the wrong patient's barcode, incorrect barcode information from a patient's ID band, or non-patient identification barcodes (e.g., medication) can cause ID errors [37,38]. A specific type of ID error is from scanning incorrect barcode information from a patient ID band with a barcode related to a previous hospitalization or a hospital transfer. Such an episode could include more than one armband and/or multiple patient accounts [37,39]. Although many potential sources of ID errors associated with barcoding have been identified, these errors appear relatively rare, generally preventable, and likely have only a negligible impact on ID error rates.

Additional benefits

The studies reviewed report other beneficial outcomes associated with barcoding including an observed reduction in misidentified patients

[40], unnecessary phlebotomy [40], labor time savings and reduced workflow process time in surgical pathology [32,33]. Implementing barcoding has been credited with improving identification of those responsible for making ID errors, thus enabling targeted measures to improve performance [37,40]. Cost savings noted from fewer ID errors associated with barcoding include reductions in specimen recollections, labor to investigate and correct ID errors, length of patient stays and legal issues [41]. Additional benefits to patients from fewer ID errors include avoiding unnecessary discomfort, inconvenience, and treatment delays from recollecting and retesting specimens [40,42].

Economic evaluation

No patient specimen barcoding practice economic evaluations (cost, cost-effectiveness, or cost-benefit analyses) were found in the search results described in *ACQUIRE: search for practice effectiveness evidence* section.⁷ Completing a resource-related inventory for barcoding practices is beyond the scope of this study but it should include the costs associated with implementing and sustaining the practice (e.g., hardware, software, equipment, supplies and labor requirements as well as resources associated with training, testing, monitoring, and maintenance) and all downstream costs and savings that occur because the intervention was performed [43].

Feasibility of implementation

The evidence reviewed clearly demonstrates the feasibility of adopting barcoding practices in a variety of hospital settings. Nevertheless, each environment is distinctive and implementation requires adequate process development and modification, training, education and testing to achieve full effectiveness. Barcoding process design issues appear more complex for surgical pathology [32,44] which typically involves more workflow process steps than patient specimens for routine laboratory or point-of-care testing. Many studies on surgical pathology describe the approach used for barcoding-related process changes in detail, along with the accompanying challenges and solutions [32,36–38,40,42,45]. Key implementation components for making barcoding technology work as intended include adequate training and education, well-designed patient ID bands, and adequate

⁷ Similarly, additional searches covering the following databases completed in September 2011 identified no economic evaluations: EconLit, Cost Effectiveness Analysis (CEA) Registry, and the U.K. National Health Service (NHS) National Institute for Health Research Centre for Reviews and Dissemination (CRD) Economic Evaluation Database (EED) and Health Technology Assessment (HTA) Database.

supplies and equipment maintained in good working order (e.g., label printers, computers, batteries, wireless networks) [13]. Shortages and performance issues were noted as problems frustrating staff that can result in using error-prone work around processes [42]. Support and involvement from all relevant departments and leaders including nursing, laboratory and information systems, were identified as critical success factors since no department typically has full ownership of implementing and using barcoding technology.

Future research needs

Standardized outcome measures and measurement methods that consistently and reliably detect ID errors are needed for robust evaluation and comparison of QI practices. For more complete and useful assessment of barcoding practices, studies are needed to address its applicability and effectiveness in ambulatory and non-hospital settings, as well as more research evaluating barcoding in surgical pathology and settings known to have relatively higher ID error rates (e.g., emergency departments). Cost-effectiveness studies evaluating investments in potentially expensive ID error reduction technologies such as barcoding are needed. There should be a focus on settings with greater potential ID error impact due to higher rates and/or more serious consequences. Addressing this requires well-constructed data collection and analysis efforts identifying and measuring resources needed for implementation and maintenance of barcoding along with outcomes of interest. Future effectiveness research can be more informative if expected barcoding effectiveness moderators including implementation variables or practice components (e.g., electronic order system interface, bedside labeling, different barcode formats) can be evaluated for their contribution to overall effectiveness. Other benefits and harms of barcoding for patient specimen identification have not been well studied or reported and may be unknown. More information on other potential practice effects is needed to evaluate the full range of consequences and to allow for a comprehensive assessment of its net benefit. In addition, more information is needed about how to maintain and enhance the effectiveness of barcoding over time.

Limitations

The LMBP systematic review methods are consistent with practice standards for systematic reviews [30], but all such methods are imperfect and include subjective assessments at multiple points that may produce bias. Like most systematic reviews, this one may be subject to publication bias, although this review includes unpublished studies which may mitigate that bias. The restriction to English language studies to satisfy the requirement of multiple reviewers for each study may also introduce bias if barcoding practices differ substantially in international settings. Quality improvement efforts typically differ from research, and are commonly observational studies that rely on natural experiments in realistic practice settings. The major drawback of these uncontrolled designs is that it is not possible to know if measured or unmeasured factors affect the outcomes of interest. Regardless of study design, by gathering evidence from multiple clinical and organizational settings, systematic reviews provide more useful assessments of the totality of evidence for a given QI practice than individual studies [46].

Barcoding and other technology or practice changes may be easier to measure than individual step process changes that may contribute to observed results. Also, these processes are rarely uniform, and are clearly very different for clinical versus surgical pathology specimens, and for point-of-care testing. While these factors may moderate study findings and the observed heterogeneity suggests that they are not insignificant, it can be observed that all studies reported support for barcoding.

Some studies comprising the barcoding body of evidence involved less than full implementation for all or a portion of the

post-implementation period which would have an expected tendency to understate the impact of barcoding on the reduction in ID error rates. In particular, some studies indicated barcoding “scan rates” of substantially less than 100% during the post-implementation period such that the effect of a non-barcoding practice (i.e., manual entry of patient identification information) is reflected in a portion of the post-implementation data. This was noted when provided, however as it was not always clearly or consistently reported it could not be used to adjust effect size estimates. As studies were done within a single institution, there may be many site-specific differences that impact their study results. Many studies were missing information including actual study sample sizes, dates for relevant time periods, and practice implementation and setting characteristics. Another perceived limitation is the inclusion of unpublished studies.

Designing and publishing controlled studies are typically not among the primary objectives of individuals collecting and analyzing quality improvement data relevant to laboratory medicine. In the barcoding body of evidence, both the published and unpublished studies had similar limitations. The LMBP experience to date in reviewing and rating study quality for both published and unpublished studies indicates that peer-reviewed journals do *not* provide assurance of high study quality.

Conclusion and recommendation

On the basis of a high overall strength of evidence of effectiveness, barcoding systems for specimen labeling and point-of-care test barcoding are recommended as best practices to reduce identification errors and improve the accuracy of patient specimen and laboratory testing identification in hospital settings. The high overall strength of evidence is due to sufficient evidence of practice effectiveness from individual studies demonstrating consistent and substantial reduction in patient specimen and laboratory testing-related identification error rates in hospital settings. The findings of barcoding effectiveness are based on 10 studies of specimen barcoding systems and 7 studies of point-of-care test barcoding assessing impact on identification errors. In every study barcoding is associated with a reduction in the identification error rate. The meta-analysis overall summary effect mean odds ratio favoring barcoding is 4.39 (95% confidence interval: 3.05–6.32) for barcoding systems and 5.93 (95% confidence interval: 5.28–6.67) for point-of-care test barcoding. There was limited evidence of additional benefits and potential harms associated with the use of barcoding for specimen and laboratory testing identification, and any effect of potential harms appears to be very small relative to its overall benefits. All included studies were conducted in hospital settings. No evidence was available for assessing the effectiveness and applicability of barcoding in other laboratory testing settings.

Glossary

Bias: Systematic error; threats to validity; tendency to produce results that depart systematically from the ‘true’ results. Unbiased results are internally valid. Four types of bias are selection/allocation, performance, measurement/detection and attrition/exclusion.

Consistency: The degree to which estimates of effect for specific outcomes are similar across included studies.

External validity: Generalizability, applicability — extent to which the effects observed in the study are applicable outside of the study to other populations and settings.

Effect size: A value which reflects the magnitude of the difference in a study’s outcome measure between the group with the intervention/practice being evaluated and its control or comparison group.

ID errors: Misidentification in matching a patient or a specimen with a laboratory test. ID errors may include specimen/test requisition mismatches (e.g., specimen labeled with another patient’s name, wrong type of specimen, duplicate orders or specimens), mislabeled

specimens (sometimes referred to as “wrong blood in tube”), specimen label with partial, missing or incorrect information (e.g., one of two patient identifiers, missing or wrong patient gender, date of birth or middle initial), and unlabeled specimens [9,12]. Different institutions may use different denominators when expressing ID errors as a rate (e.g., number of specimens, phlebotomies, requisitions, accessions). Some ID error types are more likely to be detected by the laboratory than others (e.g., mismatch versus wrong blood in tube), with those detected typically preventing the release of a test result [8]. Most ID errors are the result of human error, and causes include but are not limited to: laboratory tests ordered on the wrong patient, incorrect or incomplete entry of patient data in the laboratory information system, collection of specimens from the wrong patient, inappropriate labeling of specimens, multiple users of the same label printer, lost identification label on specimens, incorrect identification information on specimen labels, pre-printed labels from different patients, handwritten labels on specimen containers, tissue cassettes and slides, and incorrect entry of patient results in the laboratory information system [13].

Internal validity: Extent to which the design and conduct of the study are likely to prevent systematic error. Internal validity is a prerequisite for external validity.

Meta-analysis: The process of using statistical methods to combine quantitatively the results of similar studies in an attempt to allow inferences to be made from the sample of studies and be applied to the population of interest.

Odds ratio: The ratio of two odds of an event from two groups – a treatment or intervention group (a/c) versus a control group (b/d) where a and c represent the number of times the event occurs for the intervention and control group, respectively, using the formula below and the barcoding and comparison practice example table. An OR = 1 means that the two practices are equally successful (no difference in reducing risk with respect to the outcome evaluated); OR > 1 means that the barcoding practice is more successful; and OR < 1 means that the barcoding practice is less successful.

Odds Ratio estimate formula:

$$OR = \frac{ad}{bc} = \frac{p_a p_d}{p_b p_c} = \frac{p_a/p_b}{p_c/p_d} = \frac{p_a(1-p_c)}{p_c(1-p_a)}$$

Where $p_a = a/(a+b)$, $p_c = c/(c+d)$ and a , b , c , and d are proportions in the table below.

	Frequencies		Proportions	
	Success	Failure	Success	Failure
Barcoding practice	a	b	$p_a = a/(a+b)$	$p_b = b/(a+b)$
Comparison practice	c	d	$p_c = c/(c+d)$	$p_d = d/(c+d)$

Systematic review: A scientific investigation that focuses on a specific question and that uses explicit, planned scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may or may not include a quantitative synthesis of the results from separate studies (meta-analysis).

Transparency: Methods are explicitly defined, consistently applied, and available for public review so that observers can readily link judgments, decisions, or actions to the data on which they are based. Allows users to assess the strengths and weaknesses of the systematic review and associated guidance and recommendations.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <http://dx.doi.org/10.1016/j.clinbiochem.2012.06.019>.

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