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The Availability of Noninfringing Alternatives from a Lost Profits Perspective*Stuart Miller and Krishnan Ramadas*

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Improving Throughput Metrics with Reduced Labor Expenses*Nicholas Chmielewski and Kevin Browning*



Volume 9

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Letter from the Editor

Welcome to Volume 9 of the [BRG Review](#), an official publication of Berkeley Research Group, LLC. This peer-reviewed publication reviews topics based on independent analysis by our authors. The breadth of material covered provides insight into varied and interesting ongoing research performed around the world by experts and staff throughout BRG. Our experts comprise academics and private-sector professionals in fields including economics, finance, healthcare, and data analytics. BRG has over 1,200 professionals in more than forty offices worldwide who apply innovative methodologies and analyses to complex problems in the business and legal arenas.

In our first paper, published in June 2021, Stuart Miller and Krishnan Ramadas provide an in-depth discussion of the availability of noninfringing alternatives in patent infringement cases in which lost-profits are sought as damages. While patentees typically seek a reasonable royalty as the form of compensation for patent infringement damages, a not insignificant minority of patentees seek lost profits. Typically, lost profits are guided by the four Panduit factors: 1) demand for the patented product, 2) absence of noninfringing alternatives, 3) manufacturing and marketing capabilities, and 4) calculating the amount of profit lost. For factor 2, substantial attention has been paid to the *acceptability* of noninfringing alternatives. Miller and Ramadas take a deeper look into the other aspect of Panduit factor 2: the *availability* of noninfringing alternatives in pursuing a lost profits claim in a patent infringement case.

In our second paper, published in March 2021, Nicholas Chmielewski and Kevin Browning provide a case study of a hospital emergency department that was seeking to improve on staffing performance metrics. The authors describe how the hospital system formed a department performance improvement team and transitioned from a fixed-budget staffing model to a staffing-to-demand model. This study documents how this transition saved the system nearly fifteen full-time-equivalent workers from 2017 to 2019, at a time when patient volume increased by 14 percent. Performance metrics improved even while patient satisfactions measures did not show decline.

To our readers, we hope these papers stimulate discussion and discourse and deepen our relationships with fellow professionals, academics, clients, government representatives, attorneys, and other interested individuals across the world.

Finally, this is my last issue as editor-in-chief of the *BRG Review*. I'd like to offer special thank you to the reviewers and editors who work hard to ensure that the papers published within the *BRG Review* reflect nothing short of excellence. I'd also like to thank the very talented production team at BRG, led by the impeccable Matthew Caselli, managing editor at BRG, without whom we could not present such compelling articles. Going forward, we have in place a remarkable Board of Editors, including Rebbecca Reed-Arthurs, Shireen Meer, Peter Bird, Greg Russo, and Paul Diver, which leaves *BRG Review* in very capable hands. I look forward to seeing the quality articles that surely will be forthcoming.

Regards,



Cleve B. Tyler, PhD
Editor-in-Chief

INTELLIGENCE THAT WORKS

The Availability of Noninfringing Alternatives from a Lost Profits Perspective

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This paper originally was published in June 2021

Abstract

In patent infringement litigation, plaintiffs may, where appropriate, seek to recover lost profits. Defendants may argue that the plaintiff's lost profits claim lacks basis due to the presence of noninfringing alternatives. In some cases, a noninfringing alternative could have been offered by the defendant in lieu of the alleged infringing product, or may have been otherwise available on the market. In evaluating the merits of a noninfringing alternative, two factors courts have addressed are acceptability and availability. While acceptability of a noninfringing alternative has received significant attention from practitioners and courts, the issue of availability has received comparatively less attention. In this paper, we review various Federal Circuit and district court opinions addressing availability. These opinions provide insight into how the availability of an identified noninfringing alternative can be effectively evaluated.

Introduction¹

Plaintiffs in patent infringement litigation who practice the asserted patents may seek an award of lost profits and/or reasonable royalties.² In instances where lost profits may be appropriate to consider, plaintiffs may attempt to “prove up” lost profits through consideration of the four *Panduit* factors,³ the second of which addresses whether there are viable, noninfringing alternatives.⁴ As the Federal Circuit has observed, “a rational would-be infringer is likely to offer an acceptable, noninfringing alternative, if available, to compete with the patent owner rather than leave the market altogether.”⁵

The presence of noninfringing alternatives could undermine a patent holder’s claim for lost profits, because consumers might purchase these noninfringing alternatives instead of the patent holder’s product(s) in the absence of the accused product.⁶ In a lost profits context, two pillars establish a noninfringing alternative: (1) acceptability to potential consumers and (2) availability.⁷ As was addressed in *Sherwin-Williams*, failure to demonstrate *availability* can undermine a defendant’s proposed noninfringing alternative.⁸ Here we consider how the concept of “availability” (from the producer’s perspective) has been adjudicated in the context of lost profits claims.⁹

While there is no bright-line test of availability, several guiding principles are informative in determining whether a noninfringing alternative is available to an accused infringer. As we will address in this article, a demonstration of availability may be more likely if the alternative was on the market or could have been commercialized readily during the accounting period (discussed below).

1 The authors would like to thank Jeffery Stec, Cleve Tyler, and three anonymous reviewers for providing comments, which improved this article. The authors also thank Matthew Caselli for editorial assistance.

2 35 U.S.C. § 284. See also *Lucent Technologies, Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1324 (Fed. Cir. 2009), citing *Panduit Corp. v. Stahl Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1157 (6th Cir. 1978). An award of lost profits *and* a reasonable royalty would occur if only a portion of infringing sales were subject to lost profits. That is, reasonable royalty damages would be awarded on the portion of infringing sales not subject to lost profits.

3 *Panduit Corp.*, 575 F.2d at 1156. Courts have also accepted the application of a two-supplier market test (e.g., *Micro Chemical, Inc. v. Lextron, Inc.*, 318 F.3d 1119, 1124 (Fed. Cir. 2003)).

4 The 6th Circuit held that “[t]o obtain as damages the profits on sales he would have made absent the infringement, i.e., the sales made by the infringer, a patent owner must prove: ... (2) absence of acceptable noninfringing substitutes.” *Panduit Corp.*, 575 F.2d at 1156.

5 The Federal Circuit added that the “competitor in the ‘but for’ market-place is hardly likely to surrender its complete market share when faced with a patent, if it can compete in some other lawful manner.” See *Grain Processing v. American Maize-Products*, 185 F.3d 1341, 1351 (Fed. Cir. 1999).

6 In this article, we focus our discussion of availability as it pertains to the producer’s perspective. From the consumer side, consumer preferences play a role in which alternative products are available (i.e., which other products may meet consumers’ needs). That discussion goes beyond the scope of this article.

7 *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 875 F.3d 1369, 1380 (Fed. Cir. 2017) citing *Grain Processing*, 185 F.3d at 1353–55.

8 *The Sherwin-Williams Company v. PPG Industries, Inc.*, No. 2:17-cv-01023-JFC 2020 WL 1283465, at *8-9 (W.D. Penn., March 18, 2020).

9 With regard to acceptability, the Federal Circuit has held that “to prove that there are no acceptable noninfringing substitutes, the patent owner must show either that (1) the purchasers in the marketplace generally were willing to buy the patented product for its advantages, or (2) the specific purchasers of the infringing product purchased on that basis.” See *Standard Havens Products v. Gencor Industries*, 953 F.2d 1360, 1373 (Fed. Cir. 1991).

Noninfringing Alternatives: Availability Considerations

In *Grain Processing*, the Federal Circuit indicated, “[t]he critical time period for determining availability of an alternative is the period of infringement for which the patent owner claims damages, *i.e.*, the ‘accounting period.’”¹⁰ As discussed below, a proposed noninfringing alternative may meet the bar for availability if it either (1) was on the market during the accounting period or (2) was not on the market but could have been commercialized readily during the accounting period.

Availability of an alternative that is on the market during the accounting period may be demonstrated through contemporaneous evidence (e.g., actual sales records, product marketing materials, customer feedback); demonstrating availability of a proposed alternative that is not actually on the market during the accounting period may be more challenging. In *Siemens*, the Federal Circuit stated that a “substitute need not be on sale at the time of infringement, but if the substitute cannot be commercialized ‘readily,’ then it is not available for purposes of a lost profits determination.”¹¹ Indeed, in *Grain Processing*, the Federal Circuit indicated that “[s]witching to a noninfringing substitute after the accounting period does not alone show availability of the noninfringing substitute during this critical time.”¹² The Federal Circuit added, “[w]hen an alleged alternative is not on the market during the accounting period, a trial court may reasonably infer that it was not available as a noninfringing substitute at that time.”¹³

Therefore, on its face, it would appear more challenging to demonstrate the availability of a noninfringing alternative that was not on the market during the accounting period. Various considerations can aid in assessing availability and evaluating whether commercialization can “readily” take place. These considerations may include whether: (1) the necessary equipment, material, and know-how were available or acquirable by the defendant at the time of alleged infringement; (2) the proposed alternative was not prohibitively costly or time-consuming to create; (3) the proposed alternative was more than a theoretical possibility; and (4) the proposed alternative was supported by more than speculation.

Availability of Necessary Equipment, Material, and Know-How

Assessing the availability of equipment, material, and know-how can aid in evaluating the availability of a noninfringing alternative. In *SynQor*, the Federal Circuit held that “the state of the technology, and the availability of input products and equipment” are factors to consider in assessing availability.¹⁴ One potential way to demonstrate access to the necessary equipment and material is to demonstrate that the infringer could have purchased the necessary products or components from a third party. In *Calico*, the Federal Circuit stated that a “seamless substitution of the asserted product with a noninfringing, alternative product that is sourced from a third party supplier, is evidence of acceptable noninfringing alternatives under the second *Panduit* factor.”¹⁵ When sourcing from a third-party supplier, presumably there would be only a negligible delay associated with implementing the noninfringing alternative, provided the supplier could deliver the required products in a timely manner under acceptable terms.¹⁶

The availability of equipment and material in sufficient quantities to produce the noninfringing alternative also is a relevant consideration. A showing of production ability can be more straightforward when the necessary components are not heavily customized and are held regularly in inventory. In *Micro Chemical*, the Federal Circuit noted that the necessary parts to convert the infringing machines were (1) “difficult to obtain in bulk,” (2) “specially fabricated,” and

¹⁰ *Grain Processing*, 185 F.3d at 1341, 1353 (referencing *State Indus. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1579 (Fed. Cir. 1989)).

¹¹ *Siemens Medical Solutions v. Saint-Gobain Ceramics*, 637 F.3d 1269, 1288 (Fed. Cir. 2011) (referencing *Micro Chem.*, 318 F.3d at 1123 and *Grain Processing*, 185 F.3d at 1354).

¹² *Grain Processing*, 185 F.3d 1341, 1353.

¹³ *Id.*, at 1353 (referencing *Rite-Hite v. Kelley Co., Inc.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995)).

¹⁴ *SynQor, Inc. v. Artesyn Technologies, Inc.*, 709 F.3d 1365, 1382 (Fed. Cir. 2013). In addition to these factors, the Federal Circuit also referenced “the ease with which a substitute was eventually made available.”

¹⁵ *Calico Brand, Inc. v. AmeriTek Imports, Inc.* 527 Fed. Appx. 987, 997 (Fed. Cir. 2013).

¹⁶ In *Baxter*, the plaintiff argued that “availability” required that “the alternatives were offered, or could have been offered, for sale by BD [Becton Dickinson and Company] or a company acquired by BD.” In response, the court held that “Baxter interprets the term ‘available’ too narrowly.” See *Baxter International v. Becton, Dickinson and Company*, Case No. 17-C-7576 2020 WL 424918, at *6 (N.D. Ill., January 27, 2020).

(3) “not maintained in inventory.”¹⁷ The court concluded that the record demonstrated the alternative “was not available at the time of infringement.”¹⁸

However, simply establishing the availability of equipment and material may be inadequate if the defendant lacks sufficient know-how and experience.¹⁹ For example, in *Grain Processing*, the Federal Circuit drew attention to the importance of having both equipment and material along with the relevant know-how and experience. In *Micro Chemical*, the court summarized that both “the material and know-how for the alleged substitute were readily available at the time of infringement,” and that “the infringer ‘had all of the necessary equipment, know-how, and experience’ to make the substitution at that time.”²⁰

Not Cost or Time Prohibitive to Create

In evaluating availability, it may be appropriate to consider the cost and time to implement a noninfringing alternative. With respect to cost, the Federal Circuit indicated in “*Grain Processing*, [that] even the ready availability of material and know-how alone did not make the substitute process ‘available’ for the lost profits calculus”; and noted “the high cost of necessary material can conceivably render a substitute ‘unavailable.’”²¹

Even if the cost of implementation is not prohibitive, the time required to implement a noninfringing alternative could undermine the availability of that alternative. Consider the difference in time to implement the noninfringing alternatives in *Grain Processing* and *Micro Chemical*. In *Grain Processing*, the Federal Circuit commented that the infringer was “able to convert to the substitute manufacturing process in the remarkably short period of two weeks.”²² However, in *Micro Chemical*, the time to implement took longer. The court observed that an engineer for the defendant “worked full-time for several months on the design” and “continued to work part-time on the project, estimating that he tested and rejected five potential design changes.”²³ The defendant “took over four months to convert all of its infringing ... machines.”²⁴

While these two cases do not delineate a bright line on timing, at least one district court examined the timing in *Grain Processing* and *Micro Chemical*. In *Ethicon*, the district court said:

In *Grain Processing*, however, a device was found to be available when “it took only two weeks to perfect [the alternative] and begin mass producing” the product. Yet in *Micro Chem*, the Federal Circuit found that a device was not available at the time of infringement when it took over four months to convert infringing devices into non-infringing devices.²⁵

In *Ethicon*, the court noted, “[t]he record ... clearly shows that it would take [the defendant] between 46 and 62 weeks” to implement the proposed design around.²⁶ The court added, “it is undisputed, based on Covidien’s own estimates, that it would have taken over 10 months to design around the [asserted] patent—well over twice the time required to produce an alternative [which was deemed unavailable] in *Micro Chem*.”²⁷ The court granted Ethicon’s motion for summary judgment on the absence of acceptable and available noninfringing alternatives.²⁸ In this instance, it appears that the four-month period in *Micro Chemical* was used as an upper bound in gauging availability.

¹⁷ *Micro Chemical*, 318 F.3d at 1123. The court also commented that the “summary judgment record also shows that the materials for the alleged substitutions were not readily available.” The court added that the defendant had to request a 120-day delay of the injunction against its infringing machines.

¹⁸ *Ibid.* at 1124.

¹⁹ *Grain Processing*, 185 F.3d at 1348, 1354.

²⁰ *Id.* at 1123 (quoting *Grain Processing*, 185 F.3d at 1354).

²¹ *Grain Processing*, 185 F.3d at 1353.

²² *Micro Chemical*, 318 F.3d at 1123 (citing *Grain Processing*, 185 F.3d at 1346).

²³ *Micro Chemical*, 318 F.3d at 1123.

²⁴ *Ibid.*

²⁵ *Ethicon Endo-Surgery, Inc. et al., v. Covidien, Inc. et al.*, No. 1:11-cv-871, 2019 WL 2164090, at *13 (S.D. Ohio, May 17, 2019) (citations omitted).

²⁶ *Ibid.*

²⁷ *Id.* at *14.

²⁸ *Ibid.*

More Than a Theoretical Possibility

The Federal Circuit has indicated that a noninfringing alternative is more likely to be considered as available if it is more than a theoretical possibility. In *Grain Processing*, the Federal Circuit stated that “substitutes only theoretically possible will not” preclude or limit lost profits.²⁹ Thus, a plaintiff may assert that the credibility of the alternative is diminished if the defendant never implemented or commercialized the alternative.

The Federal Circuit also has addressed the circumstance in which the noninfringing alternative is commercialized years after the alleged infringement.³⁰ In *DePuy*, the defendant asserted that it could have made a noninfringing version of the accused product during the accounting period (2000 to 2003) and pointed to the fact that it later provided the product for use (in 2007).³¹ The Federal Circuit observed that the defendant “had to show that the substitute was ‘available’ during this period based on alternative actions that [the defendant] reasonably could have taken to avoid infringement.”³²

The Federal Circuit found that the defendant, despite having later commercialized the proposed noninfringing alternative, was unable to make the necessary showing of availability and pointed to evidence of “three unsuccessful attempts (in 2000, 2003-2004, and 2006-2007)” undertaken by the defendant “to develop a noninfringing ... design.”³³ The court drew attention to evidence that the proposed alternative designs of the product at issue, a medical device, were “deemed ‘too large’ by surgeons, were ‘substantially weaker’ in pull-out strength than the infringing ... model, and had never been submitted to the Food & Drug Administration for the necessary marketing approval.”³⁴ The court concluded that even if the defendant had pursued the noninfringing design, it “would not have been available or acceptable to consumers before the end of 2003.”³⁵

In assessing whether a potential noninfringing alternative is more than a theoretical possibility, it also may be appropriate to consider how intellectual property rights and third-party licensing could impact implementation. In *Baxter*, the court held:

A non-infringing alternative sold by a third party may still be available to [the defendant] in one of two ways. *First*, if a third party has not protected its non-infringing alternative with a patent or other intellectual property, [the defendant] could copy and sell the non-infringing design as its own ... *Second*, if a third-party non-infringing alternative is protected by intellectual property, [the defendant] could take a license and sell the non-infringing product as the third-party’s licensee. In both scenarios, [the defendant] would not have to choose between practicing [the plaintiff’s] patents or leaving the relevant market; it could participate in the market without infringing [the plaintiff’s] patents by selling a third party’s non-infringing design.³⁶

Therefore, the ruling in *Baxter* implies that, under certain conditions, a defendant could potentially make an argument for the availability of noninfringing alternatives sold by third parties.

²⁹ *Grain Processing*, 185 F.3d. at 1353 (referencing *Minco, Inc. v. Combustion Engineering, Inc.*, 95 F.3d 1109, 1119 (Fed. Cir. 1996)).

³⁰ *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314 (Fed. Cir. 2009).

³¹ The defendant also raised an evidentiary argument “that it was unfairly precluded from introducing into evidence” information “that would have helped the jury to understand why Medtronic did not switch to a non-infringing ... design until 2007.” See *DePuy Spine*, 567 F.3d at 1331–1332.

³² *Id.* at 1331.

³³ *Id.* at 1332.

³⁴ *Ibid.*

³⁵ *Ibid.*

³⁶ *Baxter International*, 2020 WL 424918, at *6.

Supported by Sufficient Evidence

In assessing availability, it is also appropriate to consider whether the noninfringing alternative is supported by more than speculation. In *Grain Processing*, the Federal Circuit stated that in demonstrating the availability of a noninfringing alternative, “[m]ere speculation or conclusory assertions will not suffice,” as “[a]fter all, the infringer chose to produce the infringing, rather than noninfringing, product. Thus, the trial court must proceed with caution in assessing proof of the availability of substitutes not actually sold during the period of infringement.”³⁷

In *Conceptus*, the district court offered guidance as to evidence that a defendant may present. The court referenced “research-and-development documentation, deposition testimony, or sworn declarations” as examples of evidence that could have been presented “that might demonstrate [the defendant]’s capacity to ‘implement’ noninfringing alternatives during the period of alleged infringement.”³⁸ The court noted that the only support the defendant cited was “a portion of the unsworn report of its own expert that relies exclusively on private conversations with [defendant] personnel,” which the court indicated was not appropriate evidence.³⁹ As an example of sufficient support for a proposed software noninfringing alternative, the district court in *EMC Corp.* found that reliance on “discussions with [the defendant’s] chief software architect, evidence that the redesign had already been in development, and on the reports of [the defendant’s] technical expert” to be adequate.⁴⁰

Reliance on declarations from a defendant’s employees alone may be insufficient to establish availability. In *Parker-Hannifin*, the defendant provided declarations addressing the availability of the proposed noninfringing alternative; however, the court was not persuaded. The court observed that “[n]one of the statements made by defendant’s declarants are supported by lab notebooks, meeting minutes, or documents of any kind.”⁴¹

A plaintiff might put forward evidence addressing the lack of a viable noninfringing alternative. In *Sherwin-Williams*, the district court held that the plaintiff was able to sufficiently prove “the negative” and show that “no other products existed in the market, through its interrogatory to [the defendant] and deposition questions to [the defendant]’s corporate designee”⁴²

³⁷ *Grain Processing*, 185 F.3d at 1353.

³⁸ *Conceptus, Inc. v. Hologic, Inc.*, 771 F.Supp. 2d 1164, 1179 (N.D. Cal., 2010).

³⁹ *Ibid.*

⁴⁰ *EMC Corp. v. Pure Storage, Inc.*, 154 F.Supp. 3d 81, 118 (D. Del., 2016).

⁴¹ *Parker-Hannifin Corp. v. Champion Laboratories, Inc.*, No. 1:06-cv2616 2008 WL 1843922, at *10 (N.D. Ohio, April 22, 2008).

⁴² *Sherwin-Williams*, 2020 WL 1283465, at *9.

Conclusion

In conclusion, while there is no bright-line test for availability, several guiding principles are informative in determining whether a noninfringing alternative was available to an accused infringer. An accused infringer may be more likely to demonstrate the proposed noninfringing alternative was available if the alternative was on the market or could have been commercialized readily during the accounting period. The latter can be demonstrated by establishing: (1) the necessary equipment, material, and know-how were available or acquirable by the defendant at the time of alleged infringement; (2) the proposed alternative was not prohibitively costly or time-consuming to create; (3) the proposed alternative was more than a theoretical possibility; and (4) the proposed alternative is supported by more than speculation.

Potential avenues through which defendants can augment their cases for asserted noninfringing alternatives include research and development documentation, deposition testimony, and sworn declarations. Conversely, plaintiffs seeking to challenge noninfringing alternatives may point to deficiencies in this evidence.

Improving Throughput Metrics with Reduced Labor Expenses

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Nick Chmielewski has seventeen years of emergency nursing practice, including leadership experience in emergency department manager, director, and associate CNO-level leadership roles. He has spent the last seven years in consulting roles, and his career has spanned experiences at fifty-two EDs in seventeen states. He is a published author in [multiple journals](#). His past national leadership positions with the Emergency Nurses Association include 2014 Resolutions Committee chairperson and 2019 Advocacy Advisory Council chairperson. He is an inducted Fellow in the Academy of Emergency Nursing (AEN) and the AEN Board of Directors' 2021 chairperson-elect.

Kevin Browning has thirty-five years of experience in pre-hospital emergency care, emergency care in the acute care setting, hospital supervision, ED leadership, ED performance improvement, and ED clinical redesign. His ED performance improvement projects have included hospitals of all sizes. Before BRG, he was the vice president of Emergency Services for a large for-profit hospital company, where he was responsible for hospital-based and freestanding emergency departments. His primary duties included ED clinical redesign, patient throughput, patient engagement, and staff engagement. Before that, he was the vice president of Patient Flow, Bed Management, and Emergency Services for a Florida Level 2 trauma center.

This paper originally was published in March 2021.

Abstract

A hospital emergency department within a recognized Magnet™ center of nursing excellence had exhibited longer-than-desired lengths of stay and a higher-than-desired worked hours per patient visit. A department performance improvement team was formed as part of a systemwide initiative to right-size the organization for optimum quality care at the most efficient cost and to focus on improving both length of stay and staffing practices.

The team transitioned the department from a fixed-budget staffing model to a staffing-to-demand model. Methods included both changes to permanent staffing plans and implementation of real-time staffing-to-demand tools. Comprehensive education on the methodological shift helped reduce the department's staffing by 14.9 full-time equivalents, actualizing \$3.35 million in annualized labor savings. The reduction in staffing was accomplished without unfavorably impacting the department's left without being seen rate or key length-of-stay metrics. In addition, most patient-experience scores maintained a satisfaction at or greater than 90%. These improvements allowed the department to treat a higher volume of patients at lower cost.

This case study demonstrates that implementation of staffing-to-demand methodologies can be successful in reducing labor costs while maintaining, if not improving, key performance indicators including patient satisfaction.

Introduction

Problem Description

A multihospital health system embarked on a four-year journey to right-size the organization for optimum quality care at the most efficient cost. As the implementation journey commenced in 2018, the health system included approximately 1,900 certified hospital beds, 790 nursing home beds, and 18,400 employees and had over \$2 billion in annual revenue. All hospital nursing areas were evaluated for workforce size, skill-mix, and scheduling optimization opportunities. Patient lengths of stay (LOS) also were examined for improvement opportunities.

An emergency department (ED) in a Magnet™ recognized hospital with a cardiac center of excellence was identified as a unit with opportunities for focused performance improvement. The ED had thirty-four treatment spaces with approximately 28,000 annual visits and growing volumes. The department exhibited a longer-than-desired LOS and a higher-than-desired worked hour per patient visit (wHPPV) productivity statistic.

Available Knowledge

Table 1 details baseline throughput metrics compared to various cohorts. The baseline normalized wHPPV was 6.135, placing it in greater than the 75th percentile in staffing compared to the minor teaching facility with CMI-weighted¹ adjusted discharges greater than 50,000 cohort.²

Table 1: Baseline throughput metrics

	1	2	3	4
	ED Baseline*	EDBA Cohort Median	NHAMCS 2017	Hospital Compare National Average
Left without being seen rate	1%	2%**	No data	2%***
Median minutes arrival-to-provider	43	14	16	No data
Median minutes ED discharge LOS	290	138	No data	170****
Median minutes ED admission LOS	559	261	No data	No data

1. Berkeley Research Group (BRG), Dynamic Rapidly Interactive Visual Environment (DRIVE) (2020), retrieved March 18, 2020, from a HIPAA-compliant client-specific online database.
2. Emergency Department Benchmarking Alliance (EDBA), 2018 performance fractal tables; 20-40k visit cohort, Madison, WI (2019).
3. US Department of Health and Human Services Centers for Disease Control and Prevention, *National Hospital Ambulatory Medical Care Survey: 2017 Emergency Department Summary Tables*, Table 4, "Wait time at emergency department visits: United States, 2017" (2020), retrieved from: https://www.cdc.gov/nchs/data/nhamcs/web_tables/2017_ed_web_tables-508.pdf.
4. Center for Medicare and Medicaid Services, Hospital compare (2020), retrieved March 18, 2020 from: <https://www.medicare.gov/hospitalcompare/>

* Baseline timeframe is July 1, 2017, to June 30, 2018.

** EDBA uses the term "Leaving Before Treatment Complete" (LBTC), which includes patients who leave before being seen by a qualified medical provider plus patients who leave against medical advice.

*** Criteria OP-22. Data collection period: January 1 to December 31, 2018.

**** Criteria OP-18. Data collection period: April 1 to December 31, 2018.

1 The Case Mix Index (CMI) is a relative value assigned to a diagnosis-related group of patients. A hospital's CMI reflects the combined clinical complexity and resource needs for that facility.

2 Truven Health Analytics, Action OI [Healthcare industry productivity labor benchmarking metrics for CY17] (2017), available at: <https://actionoi.truvenhealth.com/>

Rationale

Although the baseline left without being seen (LWBS) rate of the department was better than the national average, the remaining ED throughput metrics were performing worse than the national average. Nurse consultants from BRG's Care Transformation team recommended the client implement process changes to reduce patient LOS, improve patient throughput, and realign ED labor needs.

Specific Aims

The purpose of this project was to work with hospital and departmental leadership and staff to: (1) reduce ED throughput time intervals and LWBS rates, and (2) optimize labor expenses to meet/match patient demand.

Methods

Context

The performance improvement initiatives outlined in this case study also were part of a broader systemwide ED service-line performance improvement initiative. The initiative included setting standardized approaches to measure and report metrics and replacing site-specific policies with a systemwide approach to improve the door-to-provider interval.

Even though the department promoted and embraced a culture of preassigning the next arriving patient to a care team and treatment space, it continued to "process patients" through a physical triage location. This sustained an unnecessary bottleneck and impacted the arrival-to-provider time metric. Patient care events that occurred prior to the engagement resulted in an environment where leadership was not supportive of implementing immediate bedding. A "nurse greeter" met arriving patients and then took them into a traditional triage area for continued assessments prior to placement in a treatment room.

Department Leadership Framework and Staffing

The ED leadership team was composed of a dedicated and engaged emergency department medical director plus a tenured nurse manager with four assistant nurse managers (ANMs): two for the day shift and two for the night shift. The department shared a nurse educator with the Observation Unit and had daily case manager and social work coverage, plus a dedicated supply technician. Nurses were scheduled for twelve-hour shifts (7:00 a.m. to 7:00 p.m., 7:00 p.m. to 7:00 a.m.); technicians and unit secretaries were scheduled for eight-hour shifts (8:00 a.m. to 4:00 p.m., 4:00 p.m. to 12:00 a.m., 12:00 a.m. to 8:00 a.m.). The ED also used facility-employed nurse practitioners who were assigned to triage patients and enter protocol orders. The ED manager reported to a nursing vice president whose other departments served outpatient areas; the nursing VP position did not oversee any inpatient nursing units.

Nursing leaders were not familiar with staffing-to-demand or WHPV concepts. Staffing to demand was not part of the culture; leadership simply staffed to budgeted dollars.

Intervention(s)

This project was completed using the “structure-process-outcome” framework described by Donabedian (1988).³ This model has been utilized frequently by researchers and those in public policy to map out the mechanics of a particular situational process. The continuous quality improvement initiative used the DMAIC (Define, Measure, Analyze, Improve, and Control)⁴ method for process improvement. A performance work group was formed consisting of ED nursing, ED physician, imaging, and patient access leaders. ANMs and other managers also were invited to attend the work group meetings.

ED leadership was introduced to and educated on the National Emergency Department Overcrowding Scale (NEDOCS)^{5,6} and the concepts of productivity and staffing to demand. This included the need to stagger staff to match historical patient-arrival patterns. The optimal goal was to have the right quantity and type of staff at the right time to match the community demand for emergency services. The leadership team and charge nurses were educated on a staffing-to-demand tool to use in conjunction with NEDOCS to drive real-time staffing decisions. The goal was to use the web-based tools every four hours. They also had the opportunity to enter data hourly if they encountered unexpected influxes in patient arrivals.

The ED leadership team worked collaboratively on this initiative. Team members viewed themselves as having the reputation of representing the flagship hospital of the organization and thought it imperative to set labor cost containment expectations for the broader system.

The consulting team’s initial recommendations also included increasing the use of mid-shift staff positions by moving shifts from both day and night shifts into the mid-shift to realign staffing with patient census patterns. This also would reduce overstaffing at hours when the census was lower, such as 3:00 a.m. to 9:00 a.m.

Study of the Interventions

A Health Insurance Portability and Accountability Act (HIPAA)-compliant applied analytics platform was chosen for assessing the impact of the interventions. Data was analyzed within the construct of a pre- and post-intervention analysis to assess the impact of the process improvement project. Further, performance updates were shared with leaders and staff at regular intervals throughout the project. Volumes and throughput metrics were available daily and in a monthly digest. Ancillary services turnaround times, including imaging and lab data in aggregate and test-specific formats, were available and reviewed monthly. All of these metrics were reviewed to better refine/optimize individual processing times. Finalized productivity performance metrics were available and reviewed every two weeks, and real-time analysis tools were implemented to assist charge nurses in making staffing-to-demand decisions.

The study included the intentional use of the Hawthorne effect, which is an effective approach in managing human behavior to assist in achieving desired outcomes.⁷ Hospitals often implement multiple systemic performance improvement initiatives. As such, no controls were in place to correlate the interventions directly to the observed outcomes.

Measures

The measures chosen for studying the process outcomes included LWBS percentage, median door-to-provider time, median LOS for discharge patients, patient volume, and wHPPV.

3 A. Donabedian, “The quality of health care. How can it be assessed?” *Journal of the American Medical Association* 260(12) (1988, September 23–30): 1743–8, retrieved from <https://www.ncbi.nlm.nih.gov/pubmed/3045356>

4 K. Moran, R. Burson, & D. Conrad, *The Doctor of Nursing Practice Scholarly Project: A Framework for Success* (2nd ed.), Burlington, MA: Jones & Bartlett Learning (2017).

5 S.J. Weiss, A.A. Ernst, & T.G. Nick, “Comparison of the National Emergency Department Overcrowding Scale and the Emergency Department Work Index for quantifying emergency department crowding,” *Acad Emerg Med*. 13(5) (2006, May): 513–8. doi: 10.1197/j.aem.2005.12.009. Epub 2006 Mar 21. PMID: 16551777.

6 S.J. Weiss, R. Derlet, J. Arndahl et al., “Estimating the degree of emergency department overcrowding in academic medical centers: results of the National ED Overcrowding Study (NEDOCS),” *Acad Emerg Med*. 11(1) (2004, January): 38–50. doi: 10.1197/j.aem.2003.07.017. Erratum in: *Acad Emerg Med*. 11(4) (2004, April): 408. M. Fernández-Frankelton [corrected to M. Fernández-Frackelton]. PMID: 14709427.

7 T.R. Lied & V.A. Kazandjian, “A Hawthorne strategy: implications for performance measurement and improvement,” *Clin Perform Qual Healthcare* 6(4) (1998, October–December): 201–4. PMID: 10351289.

Operational Definitions

Left without being seen (LWBS) refers to patients who arrive at the ED for emergency care and subsequently leave prior to initial evaluation by a physician or other qualified medical person (QMP).⁸ LWBS sometimes is referred to as “leaving without treatment” (LWOT) or “left before being seen” (LBBS).⁹ It is expressed as a percentage. LWBS is not synonymous with leaving against medical advice.

The *door* timestamp is defined as the patient’s arrival time, as logged at the time of their quick registration on arrival by patient access.¹⁰

The *provider contact* timestamp is the documented date and time of first contact with a physician/QMP.¹¹

The *door-to-provider* interval is the number of minutes between the door timestamp and the provider contact timestamp.¹²

Worked hour per patient visit (WHPPV) is calculated by taking the total worked hours in a cost center for a specified period and dividing it by the total number of patient visits.¹³ For the purposes of calculating a WHPPV, the productivity definition of a visit is utilized.¹⁴

Ongoing Assessment

The daily department metrics were reviewed frequently and included: Arrival to Provider, Provider to Disposition, and Disposition to Depart/Admit/Transfer. ANMs were encouraged to flex staff down during periods of few patient arrivals and low numbers of patients receiving treatment in the ED. Historically, the 3:00 a.m. to 9:00 a.m. range provided the greatest opportunity to right-size department staffing. Review of the staffing-to-demand tool a minimum of every four hours provided the ANMs and relief charge nurses with the data to make informed decisions regarding the number of caregivers needed. Historical trends in the department also were taken into consideration in this decision making.

8 CMS, “Left Without Being Seen,” Measures Inventory Tool, available at: https://cmit.cms.gov/CMIT_public/ViewMeasure?MeasureId=922

9 J. L. Wiler, S. Welch, J. Pines, J. Schuur, N. Jouriles, & S. Stone-Griffith, “Emergency department performance measures updates: proceedings of the 2014 emergency department benchmarking alliance consensus summit,” *Acad Emerg Med*. 22(5) (2015, May): 542–53. doi: 10.1111/acem.12654. Epub 2015 Apr 21. PMID: 25899754.

10 Wiler et al. [2015].

11 Wiler et al. [2015].

12 Wiler et al. [2015].

13 J. Moretz & N. Chmielewski, “Emergency Department boarding: methods accounting for lost productivity,” *BRG Review* 8 (2019, June 21), 6–13. Berkeley Research Group, LLC: Washington, DC. Retrieved January 18, 2021, from https://media.thinkbrg.com/wp-content/uploads/2021/01/18144842/BRGReview_Issue8-final.pdf

14 According to Chapter 12 of the Truven Health Analytics Action OI Department Guide, LWBS patients should not be included in the visit count when calculating productivity.

Completeness and Accuracy

Data in the applied analytics platform originate from the electronic health record (EHR) and the organization's payroll system via a data transfer. This represents the complete data for a specific timeframe, and as such, no sampling techniques were utilized. While no data were excluded in calculating the visit total or hours worked, some cases were excluded when analyzing the clinical throughput data. The exclusionary criteria, which resulted in less than 0.5% of total data, were cases with:

- A null arrival time, null departure time, null disposition type, or null facility
- A LOS greater than seventy-two hours

Ethical Considerations

This performance improvement project does not meet the definition of research under 45 CFR 46.102(d). Access to relevant patient data occurred through a HIPAA-compliant analytics platform.

Results

Table 2 compares the baseline timeframe of July 1, 2017 to June 30, 2018 against the six-pay-period average ending August 3, 2019. The improvement in wHPPV represents annualized savings of \$3.35 million, determined by the formula:

$$\text{Savings} = (\text{baseline wHPPV} - \text{target wHPPV}) \times \text{Baseline Volume} / 1950 \times \text{Department Average Salary w/Benefits}^{15}$$

Table 2: Baseline (7/1/17 to 6/30/18) and post-intervention (5/12/19 to 8/3/19) results metrics comparison

	Baseline	Post Intervention	% Change
Annualized volume	28,018	31,997	14.2%
LWBS	1.00%	0.60%	-40.0%
Worked FTEs	88.2	73.3	-16.9%
wHPPV	6.135	4.468	-27.2%
Median minutes arrival-to-provider	43	24	-44.2%
Median minutes ED discharge LOS	290	267	-7.9%
Median minutes ED admission LOS	559	431	-22.9%

¹⁵ 1 FTE is commonly equated to 40 hours per week or 2,080 hours annualized. This health system defines 1 FTE equivalent to 1,950 hours annualized. The health system's definition was used in all calculations.

Discussion

Summary

Despite a 14.2% increase in volume, the department was successful in reducing its labor by 14.9 FTEs. This 16.9% FTE reduction translated to a 27.2% reduction in wHPPV. This improvement did not require human resource workforce reduction actions and was accomplished through scheduling changes, staffing-to-demand actions, and more judicious use of overtime. In addition, there were observed improvements in all key throughput metrics, namely door-to-provider (44.2%), ED discharge LOS (7.9%), and ED admission LOS (22.9%). Despite these improvements, performance improvement work continues as the team strives to meet the EDBA cohort described in Table 1.

The tenured ED leadership team was key to achieving the desired wHPPV. The department nurse manager provided reassurances and leadership within the department. The leadership team was open-minded and responsive while we assisted them in navigating and optimizing patient throughput processes. At the same time, the leadership team remained cognizant and sensitive to both staff and patient needs. This created an atmosphere of mutual trust between management and staff caring for patients. Front-line leaders became amenable to flexing down at 3:00 a.m. and having some 7:00 a.m. staff delay their arrival times based on departmental patient volumes and acuity.

Interpretation

As leadership reviewed the daily and historical trends in the staffing-to-demand tool, they realized they needed to start using those trends to inform staffing decisions. Leadership subsequently supported the recommendation to relocate positions into a mid-shift. This change helped to relieve the burden of having to flex and supported patient safety by having an additional caregiver in the department during peak census.

During initial pre-intervention department interviews, the ED leadership team believed more staff yielded better outcomes. They perceived that nurses were at a 10:1 ratio during peak times. However, this perception was not supported by data. The staffing-to-demand concept was foreign and had not been taken into consideration previously. Departmental leadership operated from a culture of fixed staffing numbers irrespective of volume. Day and night staff schedules mirrored each other with only 0.8 FTEs in mid-shift coverage. The same held true for unlicensed personnel.

Throughout the performance improvement implementation, throughput times decreased even as ambulance and walk-in traffic increased. Despite the greater volume, patient satisfaction scores ranked above the 90th percentile for most questions. After reviewing department performance and staffing trends, leadership was agreeable to achieving and maintaining a wHPPV target of 4.468. No new or additional labor or supply costs were recommended or incurred during the project. There is the inherent risk of patient surge after flexing staff down during periods of decreased or low census, though this was seldom observed.

Limitations

This work represents findings at one hospital; some actions taken may not apply to other hospitals. As previously discussed, the Hawthorne effect was used intentionally to change behavior and drive results.

Department leadership integrated the concepts of staffing to demand and wHPPV rather than budgeted dollars when making staffing decisions. The deployment of a staffing-to-demand tool was effective in matching available staff with patient demand while optimizing labor expenses. The tool assisted leaders and staff by removing the subjectivity and perceptions of overcrowding by incorporating objective measures. Also, an organization-wide Position Review committee was formed to review hiring decisions for new positions in addition to any replacement positions for departments not meeting their productivity standard.

Lessons Learned and Next Steps

Hospital nursing and emergency department leadership are essential in guiding a department toward meeting and maintaining productivity targets. Holding leaders accountable is key to ensuring fiscally responsible stewardship of human resources and budgeted dollars. Transparency in sharing key performance indicators at the staff level contributed to the project's success. Reviewing these metrics daily created a culture of ownership in which staff were engaged and empowered to DRIVE™ additional improvements.¹⁶

Next steps for the department include sustaining front-line leaders using the staffing-to-demand tool and taking necessary actions based on the results. Departmental leaders also must review volumes and productivity continually and take steps to mitigate negative trends. Further reallocation of night-shift positions to mid-shift positions is needed.

Last, while the department reduced labor expenses by 14.9 FTEs, department staffing remains above the 75th percentile compared to its cohort. Additional ongoing opportunities exist to titrate staffing and continue to achieve high-quality outcomes at the lowest possible expense without jeopardizing patient safety and satisfaction.

Other Information

The authors provided implementation consulting services for this project. This paper and the metrics included are being published on a deidentified basis with the health system's written permission.

Funding

The healthcare organization contracted with BRG for performance improvement implementation consulting services. This performance improvement initiative was funded through an at-risk benefit methodology based on the return on investment that was realized.

¹⁶ DRIVE stands for Dynamic Rapidly Interactive Visual Environment. It is a web-based BRG platform that transforms raw data into actionable information through advanced analytics and novel visualizations. BRG's Healthcare Performance Improvement (HPI) practice uses DRIVETM to provide analytic tools to enhance decision making, monitoring, and sustainability of performance improvement goals. BRG HPI's products are conducted on HIPAA-compliant platforms.

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