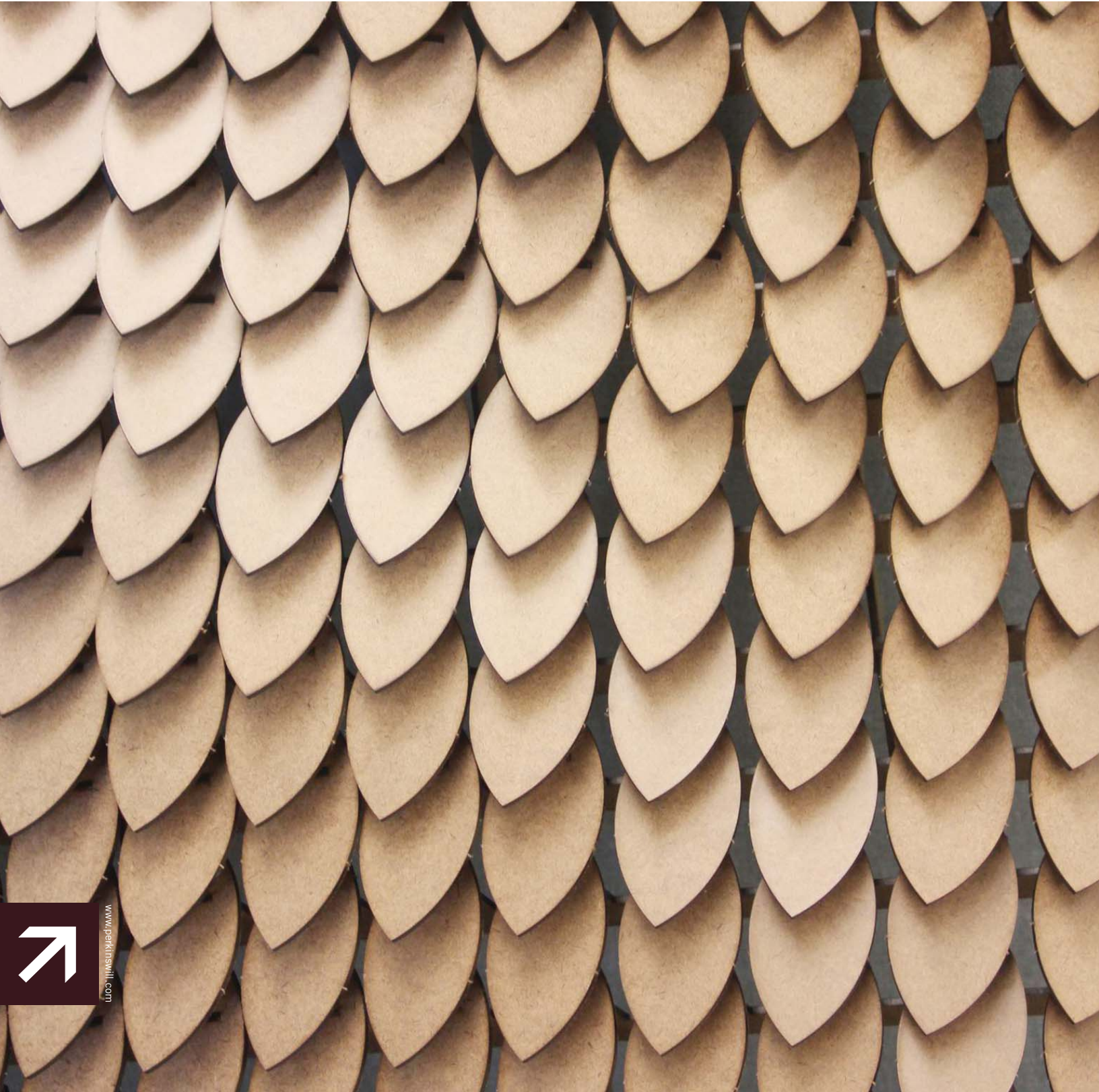


PERKINS+WILL

# Research Journal

+7  
2011 / VOL 03.02



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## 01.

### A DESIGN-BASED APPROACH TO COLLECTING EVIDENCE:

*Translating Design Investigation into a Valid Research Model*

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#### ABSTRACT

Evidence Based Design (EBD) research analyzes the built environment through a very rigorous lens, one that takes its methodology from scientific protocol. Most environmental designers are not well versed in the utility of scientific methodology for demonstrating design efficacy, even though they employ a similar method of questioning. Using a previously published study as a model, an approach to EBD research is outlined that uses shared precepts between these two seemingly disparate disciplines. Design questions are assessed as to their subjective or objective nature and translated into testable hypotheses. Literature reviews aid in understanding where a study fits within a larger body of research and in determining if it will affirm or refute prior findings. Subject populations are assessed and sub-divided to best determine the impact of design interventions. Once the subject population is determined, various methods for collecting and analyzing data are used to ensure statistical validity, though the assessment of causality may not be possible or demonstrable.

**KEYWORDS:** evidence based design (EBD), neonatal intensive care unit (NICU), healthcare design

#### 1.0 INTRODUCTION

At its most fundamental level, the design process is a method of problem solving similar to scientific inquiry. Though it is rarely expressed in those terms, the nature of design problem solving—the posing of questions and application of responses to seek the best overall solution—closely resembles the preliminary questioning and hypothesis formulation steps inherent in scientific methodology. Each new design challenge poses a number of questions, whether initiated by the client or the design team. Should the proposed solution address an aesthetic or functional deficiency with the previous design? Does the design improve upon an already established typology or create a new one? Are there operational or technological factors that influence the design response? The design process involves the creation of scenarios that determine which design concept is the best fit for the existing project constraints, the client's or user's concerns, the desired aesthetic or environmental enhancements and the economy of material and technology. Having arrived at satisfactory answers to design questions such as these, testing the efficacy of those solutions represents a logical extension of the design process into the realm of scientific inquiry.

For a culture predisposed to consider scientific inquiry and design study as emerging from entirely different approaches and points-of-view, these avenues may seem antithetical. Historically, the creative process of design was perceived to be hindered by the goal of obtaining measurable results. Yet, creativity is just as applicable to the construct of quantifiable tests of a design's functionality as it is to the design itself. The psychological response to architectural design is often described in terms more perceptual than quantifiable. It is a commonly held misconception that design protocol proceeds, unlike hypothesis-based science, with the goal of unanticipated consequences. If asked, most designers would say they approach any design problem with the desire to provide both functional and aesthetic benefits, though these benefits often defy qualification or quantification. As the professional practice of architectural, interior and landscape design (referred to here as “environmental design”) becomes increasingly specialized by building type, there is a consequent push to create a published body of knowledge around the various highly-specialized or highly-technical building types. It is important to create schools where children learn well, offices that facilitate productive and stable workers, hospitals that contribute to healing and there

are resultant pressures to show that the resource commitments to these projects yield demonstrable results.

The term “Evidence Based Design” has come into parlance to define a dialogue around the results of design inquiry. Evidence Based Design (EBD) can be defined simply as the application of research-based, quantifiable metrics to design decisions. It can involve either consulting research studies before making design decisions or using a completed design to test a new hypothesis. Though applicable to many project types, the term has been applied most often to healthcare projects because of the conceptual synergy with Evidence Based Medicine. Sackett, a pioneer in evidence-based medical practice, describes it as “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of the individual patient...integrating individual clinical expertise with the best available external clinical evidence from systematic research.”<sup>1</sup> Similarly, Evidence Based Design requires viewing the built environment through a very rigorous lens, one that takes its methodology from scientific protocol. Though it is an approach to design validation with which most environmental designers feel uncomfortable, the pressure is increasing to contribute to this emerging body of knowledge. This urgency fuels hasty attempts at EBD studies, many of which only confuse the issue by making it difficult to find actionable data within a body of indecisive research. By applying scientific methodology to the questions that most designers can easily articulate, a process can be mapped for translating a design question into a problem that lends itself to quantifiable study. Just as design itself is a methodology with discreet steps, designing a research project can be approached in a similar manner.

## 2.0 METHODOLOGY AND FINDINGS

To illustrate the research design process, a published EBD study by an interdisciplinary team of an architect, medical director, researcher and nurse will be referenced. For specific details regarding the experimental protocols and findings, the reader is referred to the Journal of Perinatology papers on “Documenting the NICU Design Dilemma.”<sup>2,3</sup> In 2008, Perkins+Will and Cabell Huntington Hospital completed the design and construction of a new, single family room neonatal intensive care unit (NICU) to replace an existing multi-patient, open bay ward facility. Since both the hospital and the architectural firm were interested in exploring the efficacy of the new design, a study was initiated to test the impacts of building design on patient medical

progress, their parents and the attending NICU staff. The research team was assembled early to monitor all stages of the transition from the multi-patient ward, through the relocation and into occupancy of the new unit. Marshall University Institutional Review Board for Research with Human Subjects (IRB) approval was secured for the complete research protocol including all surveys and patient records access. Since the research team was multi-disciplinary, data were collected from a number of sources and examined from a variety of perspectives.

The first step in resolving either a design problem or a scientific problem is to determine its subjective or objective nature. When thinking about the issues addressed by a design, it is useful to consider the most basic goals of the project and attempt to pose them as questions. Was there a specific client concern addressed by the project team? Did the design team approach the project with a proposed improvement to an existing condition or with a response to a previous project? It is more likely that many issues were being addressed at once: the complex nature of environmental design means that there are many agendas being balanced in the search for a favorable solution. Sometimes these agendas are at odds. Is the best design also the most economical solution? Can enhanced space and privacy coexist with efficiency and travel distance? Do existing conditions prevent the most ideal solution from prevailing? In the referenced study, the core question was twofold. When debating the investment in a larger, more expensive facility, would neonates have improved outcomes in a private room environment and would staff and parents demonstrably benefit from the new facility?

Once the problem has been stated, it must be analyzed as to the nature of the questions it provokes. Some questions lend themselves to quantifiable answers. In the case of healthcare projects, when one is dealing with an ailing patient population seeking treatment in a physical plant, one can ask “how much improvement occurred that could be attributed to the facility design?” or, “did the patient population improve more quickly in one design compared to another?” Numerical data can be collected to answer such objective questions. However, it is also possible to ask, “how much more satisfied were the subjects with the new environment?”, “did patients or staff prefer one setting over another?” Even such questions exploring subjective perceptions can be assessed with a quantifiable tool, such as a survey questionnaire, that can define the perceived degree of preference. Just as human performance metrics, such as efficiency or stress levels, can be measured, so can

levels of perceived efficiency or stress. It is important to distinguish between measures of reality and perception, as both can be valid indicators of design performance. The referenced study allows for both. The investigators are able to collect realistic data regarding the physical outcomes of the neonates in two dramatically different NICU environments and they are able to ask parents and staff how they feel about the two contrasting environments quantifying their perceptions with validity-tested questionnaires.

Scientific inquiry is founded on the fundamental principle of the repetition of experimentation in a controlled setting. The validity of scientific conclusions is based on achieving comparable results from an experimental design over numerous replicates. Studies of environmental design do not exist in a laboratory setting where an identical study can be easily repeated. That does not mean it is not important to recognize that any EBD study fits within a larger body of research and contributes to a research dialogue. It is important when applying EBD to a design problem to search the existing literature and to become familiar with similar studies that have been performed and published. More importantly, a literature search provides insight into structuring the problem statement. It can yield a better understanding of the subject population while providing a guide for structuring a similar study. This protocol allows new research to affirm or to refute prior findings, thus advancing the body of knowledge in the discipline.

Once the problem has been identified and a review of other studies undertaken, a hypothesis can be developed. The hypothesis differs from the problem statement in that it defines the parameters to be tested. It is not a question, but a statement to be proven or disproven. If the hypothesis forms a subjective statement, it will lead to one kind of methodology for investigation. If it is an objective statement, it will dictate another. In the referenced NICU study, there were two hypotheses that resulted in two study designs, one subjective and one objective. The first hypothesis was that the parents of neonates would prefer a private room environment, but that clinicians would not. This hypothesis was derived from a literature search that revealed a prediction of different effects of single family rooms on the differently impacted NICU constituencies.<sup>4</sup> Because this hypothesis was based purely on subjects' perceptions of their environment, it required survey questionnaires to generate quantifiable data.<sup>5</sup> The second study hypothesis was that neonates would progress more rapidly in their development and be discharged more quickly in a private room environment. Again, the lit-

erature suggested that a hygienic, quiet, private room with controllable lighting and parental bedside access would decrease neonate apnea, facilitate infant feeding tolerance and increase maternal breast milk production and breastfeeding success. These factors could lead to shortened patient length of stay, an outcome desirable to both families and hospital administration. Since the research team had secured prior approval for research with human subjects, they could access clinical progress metrics and discharge times to collect the essential data for testing this hypothesis.

Hypotheses such as these are similar to what designers refer to as a "parti". Though the parti defines the goal of the design study, it does not prescribe the precise design solution. There could be many options for a design that could support a given parti, but one will be chosen for its sufficiency to balance the requirements of the project. Similarly, in developing an EBD investigation, there may be several scenarios that could be constructed for testing a hypothesis, but one should emerge as the best case. In a subjective study, the scenario-testing problem is one of selecting survey questions that will yield valid responses. The design of a good questionnaire is not simply a matter of assembling a set of questions, as any of us who have confronted a vague or confusing survey can attest. A reliable survey is "validity tested" to ensure that there is little chance of poor phrasing yielding ambiguous results. If this route of investigation is chosen, a thorough literature search may yield a validity-tested set of questions that could be applied to the problem being addressed. If no similar validity-tested survey tool can be located and permission secured for its use, it is advisable to consult a psychological or sociological researcher to assist in preparing a questionnaire together with any required disclaimers and anonymity statements.

Institutional Review Boards exist in research institutions as a means of protecting the health, welfare and privacy of human study subjects. Institutional Review Boards for Research with Human Subjects commonly have template forms detailing the measures required to ensure subject awareness, confidentiality and anonymity in a research protocol. Such templates can be adapted by prospective researchers to fit their unique situations. Whether collecting survey data or clinical metrics from human subjects, IRB approval will likely be required. Though protocol details will vary from one IRB to another, the approval process is likely to be time consuming and it should be undertaken as soon as a project prospectus is finalized. The IRB will need to approve the study design, review the qualifications of the

researchers and understand the types of information required and the methods for its collection. It is therefore helpful and often necessary, to collaborate with a clinician or researcher associated with the institution in question who has the required credentials and can liaison with the IRB. It is also important when dealing with data involving human subjects to work with a clinician or researcher who understands the study population in question and who can protect participants' privacy and overall welfare.

In an objective study, in which data is collected about a subject population, particularly a patient population in a healthcare setting, the design of the investigation is even more critical. Many research studies err by casting too broad a net of study subjects. It is critical to examine the nature of the subject population to determine where the largest impact of the design intervention might be seen. To minimize statistical variability in the resultant data, it is best to focus on a sub-set of subjects who can best reflect the intervention. The neonate subject population is an excellent example. Babies enter a neonatal intensive care unit with a variety of clinical diagnoses and likely outcomes. Sadly, a segment of that vulnerable patient population may be too critically ill to respond to any intervention. Another segment of the NICU population includes infants who have been admitted for minor post-natal complications that need short-term observation before being sent home. They are on the unit for far too little time to benefit from any design modifications. For these reasons, in the referenced study, the admitting neonatologist agreed to triage the study patients into five subgroups according to illness severity as defined by the Physician's Estimate of Mortality Risk (PEMR).<sup>6</sup> While the study recorded imminent mortality events (PEMR = 5), it limited the recording of patient progress to only the middle-scoring PEMR groups 2-4. This protocol provided test and control populations that represented the majority of typical NICU admissions and that could best reflect resultant outcomes from time spent in each of the unit designs.

Though there are a variety of conditions in the built environment from which data and research can be collected through quantifiable means, many EBD studies are focused on the impact of a design on human subjects and seek to describe the impact of a design feature on a population of building users. Traditional scientific inquiry involves designing research studies around the observation of specifically selected variables while controlling as many other related variables as possible, meaning that all conditions affecting the experimental and control variables must be identical except for the

one being investigated. Adjusting one variable within a context of several constants provides an immediate indication of the effects of treatment and can often be a strong indication of a causal relationship. However, such a strictly controlled experiment is difficult to achieve with multivariate human subjects and design environments.

To further complicate the picture, a design solution by its very nature seeks to adjust or improve upon many environmental factors. This means any study design must contend with multiple variables. Therefore, rather than attempting to control or limit these environmental variables in the entire study population, the researcher must seek to limit the study to a smaller subgroup of subjects experiencing selected aspects of the design environment. If the characteristics of experimental and control subgroups can be more narrowly defined, a lesser degree of variability will be seen in the study population and a smaller sample size will be needed for statistical validity.

Understanding the nature of the study population and carefully documenting the demographic characteristics of its members also allows experimental and control populations to be "pair matched." Pair matching means that individuals can be paired with other similar individuals within test and control groups to determine the effects of a selected environmental modification on similar subject pools. The need for pair matching can impact the scope of data collection significantly by requiring an increased number of study participants to ensure that there are sufficiently large subject pools for statistical comparison. The NICU design study referenced here collected data on 240 neonates and showed dissimilar representation of PEMR groups 1 and 4 in the study groups. After pair matching according to gender, gestational age and PEMR category, only 170 subjects were available for comparison, but all PEMR categories were comparably represented in both experimental and control subgroups (Figure 1). Consequently, a number of the neonates on one unit did not have a similar pairing in the other facility and could not, therefore, be included in the sample. Some of the resultant study groups became so small that they could no longer be compared with statistical validity. PEMR 4 subjects, the highest acuity category in the study, had only six matched pairs and therefore no definitive conclusions about comparative progress could be determined for this subject group.

Unlike traditional laboratory research in which an experiment is designed so that it may, and should, be

repeated, research related to the built environment is often limited by time and resources to a single event. Construction of a new facility often means the demolition or repurposing of an older facility that represented the baseline control conditions for the study. If valid comparisons are to be made, it may be necessary to proceed with the initial data collection in the existing facility while the new facility is being planned or constructed. Software programs are available that can aid in analysis of data and in estimating sample size for a study investigation, but some preliminary data are required to estimate the statistical variability from the proposed study groups<sup>1</sup>.

Given the innate variability of human subjects, it is likely that a large number of subjects for both experimental and control groups will be required for statistical analysis. Without the ability to perform a pilot study or to repeat an observation, as is common with laboratory experiments, it is advisable to err on the side of more data than less. Additionally, recording all possible demographic information about the study population ensures that information, seemingly insignificant at the outset, will be available if needed when final analyses are performed. Information collected about clinical roles and prior experience proved critical in interpreting the data from healthcare staff and subject parents in the Cabell NICU study. A serendipitous correlation between facility preference and clinical role was seen with healthcare staff, which would have been impossible to determine retrospectively given the anonymous nature of the survey (Figure 2). When using subjective study questionnaires, it is also important to control for naïveté among study participants who may have experience with only one facility design and may be inherently biased for or against a given built environment. In the referenced study, transitional parents, those present over the relocation from the existing to the new facility and with experience in both unit designs, served as a control for naïve parents who had seen only one of the two designs (Figure 3).

Focusing on selected modifications to the environment and attempting conclusions related to the effects of such modifications may ignore other, equally significant variables. For the referenced NICU study, measurements of light levels, sound levels and indoor air quality were taken at varying distances from the entrances and nursing stations to ensure that the study could completely and adequately describe the physical differences between the older and newer environments. Showing that noise and light levels were better controlled in the private room NICU environment allowed researchers to reference other studies on the effects of noise and light cycling on neonatal development and to posit that improved outcomes were affected by the more controlled environment of private rooms. Though improved neonate progress and breastfeeding success could be demonstrated on the private room unit, a direct causal relationship could not be attributed (Figures 4 and 5). Similarly, research findings demonstrated convincing positive correlations between noise levels, airborne particulates and CO<sub>2</sub> levels with periods of heavy visitor and staff activity on the older, open bay unit. Excessive noise can distract healthcare staff, increasing the likelihood of errors while also disrupting sleep patterns of neonates and retarding their developmental progress. The consequences of excessive noise could increase lengths of stay and add to the costs of hospitalization.

In studies involving human subjects, outcomes could reflect the result of any one of several changed variables or some combination. In deriving conclusions from a completed study, it is important to state only the clearly verifiable results and to describe the controlled parameters without attempting to address a causal relationship that may not be supported by the data or the study design. Including discussion of the possible reasons for study outcomes may, however, inspire or assist others who are planning similar studies or facility modifications.

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[1] Systat Software, Inc., San Jose, CA. Retrieved on 11/2011 from [www.sigmaplot.com](http://www.sigmaplot.com)

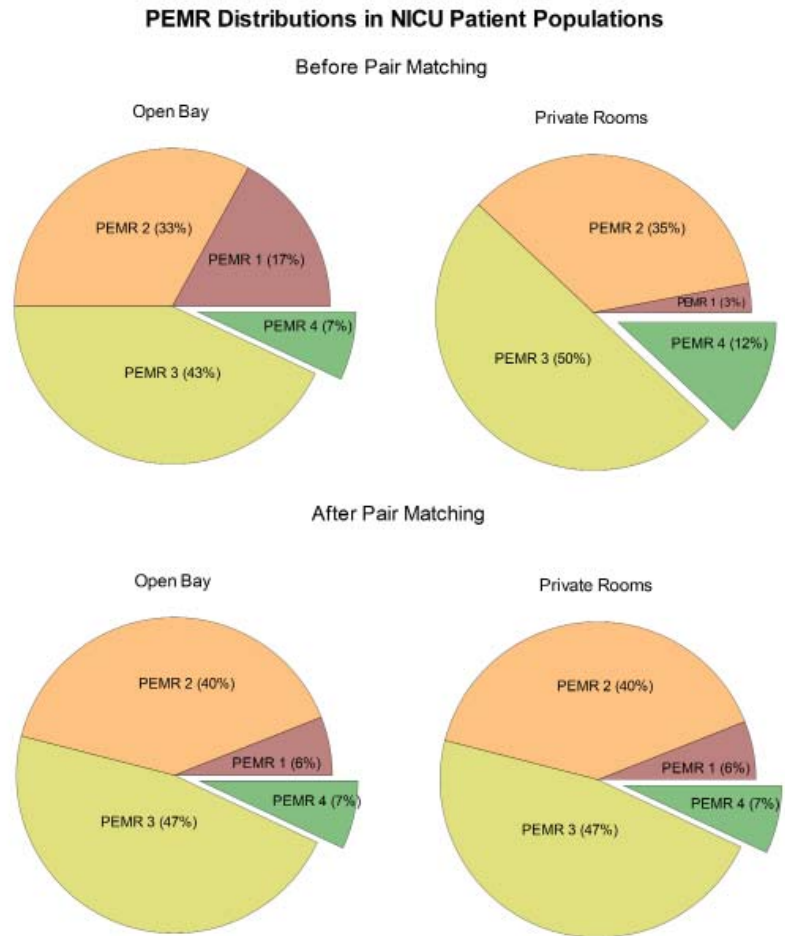


Figure 1: PEMR Distributions in NICU patient populations.

The advantage of pair matching study subjects was seen when examining critically the Physician’s Estimate of Mortality Risk (PEMR) triage distributions (Figure 1 above). Before pair matching, moderately ill (PEMR 1) and severely ill (PEMR 4) groups were disproportion-

ately represented in the test and control populations. Such disparities could have biased patient progress and length of stay metrics, introducing undesirable variability and obscuring statistical significance in final data analyses.

# A Design-Based Approach to Collecting Evidence

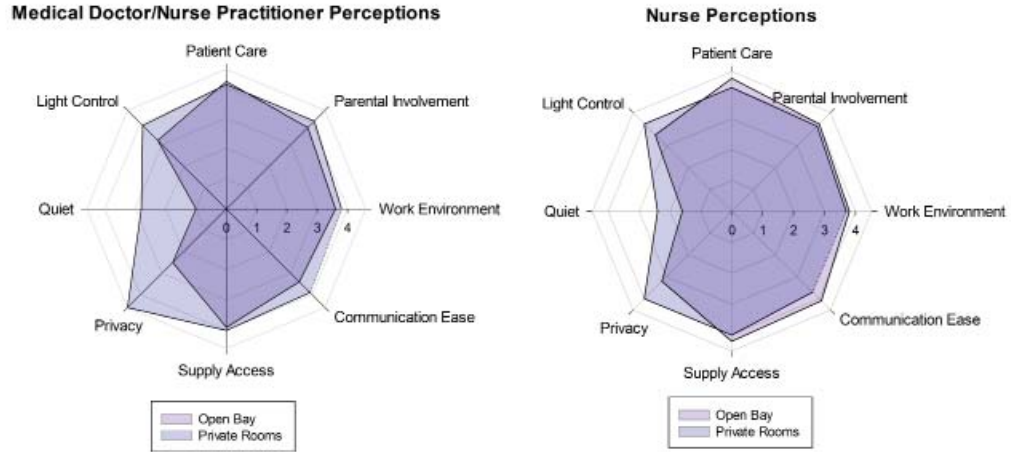


Figure 2: NICU Staff perceptions of physical facility.

Figure 2 above, compares NICU staff responses grouped by staff position demonstrating that prior experience can bias perception. Physicians and nurse practitioners, more likely trained in private room situations, showed preferences for healthcare delivery in the single family room facility. Nurses, more commonly trained in ward-type facilities, preferred an open bay facility design. Nurses expressed concerns for adequacy of patient care and were apparently uncomfortable with dependence upon electronic monitoring and communication in the private rooms. However, both staff groups appreciated the increased privacy, light control and noise reduction in the private rooms.

Figure 3 below, demonstrates that naïvete existed with-in parental survey data by comparing inexperienced parental responses, those with experience in only one of the two facility designs, with those from experienced, transitional parents who were present through the relocation and had seen both facility designs. Naïve parents saw differences only in lighting control, overall privacy and socialization opportunities with other parents. Experienced parents generally preferred the private room environment in all instances except for socialization with other parents, a problem anticipated with isolating patients and their families in private rooms. It is remarkable that noise disturbance was perceived as a problem only when parents had experienced the quieter, private room environment.

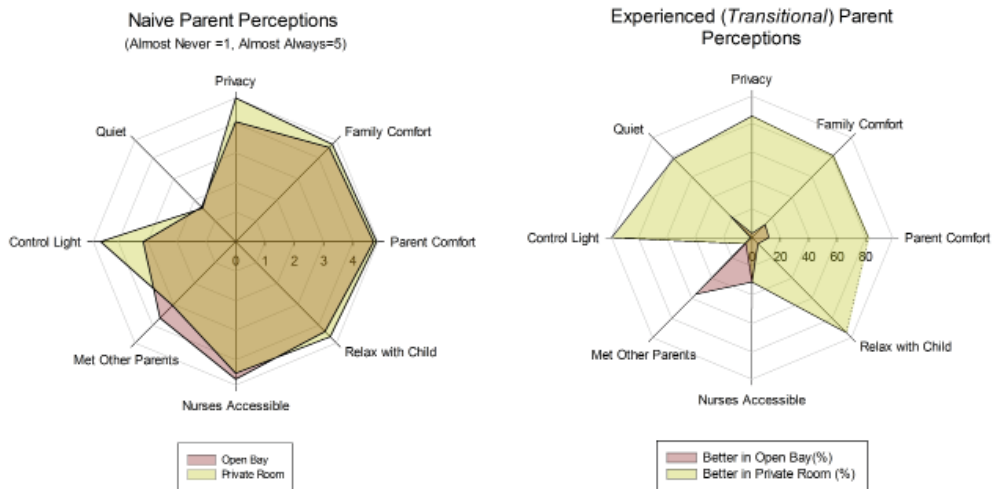


Figure 3: Subject naïvete in parental survey data.



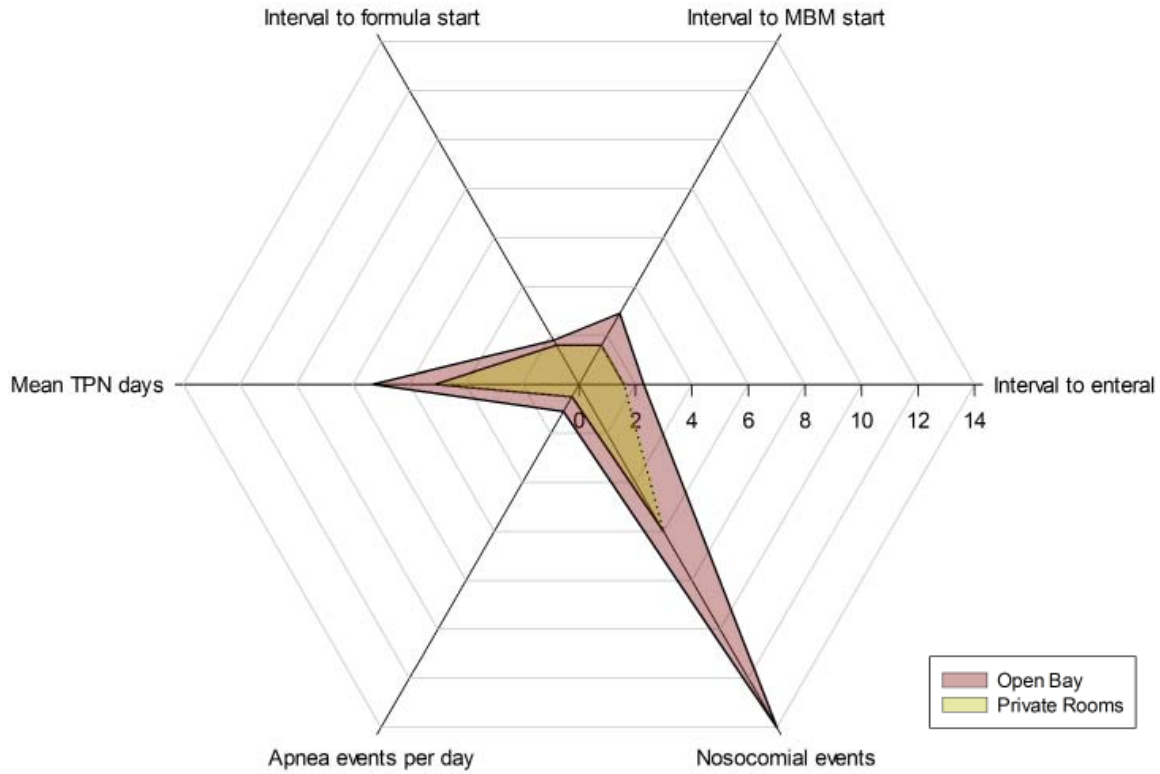


Figure 4: PEMRs 2 and 3 patient progress.

Figure 4 above, demonstrates that neonates in private rooms showed fewer apnea events, nosocomial incidents and total parenteral nutrition (TPN) days than the open bay cohort. They transitioned earlier to enteral nutrition with shorter intervals to formula and mother’s breast milk (MBM) start.

Figure 5 below, shows that neonates in private rooms transitioned from total parenteral nutrition (TPN) to mother’s breast milk (MBM) earlier and more maternal-infant dyads were discharged breastfeeding. More mothers in private rooms sustained lactation beyond the immediate postpartum surge in milk production.

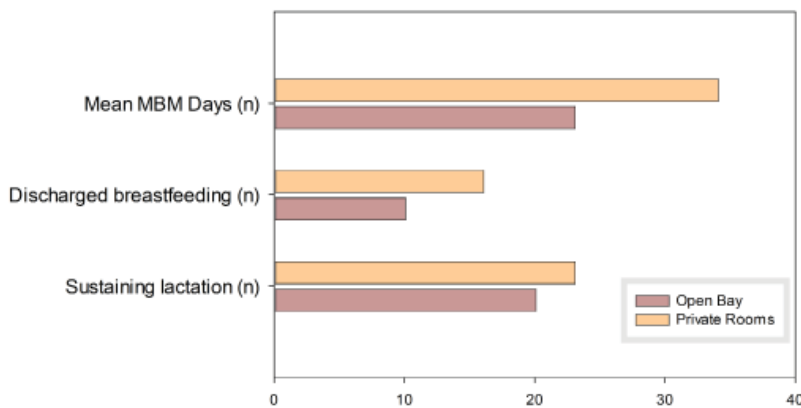


Figure 5: Breastfeeding success.

## 3.0 CONCLUSION

The formulation and execution of a research study requires significant resources and time for designers and their clients. The extensive financial and manpower resource requirements, combined with the one-chance nature of data collection, highlight the importance of careful and early experimental design. Creativity can be practiced in the construction of research studies to yield innovative solutions to the design-related challenges of the built environment. The subjective nature of the design process and the multivariate nature of human subjects and environments require researchers to be creative in structuring investigations and cautious in assuming causal relationships. Nevertheless, it is important to accumulate a body of research pertaining to the built environment from as many different investigative sources as possible. The more valid and creative studies that can be performed, the more credence is added to the design decision-making process, all the while documenting the benefits of professional intervention in the spaces that structure much of our lives.

## Acknowledgments

The authors would like to express appreciation for the efforts of the staff and leadership of the Cabell Huntington Hospital NICU, particularly Renee Domanico, MD, and Fina Coleman, BSRN, for their data collection and co-authorship of the referenced EBD study. Jeff Tyner, AIA, continues to provide tremendous support to the ongoing EBD research within the Atlanta office of Perkins+Will.

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