

Understanding Pupil Sizes as Clinical Indicators for Impairment Based on the "Values for the Majority Of Normal People" and "The Range of Values for the Majority Of Normal People"

For DRE Students and Instructors
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Introductory Comments:

During the past 10 years, advances in medical information, technology, diagnosis, and treatment have occurred at an accelerating rate that is both amazing and challenging. Many new advances had led to changes in the way we diagnose and treat many illnesses. For example,

- Relationship found between higher levels of "good" cholesterol (high-density lipoproteins, or HDL) and lower rates of heart disease.
- New antihistamine introduced that does not cause drowsiness
- A gene that triggers breast cancer is identified.
- Scientists locate genes for Alzheimer's disease, colon cancer, hyperactivity disorder
- Genes located for Alzheimer's disease
- Routine blood test (PSA) introduced to improve diagnosis of prostate cancer.
- New skin patch test developed for diabetes
- New inhaled medicine helps treat flu and shorten the length of the common cold.

Over the past decade, pharmaceutical companies have pushed the technical boundaries, working at the cellular and molecular levels to dramatically advance the diagnosis and treatment of disease. At the end of 2002, 28 percent more medicines were being investigated by pharmaceutical companies for approval by the Food and Drug Administration (FDA) than was true one decade before. More than 1,000 medications are now in the development pipeline.

Between 1993 and 2003, more than 300 new drugs, biologics, and vaccines that prevent and treat over 150 conditions were approved by the FDA. The FDA also gave the go-ahead for numerous new indications for previously approved medicines, allowing physicians to tailor diagnostic and treatment strategies to meet a patient's individual disease status, past medication history, side effect

tolerance, and preferences. The new medicines that are the product of this decade of innovation have dramatically changed the "standard of care" for several major conditions.

The past 10 years have witnessed important changes in virtually every aspect of diagnosis and treatment for breast cancer. Research, diagnosis, and treatment of breast cancer have undergone significant changes since 1993. Today, there are more breast conservation surgeries and fewer mastectomies, increased benefit from adjuvant chemotherapy, and many new effective agents for breast cancer treatment and prevention. These important

changes can be directly attributed to improvements in breast cancer diagnosis and treatment.

THE KEY OUTCOME of this activity and changes from these advances is the CONTINUAL REVISING of clinical diagnosis and treatment guidelines to recommend IMPROVED diagnostic and treatment protocols . This led to new clinical evaluation methods which are more precise and more sensitive for documenting the health and functional status of the individual with various diseases and impairments.

In particular in the DEC program, recent research on pupil sizes, HGN, and new drug effects have led to recommend IMPROVED guidelines for evaluation and interpretation protocols .

Changes in the DEC and DRE program

The DRE training program and the drug evaluation and classification process is considered standardized and systematic. It utilizes a variety of readily observable signs and symptoms that are CLINICAL INDICATORS and are based on accepted procedures within the medical and health care community. During a DRE examination, the DRE using these clinical methods, assesses the suspect's pulse, blood pressure, body temperature, pupil size and reaction to light, and psychomotor function. The DRE also examines the suspect's ocular tracking, smooth pursuit and Horizontal and Vertical Gaze Nystagmus (HGN and VGN).

The DRE must choose from and interpret a large variety of clinical indicators while facing pressure to decrease uncertainty in the clinical decision process . The essence of clinical decision making involves the task of determining what information to gather, which tests to do, and how to interpret and integrate this information into the best diagnostic possibilities,

A clinician as well as a DRE must use his/her best judgment--from all clinical indicators available with an understanding of the clinical indicators probability of being related to drug impairment. Once this is done, then reasonable estimates of such probabilities can be made. This is why a drug recognition expert is trained to reach a conclusion of impairment based on the interpretation of ALL these clinical signs and indicators as well as the facts of the situation in its entirety. A decision is not based simply on one or two elements of the examination.

So How Does This Relate To The DEC And DRE Program ?

During the Opinion phase of the DRE evaluation process, a judgment is formed , based on the totality of the evaluation, as to whether the suspect is impaired. If the DRE determines that the suspect is impaired, it is then now determined what is the possible the cause of the suspect's impairment. This requires the DRE to determine the best possibilities of what category or categories of drugs may explain the impairment.

Since there have been and continue to be significant advances in diagnostic methods in health care over the past years and the DRE program utilizes such clinical methods and their indications, it is crucial that the program and its evaluation protocols be flexible and adaptive one to keep up with such scientific changes and new information. The challenge is to integrate changes with the emergence of new information. However, the outcome historically in clinical health care has been to adapt and create a BETTER, MORE ACCURATE, and APPROPRIATE method of clinical decision making.

Traditionally, clinical decisions have followed logical "if . . . then . . ." rules. Often, the guidelines are condensed and sometimes do not fully account for differences among subjects. Guidelines can aid in the management of many clinical assessment problems, but the DRE must always use appropriate clinical judgment and interpret conflicting data that fall between the rules. To include ambiguity into DRE decision making and to follow the logic underlying decision rules, DREs must understand the basics of probability using the clinical indicators and facts from the evaluation

It is by incorporating new information regarding the DRE clinical indicators and the application of adapted and newer DRE clinical decision making approaches that will lead to a more efficient and self confident drug recognition expert.

How Does this Apply to the Pupil Assessment and the updated Normative Values?

Since many of the DRE Test results involve the concept of "NORMATIVE VALUES", it is quite important for the DRE student and instructor to understand what this Concept of "Normative Values for the Majority Of Normal People" and "The Range of Values for the Majority Of Normal People" means as it applies to the CLINICAL INDICATORS of physiological function in the area of PUPIL Assessment . This may well simply lead to better understanding, decision making, and interpretation of the DRE findings and their explanations.

FOR A "NORMAL" NON-IMPAIRED PERSON,
THE AVERAGE PUPIL SIZE FOR

Room light is approximately 4.0 mm.
with an average range of normal pupil sizes
ranging from 2.5 to 5.0 mm.

Near Total Darkness is approximately 6.5
mm. with an average range of normal pupil
sizes ranging from 5.0 to 8.5 mm.

Direct light is approximately 3.0 mm with an
average range of normal pupil sizes ranging
from 2.0 to 4.5 mm

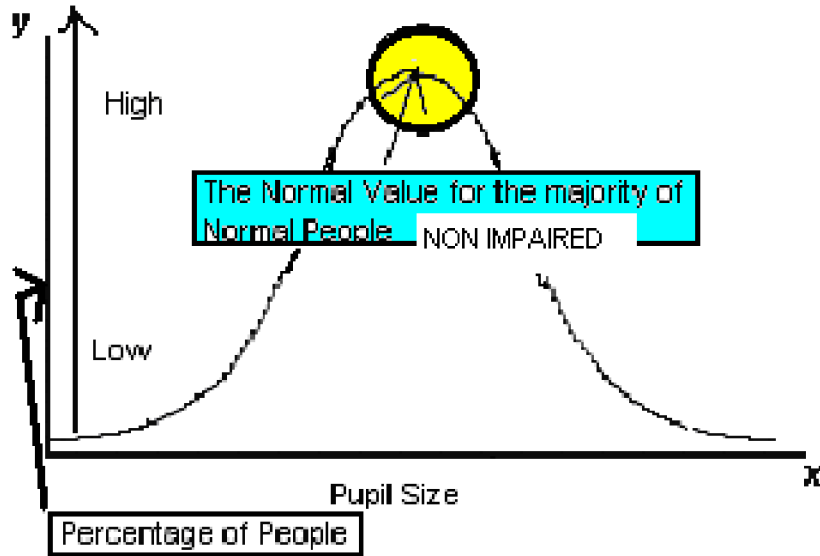
1. What Does "Normative Values for the Majority Of Normal People" and "The Range of Values for the Majority Of Normal People" Indicate?

In scientific and clinical information, you probably won't see the words "Normative Values for the Majority Of Normal People" and "The Range of Values for the Majority Of Normal People". Rather, it will be described as the "Mean", or "Average" or "Normative Values" or "Average Range". They are ALL the same thing.

The "Average" or "Mean" value is the total of a group of numbers divided by the total number of values in the group. Sometimes "average" means the value for "normal." Other times it refers to some number "in the middle"; there are several different ways to characterize an average or mean value.

HOWEVER, the best way to describe what Average means is that it is the Number that represents the value that the "MAJORITY OF NORMAL PEOPLE" would exhibit or have in a specific test. Usually, "normal" means the same thing as "healthy" or "non-impaired".

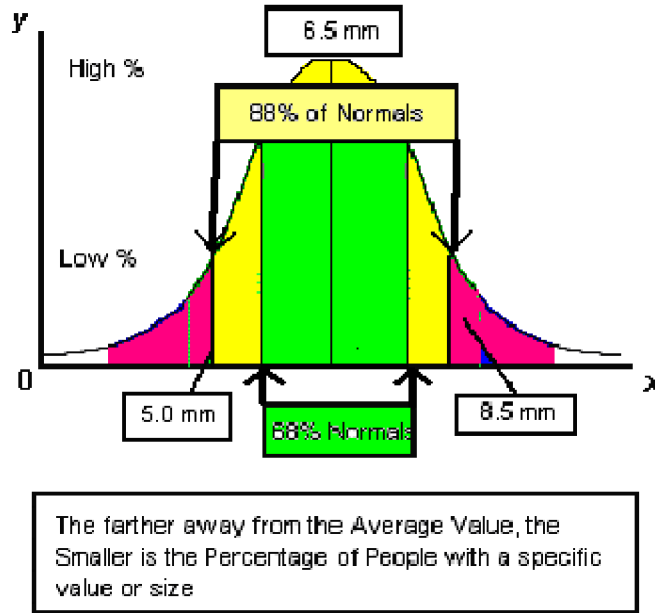
- For example, the "Average" or "Mean" value for pupil size in near total darkness is 6.5 mm. This means that when ALL the sizes were measured in a large number of pupils in healthy normal adults, the average or "NORMAL VALUE for the MAJORITY OF NORMAL PEOPLE" had a pupil size about 6.5 mm and this was the LARGEST percentage of people with that size pupil.



How are reference ranges determined?

The standard deviation is a statistic that tells you how tightly all the various values are crowded together around the average value in a set of data. One standard deviation (1.0 SD) away from the mean in either direction on the horizontal axis (the yellow on the graph below) accounts for somewhere around 68 percent of all the people in this group. Two standard deviations away from the mean (the yellow and green areas) account for roughly 95 percent of the people. The blue area is 2.0 SD and represents only 5 % of the majority of people. We used One and a Half standard deviations away from the mean accounting for roughly 88 percent of the people.

For example, a group of males and females would be given a specific test, e.g., pupil size measurement in near total darkness, and the results were determined for the average and 1.5 standard deviation in order to create the reference range for that group. Though the average pupil size was approximately 6.5 mm, the average range for the majority of normal subjects was 5 mm to 8.5 mm.



2. How are test results interpreted?

The Farther Away from the mean or "MAJORITY " a value is, the LOWER is the percentage of NORMAL people having this number.

When this value falls beyond one standard deviation (1.0 SD), which is approximately 68 of the Normal values, then we now have to consider that the subject is going "OUTSIDE THE AVERAGE RANGE FOR THE MAJORITY OF NORMAL PEOPLE". That is why we chose 1.5 standard deviations for the edge of normals for pupils so there is even less question that the subject is in the minority and outside the range of normals.

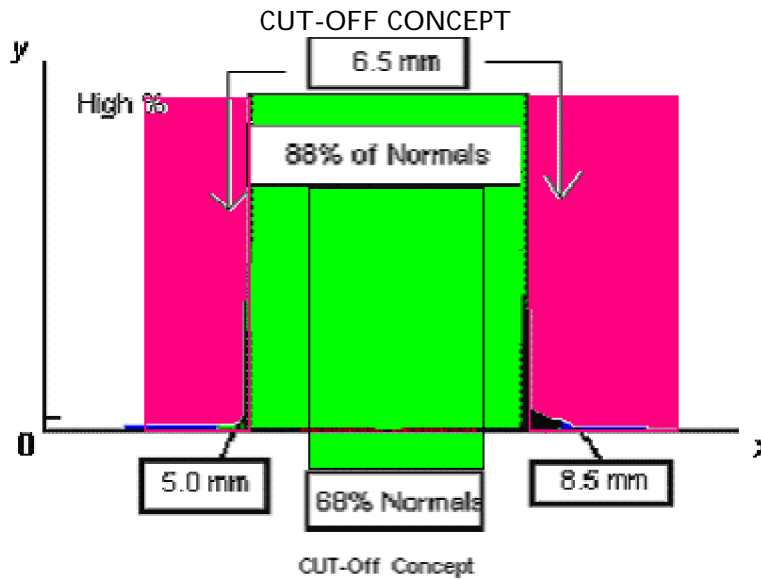
Is there such a thing as a "normal" or "abnormal" result?

No matter whether your results are within or outside the AVERAGE RANGE FOR THE MAJORITY OF NORMAL PEOPLE". ..., it is up to YOU to determine whether your results are normal or abnormal based on the specific test results and the TOTALITY OF THE DRE EXAMINATION FINDINGS .

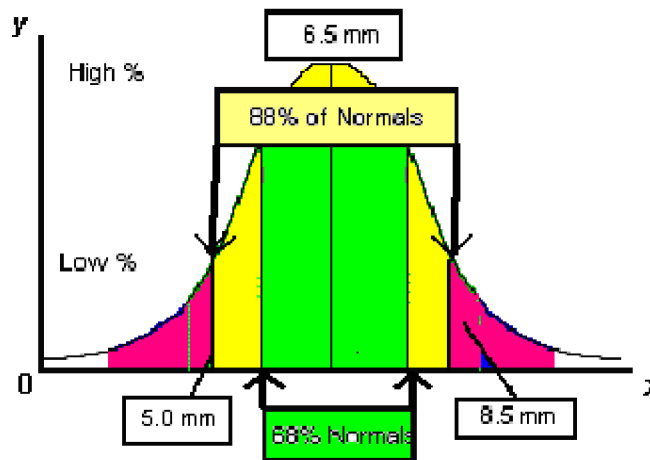
Why is this Different from the Present Method of "Cut-Off " Values method ?

The "CUT-OFF " CONCEPT is often used inappropriately and can lead to errors in decision making. The "Cut-Off " implies that as long as a suspect is within the " Average for Normals" then they are Normal. It gives the impression that if you are within the "Average Range ", then you are not impaired and once you go just outside of the range,

then you are impaired. Clarify that if we are 1 std outside , that now start going into abnormal ranges.



NORMAL RANGE OF VALUES CONCEPT



The farther away from the Average Value, the Smaller is the Percentage of People with a specific value or size

For example:

1. Using the "CUT-OFF " CONCEPT , a person with a 8.0 mm pupil would fall INSIDE the range and may be then considered OK or normal. That is Incorrect.
2. Using the "Range of Average for the Majority of Normal People", This result is INSIDE the average range for the majority of normal people. However, it

is very close to the edge of the normal range and represents less than 9 % of normal people.,_therefore, the PROBABILITY is HIGHER that there may be impairment present when the results are compared with all the other DRE test findings.

This would be considered a "DILATED " pupil.

Another example in clinical care is Cholesterol levels:

There is no absolute "Cut-Off", rather there is levels that indicate greater or less risk for a problem.

For example, if you have a total cholesterol less than 200 mg/dL and HDL less than 40 mg/dL you should have your LDL ("bad") cholesterol level checked annually. However, if you have a Total cholesterol 200 to 239, HDL 40 mg/dL or higher and FEWER than 2 risk factors, you may have twice the risk of coronary heart . When it gets to a total Cholesterol 240 and above, you risk of coronary heart disease is high. It's even higher if you have other risk factors for heart disease. As the level goes up and the farther away from the normal values for the Majority of Normal People, the risk factor increases for impairment (in this case, coronary heart disease).

This is similar to the DRE pupil size indicators. The farther from normal value for the Majority of Normal People, the greater is the risk that there is impairment. If other clinical indicators are present, e.g., increased blood pressure, pulse, etc, the greater is the risk and probability of impairment .

How Does this apply to the Pupil Findings?

1. If your results are outside of the AVERAGE RANGE FOR THE MAJORITY OF NORMAL PEOPLE , does it mean there is impairment?
 - Most likely, yes. It is feasible, though unlikely, to have an end result outside of the average range even though nothing is wrong, i.e., impairment, with the person.

2. If your test result is within AVERAGE RANGE FOR THE MAJORITY OF NORMAL PEOPLE, does that mean everything is okay?
 - Not necessarily. It is important to look at HOW FAR FROM THE "AVERAGE" the results are and how close the results are near the edge of the "normal" range even though it is still within the "normal" range.

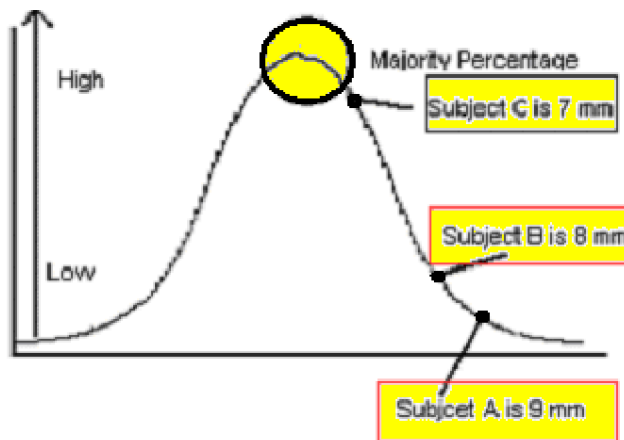
To illustrate this, Let's take THREE different pupil sizes under near total darkness.

Subject A: a pupil size measurement in near total darkness is taken and the subject shows a 9 MM PUPIL. We know that average range for the majority of normal people, was 5 mm to 8.5 mm. However, since this result is outside the average or reference range and represents VERY SMALL PERCENTAGE of Normal people (Less than 5%) , then it may be considered "abnormal" or sign of possible impairment. The probability is greatly increased that there is impairment present when the results fall farther and farther away from the "Average of the Majority of People" value. This would be considered a "DILATED " pupil.

Subject B: a pupil size measurement in near total darkness is taken and the subject shows an 8 MM PUPIL. We know that the average range for normal subjects was 5 mm to 8.5 mm. This result is WITHIN the average range for the majority of normal people. However, it is very close to the edge of the normal range and represents less than 9 % of normal people., the PROBABILITY is HIGHER that there may be impairment present when the results are compared with all the other DRE test findings.

This would be considered a "DILATED " pupil.

Subject C: a pupil size measurement in near total darkness is taken and the subject shows a 7 MM PUPIL. We know that average range for the majority of normal people was 5 mm to 8.5 mm. However, since this result is closer to the MAJORITY or Average value, it may be considered to be a "NORMAL" pupil.



GENERAL RULES:

#1 The closer the test finding is to the average value for the majority of normal people, the more likely it is "normal"

2 The farther away from the average and the closer to the edge of the "Average range for the Majority of People ", the more likely the test finding is "abnormal" finding and indicates impairment

#3 The farther outside the range for the majority of normal people, the higher is the chance that the test finding is truly abnormal and there is definite impairment.

When do I describe a Pupil as Dilated or Constricted?

Using the Average Range method, it gives you leeway to make a clinical decision and call it dilated as you see it based on how far away from the Normal Mean value for the majority of people. For example: a 6.5 mm pupil would not be considered dilated, but a 7.5 mm could be considered dilated. A 5.5 mm pupil in NTD could be considered Constricted even though it is within the normal range since approximately only 10% of the Majority of Normal People have this. The judgment of being "Dilated" or "Constricted" is not simply based on objective pupil size measurements but requires observation. By just looking at the person and deciding that the pupil looks dilated or constricted as well as using the pupil size, a decision is made. This is what most doctors and nurses do clinically. Using the "Cut-Off" method, you would simply tend to conclude and say it is " normal" and the probability is that it may well not be and you were wrong !

How Do I explain this in Court ?

1. Since Three Sizes are taken, each one should be assessed individually. When this is done with the old range of 3.0 to 6.5 mm, many Room Light and Direct Light results were considered "Normal". With the THREE new ranges, many of these Room Light and Direct Light findings were, in fact, showed impaired findings.

ThereforeThe Use of Three Distinct Pupil Size Ranges for Each of the Different Testing Conditions is Considered More ACCURATE and Useful in the evaluation to Determine Impairment Vs. Non Impairment.

2. The ORIGINAL 3.0 to 6.5 mm "values" were not WRONG, they were most likely the AVERAGE for all the Three conditions. However, they were NOT the AVERAGE RANGES individually for each of the pupil test conditions . Then, one range for all conditions would not be the best way to interpret pupil sizes.

3. By using the Normal range of Averages and making a clinical decision based on how far away from the Normal mean value the result is in combination with all the findings from the DRE evaluation, you are in a much better position to defend your decision in court. It is You and your decision making interpretation based on all the information combined with your training and experience of the how the suspect performed in each of the clinical indicators that matters. You, as a DRE, are making a decision of impairment and possible drug categories not SOLELY based on "cut-off" values and plugging them into a abbreviated matrix, but rather on the totality of all the clinical indicators and the facts in the case. Remember, the matrix is a ONLY a GUIDE for assisting you in your final your decision making impressions of impairment and its cause.

4. I don't think you can avoid the word NORMAL". Labels are part of our world, especially in law and medicine. The use of "Within Normal Limits" is so common on all tests, reports, etc., it cannot be avoided. No matter what is said, the defense will push the issue. In court, when it does come up, link NORMAL to the words "NON-IMPAIRED". Then explain there is a RANGE of sizes for NON IMPAIRED individuals. Then go into using ALL the other signs of IMPAIRMENT, not just one set of findings.

5. Did the original pupil range of 3.0 to 6.5 mm lead to errors or wrong decisions ? In my opinion ...NO.

In effect, it may have actually reduced the use of all the potential signs of impairment that would have potentially been seen in the Pupils with the new guidelines. Therefore, it would most likely be to the suspects' advantage , not disadvantage!

How will this new data and view of interpretation Strengthen the DRE evaluation and program ?

If the DRE program is to move forward, the DRE is going to need to know how to understand and use clinical indicators and the clinical decision making process that clinicians in health care use. This is a giant step in that direction. The more the DRE understands these findings and interpretation, the better they will be able to explain and defend their decision in and out of court.

Reference: Richman JE, McAndrew KG, Decker D, et al. An evaluation of pupil size standards used by police officers for detecting drug impairment. Optometry 2004;75 (3) March