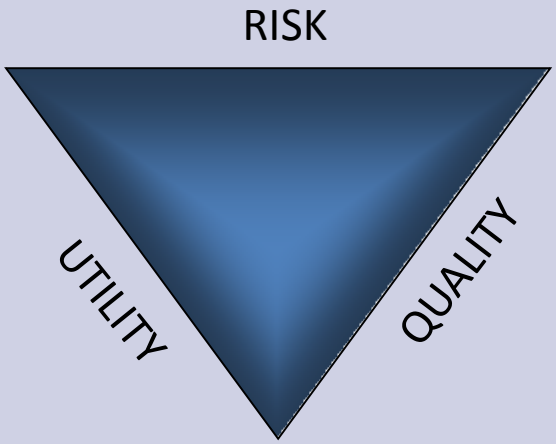
REDUCING DIAGNOSTIC ERROR IN MEDICINE

THE EARLY BIRD LOOSES THE DIAGNOSTIC WORM



Mark Gusack, M.D.
President
MANX Enterprises, Ltd.®

DIAGNOSTIC ERROR IN MEDICINE CONFERENCE
6 NOV 2016

SPECIAL THANKS TO

Mark Graber, M.D.
Laura Zwann, PhD.
Robert El-Kareh, M.D.
Janice Kwan, M.D.

For allowing this time with you ‘hear’ today.

ACKNOWLEDGEMENTS

William S. Yamamoto, M.D. as mentor and inspiration in medical informatics and artificial intelligence

Barry W. Walcott, COL MC, RET as mentor and teacher in medical systems and heuristics

AND THERE ARE MANY OTHERS I OWE MY STATE OF KNOWLEDGE

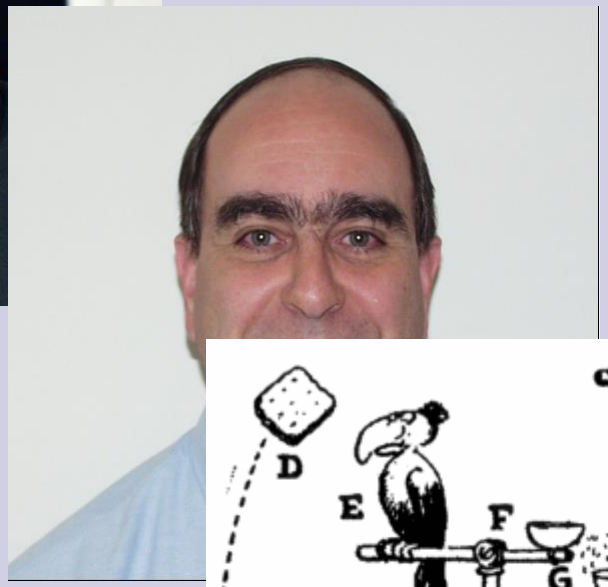
WHO AM I?

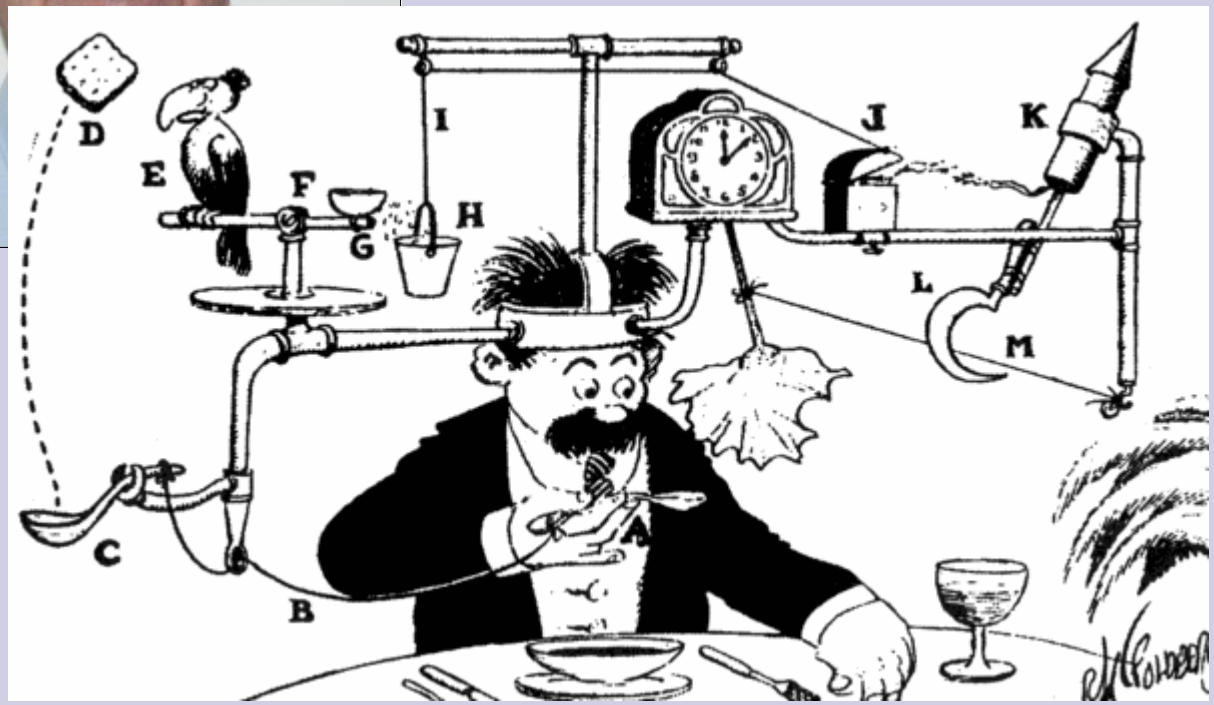
THIS IS HOW I SEE MYSELF!

WHO AM I?

THIS HOW I USED TO LOOK…

WHO AM I?





AFTER READING THE PRESENTATION, THIS IS HOW YOU WILL SEE ME…

PRESENTER

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AVAILABLE TO CONSULT TO YOUR NEEDS

Dr. Gusack has over 45 years experience in the Laboratory field starting as a Nuclear Medicine Technologist in the early 1970's, then working as a clinical engineer, and then becoming a physician and pathologist. He is AP/CP boarded, has held positions in a variety of hospital and reference based laboratories as a medical director and as staff pathologist. During this time he has also been a consultant and practiced as a Licensed Health Care Risk Manager in Florida. Dr. Gusack has been involved with all aspects of laboratory development and management including startup, licensing, as well as designing integrated management systems for clinical laboratories.

The opinions expressed in this presentation are those of the author and do not necessarily represent those of anyone else on Earth

SITUATION PART I

*"…the vast scale of political, economic, social, and technological change confronting modern organizations is placing unprecedented information-processing burdens on the individuals and groups working within them."**

*Hodgkinson, GP Healey, MP **Cognition in Organizations**; The Annual Review of Psychology 2008. 59: 387-417.

SITUATION PART II

- Accelerating improvements in healthcare have created a paradox of **increased capability** offset by **increased complexity**.
- This has challenged our **cognitive capabilities** to understand and control the behavior of the **complex systems** we have put into place to deliver healthcare.
- This has increased **latent** organizational **systems problems** that impact **cognition** during the diagnostic process.
- **Taxonomy** that **addresses systems and cognition separately** leads to inherent weakness in the creation of knowledge as well as its organization limiting its usefulness.
- The result; a body of work regarding diagnostic error **lacking a unified architecture** that hinders the **Reduction of Diagnostic Error in Medicine**.
- And this has led to the increased ***Perception of error*** on the part of the patient and of a society whose expectations have grown with the rise of modern medicine.

As the recent Institute of Medicine [**IOM**] report of September 2015 Improving Diagnosis in Health Care notes, the present approach to managing this complexity to reduce error has not been successful.

HOW DO WE GAIN CONTROL OVER THIS COMPLEXITY?

BUT BEFORE WE GO FURTHER THERE'S THE BUG-A-BOO OF PRECISION MEDICINE

Today there is a lot of talk about "**Precision Medicine**." However, articles attempting to define what this means fail miserably.

In a recent Perspective article in the New England Journal of Medicine David Hunter quotes a recent National Academies Press work by the Committee on **A Framework for Developing a New Taxonomy of Disease** and notes that the term Precision is used:

"…in a colloquial sense to mean both 'accurate' and 'precise'"

he notes this **implies a high degree of certainty** and then shows this is **just the opposite of the truth** which is that it leads to ***greater uncertainty.***

The Early Bird Poster Illustrates this problem when highly sensitive screening modalities are employed

WE NEED TO DO BETTER THAN THIS

SO, HOW DO WE PROCEED?

BEFORE WE CAN SOLVE THE PROBLEM OF DIAGNOSTIC ERROR WE NEED TO AGREE ON:

TERMINOLOGY	**DEFINITIONS OF MEANING OF WORDS DESCRIBING DIAGNOSTIC ERROR**
TAXONOMY	**ORGANIZE OUR KNOWLEDGE ABOUT DIAGNOSTIC ERROR EFFECTIVELY**

"*Careful and correct use of language is a powerful aid to straight thinking, for putting into words precisely what we mean necessitates getting our own minds quite clear on what we mean*."

WILLIAM IAN BEARDMORE BEVERIDGE

I HUMBLY PROPOSE SOME TERMINOLOGY

DIAGNOSIS Classification based on specified clinical criteria

A classification founded upon a set of observable **patient characteristics** that describe at least one **pathophysiologic state** associated with a single **underlying cause**.

DIAGNOSTIC CRITERIA Observable patient characteristics used in classifying a patient's state of health

A set of generally agreed upon metrics that define a **Medical Decision Point** based on observable patient characteristics that describe a single diagnosis.

DIAGNOSIC PROCESS Seeking a set of patient characteristics that reliably classify this state

A methodology **founded upon** inductively established relationships between **prior observations** that provide a means for **applying** deductive and abductive logic **to a set of future patient centric observations** leading to a **reliable classification of their clinical state** as the outcome of at least one **pathophysiologic state** and at least one **underlying cause**. [There may be many diagnoses]

DIAGNOSTIC ERROR Inaccurate/imprecise observation or erroneous decision making ⇨ DX error

Inaccurate/imprecise observation of patient **clinical state** and/or ***decision*** as to **pathophysiologic state**(s) and/or **underlying cause**(s) for correctly observed patient clinical state(s).

DIAGNOSTIC FAILURE Error leading to an unacceptable patient outcome

Diagnostic error that leads to an ***unacceptable*** state of patient safety, quality of life, cost.

Unacceptable to whom?

WE CAN ARGUE OVER THESE DEFINITIONS BUT AT LEAST THEY FORM A BASIS FOR THIS

I PROPOSE SOME MORE DEFINITIONS

DIAGNOSTIC ACCURACY: [Another way to define diagnostic error]

Of all the most likely diagnoses – based on our observations of the patient's clinical state – the correct one is chosen to a degree ***acceptable*** to the:

- Patient
- Clinicians
- Society [Oversight Institutions/Regulatory Agencies]

DIAGNOSTIC PRECISION:

Given an accurate diagnosis, characterization of that particular instance in a single patient regarding subtype, severity, extent, prognosis, stage, etc. is correct to a degree ***acceptable*** to the:

- Patient
- Clinicians
- Society [Oversight Institutions/Regulatory Agencies]

DIAGNOSTIC TIMELINESS:

The time taken to arrive at an accurate and precise diagnosis so as to avoid, prevent, or mitigate:

- **RISK**: A serious adverse outcome ***unacceptable*** to the patient/clinicians/society
- **QUALITY**: Undue Suffering of the patient ***unacceptable*** to the patient/clinicians/society
- **UTILITY**: ***Unacceptable*** cost for the patient/healthcare facility/society

So now we see that we need to define a process by which we establish what is acceptable and what isn't.

WE CAN ARGUE OVER THESE TOO!

ANOTHER WAY TO LOOK AT WHAT A DIAGNOSIS IS!

PROBLEM IDENTIFICATION	If we cannot reliably identify patient problems we can never solve them except by accident
PROBLEM SOLVING	If we cannot reliably solve problems then we cannot help our patients achieve optimal health
PREDICTING THE FUTURE	The ability to speculate on what might happen based on planned actions allowing us to choose between diagnoses to achieve the best outcomes

Acquisition of knowledge based upon factual information allows for a number of very beneficial capabilities that leads to a reduction in **DIAGNOSTIC ERROR IN MEDICINE**.

Therefore, given the incredible complexity of our field of endeavor:

- Scientifically
- Technologically
- Legally
- Regulatory

WE MUST PUT INTO PLACE EFFECTIVE KNOWLEDGE MANAGEMENT ACTIVITIES

BEFORE WE CAN PROCEED WE NEED TO DEFINE OUR MISSION

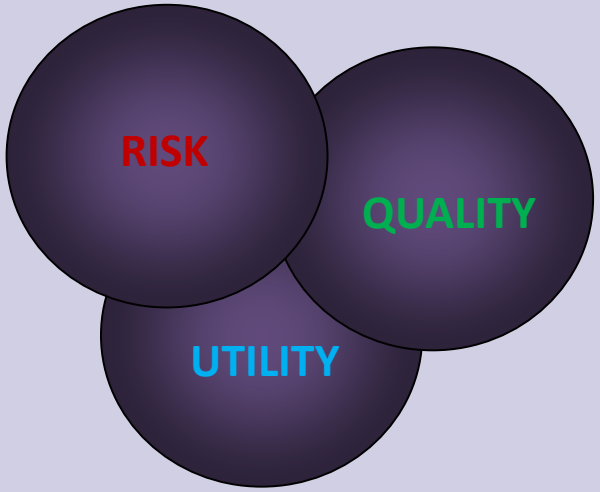
TO CARE FOR OUR PATIENTS

AND OUR GOALS?

RISK	*Maximize patient safety* with accurate, precise, and timely diagnoses
QUALITY	*Minimize pain and suffering* from inaccurate and/or imprecise, and/or delayed diagnoses
UTILITY	*Minimize expenditure* of scarce resources through cost effective diagnostic processes

HOW DO WE APPROACH THESE?

THESE THREE FULLY DEFINE ANY ACTIVITY WE PURSUE AND PROVIDE A MEANS OF COMPLETE ASSESSMENT



THEY CAN ACT SYNERGISTICALLY OR… THEY CAN CONFLICT WITH EACH OTHER

INTEGRATED SYSTEMS MANAGEMENT

THE EARLY BIRD LOOSES THE DIAGNOSTIC WORM

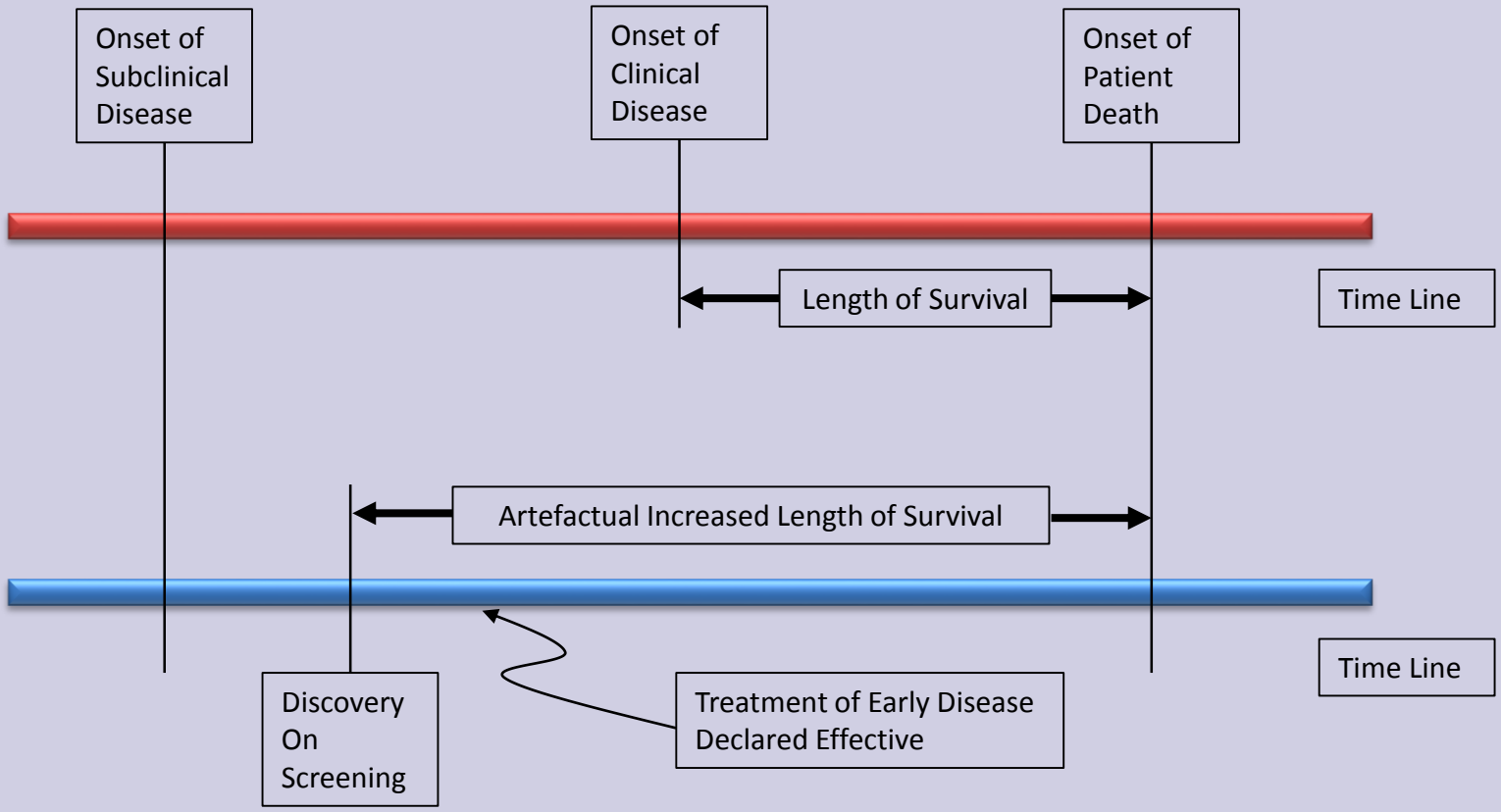
1. Describe how advances in our capacity to screen for early disease has led to greater frequency and significance of diagnostic error.

2. Explain how societal pressures have forced an increase in false positive diagnosis leading to inappropriate therapy.

3. Discuss how the resulting harm this trend has caused our patients.

LEARNING OBJECTIVES

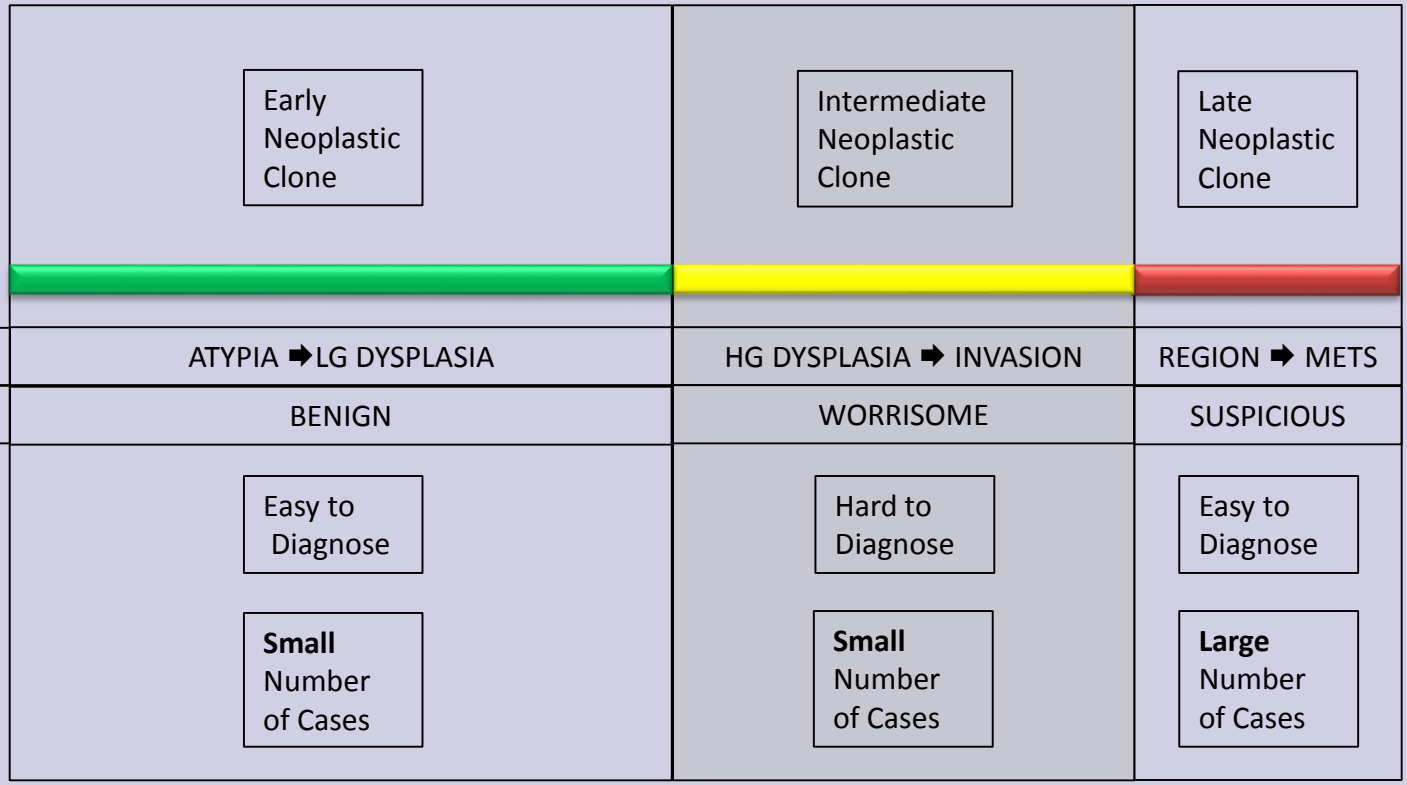
THE PARADOX OF SCREENING TO DIAGNOSE EARLY AND REDUCE SUFFERING I



SCREENING CONFOUNDS DETERMINING EFFECTIVENESS OF THERAPY

THE PARADOX OF SCREENING TO DIAGNOSE EARLY AND REDUCE SUFFERING II

BEFORE SCREENING



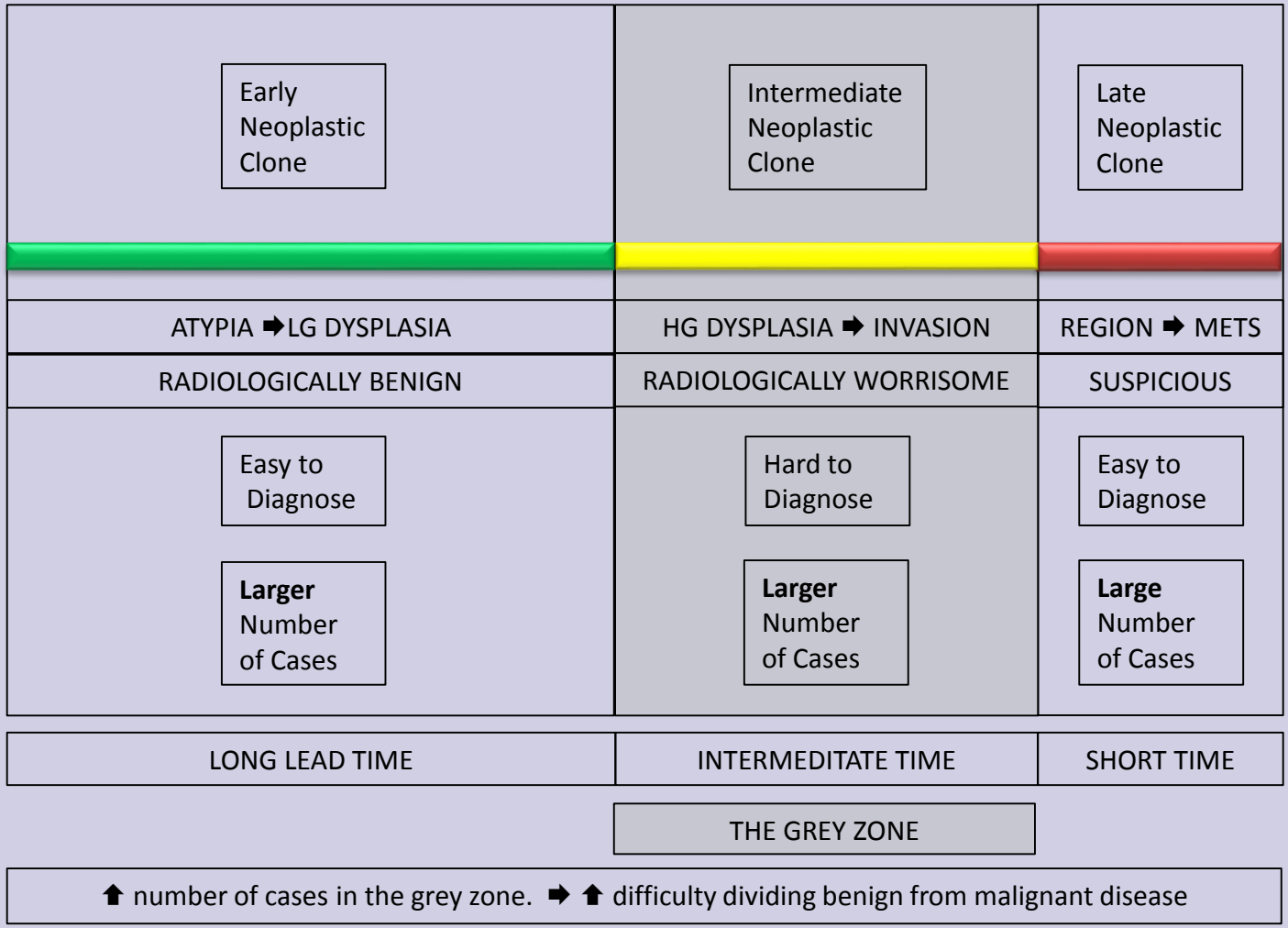
These three zones are not discrete. They overlap radiologically, histologically, and genomically.

However, prior to screening, most lesions coming to clinical attention are late and so easily diagnosed

DIAGNOSIS, PROGNOSIS AND THERAPEUTIC EFFECTIVENESS CLEAR

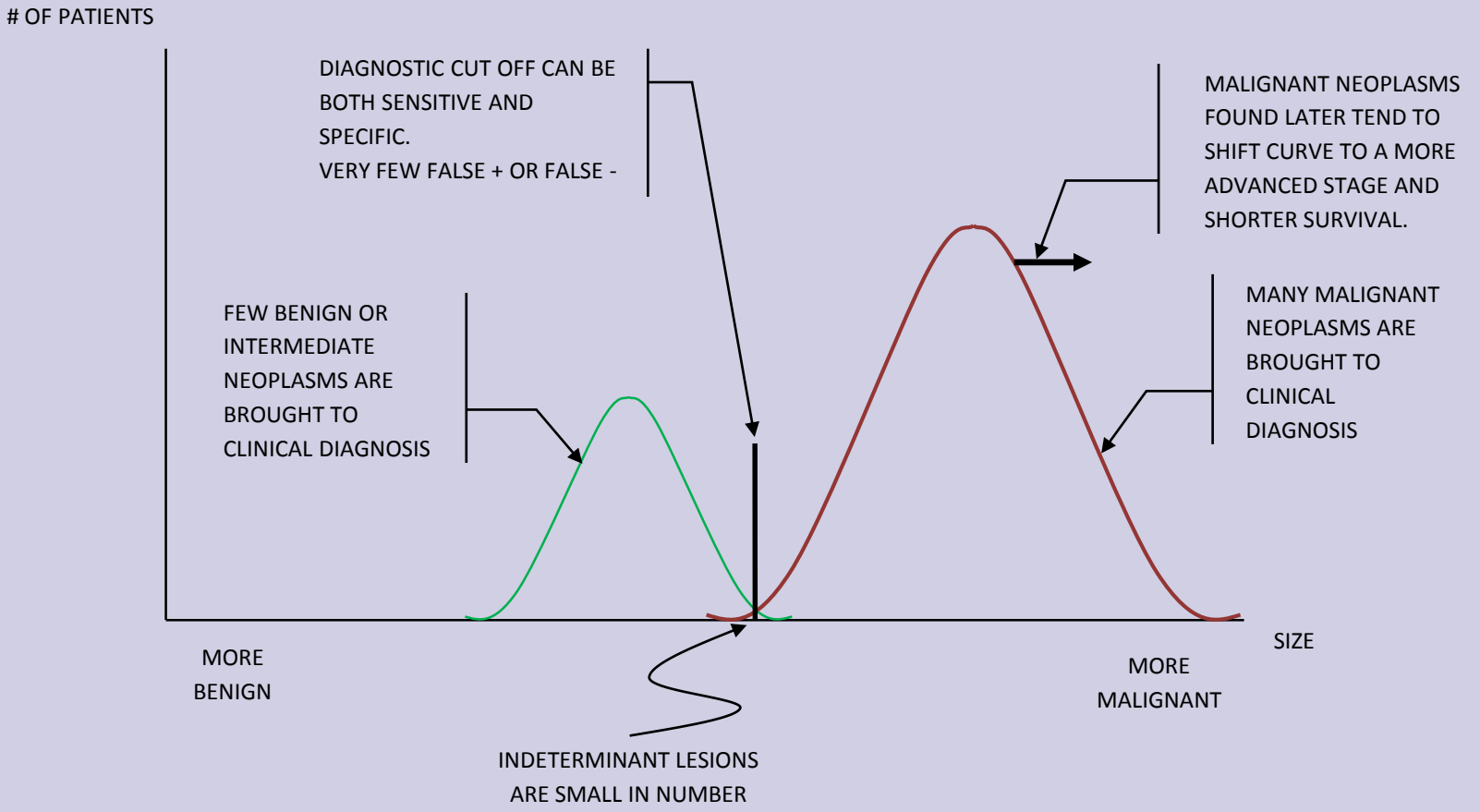
THE PARADOX OF SCREENING TO DIAGNOSE EARLY AND REDUCE SUFFERING III

AFTER SCREENING



THIS CONFOUNDS DIAGNOSIS, PROGNOSIS AND THERAPEUTIC EFFECTIVENESS

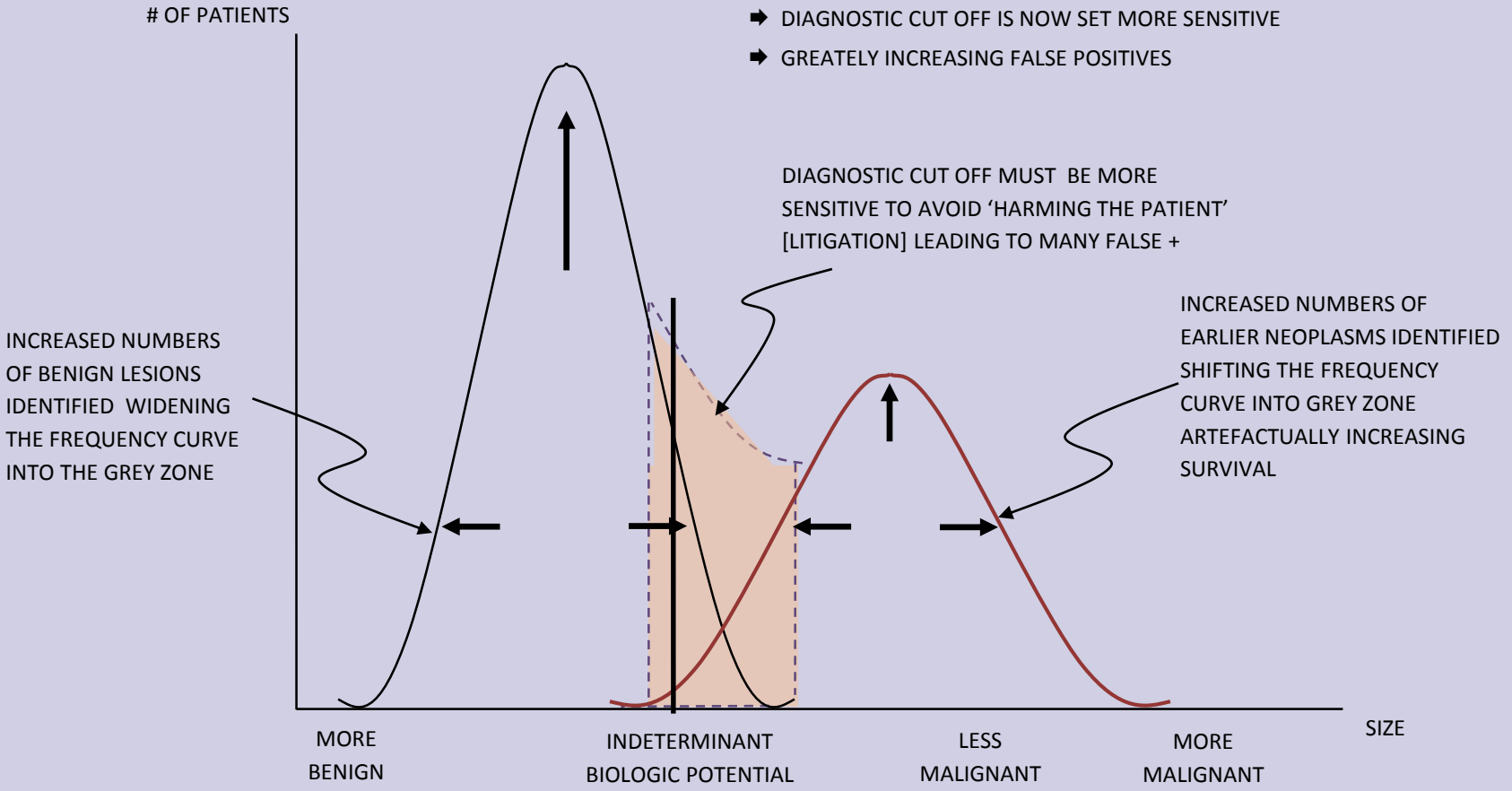
BEFORE SCREENING FOR DISEASE IS FEASIBLE OR SOCIALLY ACCEPTABLE



GOOD SEPARATION BETWEEN BENIGN AND MALIGNANT: FEW DIAGNOSTIC ERRORS

AFTER SCREENING FOR DISEASE BECOMES FEASIBLE AND SOCIALLY ACCEPTABLE

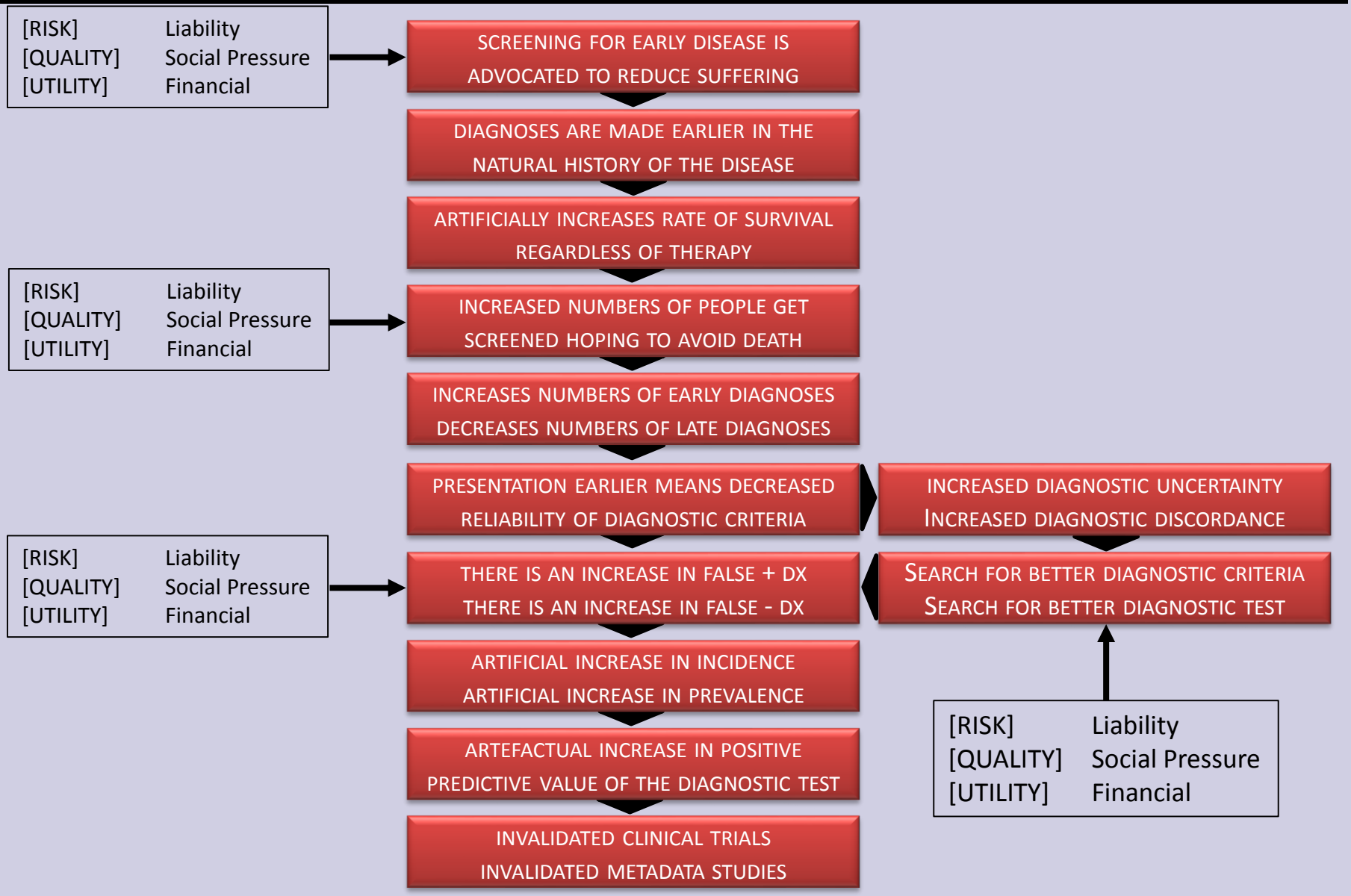
- NOW THERE IS A HUGE OVERLAP BETWEEN BENIGN AND MALIGNANT LESIONS
- REMOVING A SMALLER MASS IS LOW RISK AND MISSING A CANCER IS HIGH RISK
- OLD CUT OFF CREATES TOO MANY OF FALSE NEGATIVE DIAGNOSES [LAW SUITS]
- DIAGNOSTIC CUT OFF IS NOW SET MORE SENSITIVE
- GREATELY INCREASING FALSE POSITIVES



THE RESULT: GREATER NUMBERS OF UNNECESSARY BIOPSIES OF BENIGN LESIONS MANY OF WHICH ARE DIAGNOSED AND SO TREATED AS CANCER. THIS ADVERSELY AFFECTS VERY LARGE NUMBERS OF PATIENTS AT GREAT COST TO THEM AND TO OUR SOCIETY.

POOR SEPARATION BETWEEN BENIGN AND MALIGNANT: MANY DIAGNOSTIC ERRORS

THE PARADOX OF EARLY SCREENING TO REDUCE SUFFERING



SO WE MUST UNDERSTAND DIAGNOSTIC ERROR GOES UP WITH DIAGNOSTIC CAPABILITY

NEED CONSULTING SERVICES?

I have extensive experience an knowledge in the following areas:

- Laboratory Medicine – 45 years
- Anatomic Pathology – 38 years
- Risk Management/Quality Management/Resource Management [**ISM**] – 35 years
- Failure Mode and Effect Analysis [**FMEA**] – 20 years
- Information Management – 50 years experience including computer programming
- Document Management – 35 years
- Knowledge Management – 25 years
- ISO 15189 Assessments – 1 year (Oh well…have to start somewhere)

Contact me at

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AVAILABLE TO CONSULT TO YOUR BOTTOM LINE; NOT OUR BOTTOM LINE

ALLOW ME TO HELP YOU APPLY INTEGRATED SYSTEMS MANAGEMENT [ISM]