Knowledge Translation
From Bench to Bedside

How do we know how to effectively intervene with a given disease/disorder? We live in an era where new research hits the news before it has undergone review, news outlets rarely understand what the research is actually telling us, and the populous rejects evidence if it does not fit their pre–existing world views. Effectively intervening requires clinicians to translate evidence into practice, but to do so they must also understand when to implement new treatments/approaches and be able to effectively communicate with their patients.

Topics: Nested Model of Health — Health Literacy — Knowledge Translation — Sources of Information — Clinical Trials — Sample Size

Healthy People is a national public health initiative to improve health and wellness over the next decade. The Healthy People initiative began in 1979 when Surgeon General Julius Richmond issued a landmark report titled "Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention" that described the present state of the nation's health and provided a list of objectives that should be addressed to promote greater population health and wellness. Healthy People 2030 — the fifth iteration of the initiative — characterizes key health objectives across health conditions, health behaviors, specific populations, settings and systems, and social determinants of health.

The **health conditions** reflect diseases and disorders which have prominent impacts upon mortality and morbidity (e.g., heart disease, cancer, respiratory diseases, stroke, osteoporosis, obesity). **Health behaviors** reflects more than just nutrition and physical activity, but also encompasses factors such as drug–alcohol–tobacco use, emergency preparedness, preventative care, sleep, and vaccination status. Objectives within **specific populations** highlight those critical outcomes within particular populations (e.g., infants, children, individuals with disabilities) that may be distinct or have greater relevance to the particular population than to the population as a whole. Objectives within **settings and systems** highlight factors such as environmental health, healthcare services, schools, housing, and transportation. Lastly, **social determinants** consider those social factors (e.g., relationships and interactions with family, friends, co-workers, and community members; economic stability; access to quality health and educational services) which are often ignored but critical factors for enhancing health and wellness. These social

determinants also consider factors associated with social, economic, and/or environmental disadvantage that result in preventable disparities in health and wellness.

Nested Model of Health — Attempts to improve health will not be successful unless overarching contexts are first addressed.

The alignment of health objectives reflects the targeting of each level of the nested model of health. To address a particular health condition, it is necessary to treat the immediate circumstances of the condition/disease. But if the health behaviors that surround that condition are not also addressed, it will simply re–emerge. While general health behaviors are beneficial, it is also necessary to adapt them to meet the specific conditions and contexts appropriate for specific populations to best meet their needs. All of these factors ultimately exist in the context of settings and systems, which if not aligned with the underlying goals of improving health will minimize the effectiveness of the specific treatment and behaviors. Finally, even these settings and systems are influenced by social determinants. So attempts at improving health cannot stop just at the specific condition or the attempt will be unsuccessful.

Figure: Nested Model of Health.

Personal Health Literacy — The degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.

Organizational Health Literacy — The degree to which organizations equitably enable individuals to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.

Healthy People 2030 also put forth health literacy as a priority area for disease prevention and health promotion. Health literacy involves more than communication between medical practitioners and their patients, or developing written materials in plain language, although these are important components. Problematically, we often choose to "let science speak for itself," neglecting that without translation or clear explanations of scientific information, many will miss opportunities to improve their health. Compounding this, people receive many health messages every day from a variety of sources — most often from sources focusing more on entertainment than accuracy. Intricate and often conflicting messages pose a challenge for the public, making it difficult to understand and act on health information. Yet this ability is essential for understanding a health risk, voting on an environmental issue, recognizing biases in health information reported by the media, or responding to alerts and warnings.

While in some ways it is reassuring that the vast majority of the population (over 50%) has sufficient literacy skills to make simple inferences regarding information they are provided and read a graph, those skills are grossly inadequate for the purposes of being able to integrate, synthesize, and analyze multiple pieces of information which may present competing or conflicting viewpoints. It is this ability that is necessary to fully be able to prevent disease and protect their health. Data from the National Assessment of Adult Literacy found that only 12% of the adult population has this full range of health literacy. Even more problematic is that over a third of the population has a only a basic or below level of health literacy. For these individuals, effectively communicating health needs becomes highly problematic as they lack the fundamental skills to allow for effective knowledge translation.

> **Below Basic level** — Has only the most elementary literacy skills. These skills range from being non-literate to being able to locate easily identifiable information in short, commonplace prose text. An adult at the below basic literacy level might be able to locate and circle the date of a medical appointment on a hospital appointment slip. Approximately 14% of the population (30 million people) has health literacy skills at this level.
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> **Basic level** — Has the skills necessary to perform simple, everyday activities such as reading and understanding information in short, commonplace texts. An adult at the basic literacy level might be able to state two reasons a person with no symptoms of a disease should be tested for the disease, based on information in a clearly written 1–page pamphlet. Approximately 22% of the population (47 million people) has health literacy skills at this level.
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> **Intermediate level** — Has the literacy skills necessary to perform moderately challenging activities, such as summarizing written text, determining cause and effect, and making simple inferences. An adult with intermediate literacy skills might be able to determine a healthy weight range for a person of a specified height by looking at a graph that relates height and weight to body mass index. Approximately 53% of the population (114 million people) has health literacy skills at this level.
>
> **Proficient level** — Has the skills to perform complex activities, such as integrating, synthesizing, and analyzing multiple pieces of information. An adult at the proficient level might find the information required to define a medical term by searching through a document. Approximately 12% of the population (25 million people) has health literacy skills at this level.

While we have little ability to dictate the level of personal health literacy of the individuals we are tying to work with, efforts to enhance **Organizational Health Literacy** center around recognizing communication barriers and trying to address them to enable the public to understand and act on health related information. Research in this area has observed that the use of technical or medical terminology is most often misinterpreted/misunderstood — a characteristic marketing companies capitalize on. Further, as a result of influencers, celebrities, and politicization surrounding some words (e.g., pandemic, immunize, family planning), communication can break down and

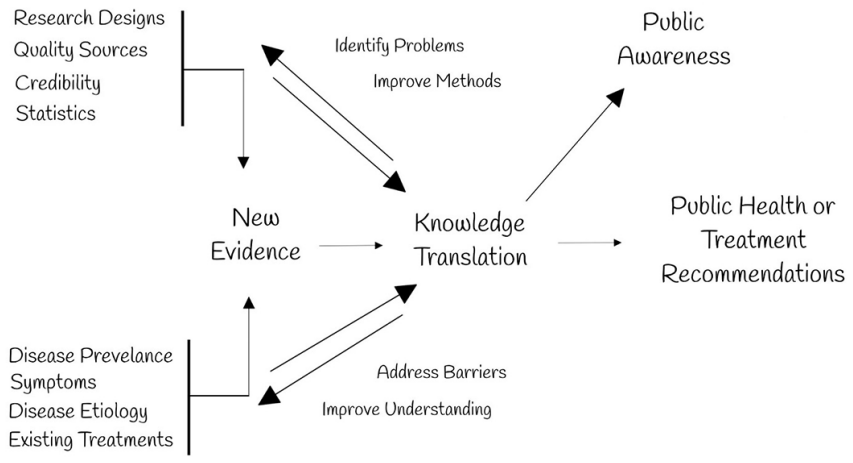
health-related messaging can be lost if we do not take these factors into account. A related issue is that cultural differences and differences in language and word meanings can lead to misinterpretation and poor understanding. For instance, consider that the term 'transition' is most often used within the context of healthcare to reflect the shift from curative health approaches to palliative (end of life) care. But efforts to promote greater awareness of the need for transition care services within a community are likely to be interpreted in a vastly different manner.

Research in this area has identified three major ways in which knowledge translation would be enhanced through improving organizational health literacy. The largest benefit occurs by **using plain language**. This presents as a challenge as most experts have spent their careers being taught to use very precise technical terminology — using terms that provide the precise location, orientation, function, and state of a given tissue, however when communicating to the general public they likely lack sufficient personal health literacy to fully understand such technical terms. Conversely, we also have to be aware that evidence also shows us that when public health campaigns only use plan language that those with greater health literacy push back against it because of a lack of precise language — they have enough knowledge to devalue statements that lack the technical precision they have come to expect. Accordingly, the second way to enhance knowledge translation is to **keep the intended audience in mind and specifically seek out and engage their help to ensure that the information you are trying to convey is being received**. Engaging with those within the community at that level and tailoring messaging to each health literacy level as a part of a cohesive approach has generally been found to be more effective. Finally, a criticism of many public health campaigns is that they focus only upon information (i.e., risk of cancer), rather than actions. By **focusing communication efforts on what we want the public to do** rather than what they should know, we are more likely to achieve improved public health.

Translating Evidence into Practice

Understanding these factors is critical in clinical practice for working with those under our care, but how do we inform and revise our actual clinical practices? Stated differently, how does new evidence/findings make its way into public health messaging and treatment recommendations? Although medical practitioners do receive training in basic research, findings from this area consistently show that the vast majority of clinicians lack the skills needed to effectively determine how and when to implement new findings into their clinical practice. In many ways, data on such abilities mirrors that of the general public with regard to health literacy. Being able to effectively incorporate research findings into clinical practice is itself a skill that requires considerable expertise. Even among those clinicians who are MD/PhDs (meaning they completed dual degrees in medicine and research), there is considerable variability in such abilities. Such variation is largely attributed to the wide degree of program emphasis where some programs chunk the training such that students complete their research training first before going on to their medical training — thus having similar training as someone who did a PhD alone; while other programs have students complete their research and medical training concurrently — with some students obtaining less than 10% of the research training a typical PhD student would receive.

Figure: Knowledge Translation Approach.



Being able to understand new research evidence requires considerable knowledge and skill. Research expertise regarding research designs, quality sources, research credibility, and statistics all must be utilized to critically evaluate the quality and impact of the findings. Similarly, medical expertise on the disease prevalence, symptom presentations, disease etiology (underlying causes), and

existing treatment must be utilized to examine the relevance of those findings for a particular population, within its given context — drawing from the Nested Model of Health. The basis of effective **knowledge translation** is that these different areas of expertise come together to inform the research that is conducted but also how it should be interpreted and the weight any given findings should be given.

Ideally such knowledge translation forms a bidirectional relationship such that the new evidence is able to address barriers and improve understanding with regard to medical expertise as well as to identify problems and improve methods with regard to research expertise. Such a cyclic approach optimizes the potential insight new findings can provide with regard to clinical practice. At which point, the findings can be critically evaluated to determine how they might alter clinical practice and make their way into public health recommendations and treatment approaches. Ideally it is only after this point that public awareness campaigns begin. Given the expertise required, some medical specialties have adopted a knowledge translation approach where they specifically employ individuals with the relevant expertise to perform this process and make recommendations for changes in clinical practice. However, within the US there is a great deal of variation in this as some medical groups rely on individual practitioners to `keep up with current research', others pay for–profit companies to attend medical training sessions where the company tells the clinicians what practice they should be doing, and some groups rely upon the insurance companies to decide what is the best treatment delaying implementing the newest approaches until they have been assigned billing codes and are accepted by the insurance company.

In order to properly evaluate any new finding, it is important to understand the nature of different sources of information. **Systematic Reviews** are publications that offer expert summaries of how other studies and findings fit together to inform a body of literature. **Meta–analyses** are publications that utilize statistical approaches to combine the findings of other research to provide a more robust assessment of the question of interest or tease apart relevant factors that may not have been assessed within the individual studies. Systematic Reviews and Meta–analyses represent **filtered sources** of information as the authors are combining many different research findings to help eliminate inconsistent findings (i.e., noise) and ensure that the conclusions represent findings of high quality research — or at least providing an assessment of the quality of the research. **The general recommendation is that clinicians/practitioners should only be looking at these sources of information to inform their practices**, as they reflect a source of information that is less likely to be skewed.

Figure: Sources of Information.

Unfortunately, examination of where clinicians/practitioners and even the general public get their `research' from indicates that the vast majority rely upon **Editorial** sources which include things like letters to the editor, blogs, hospital websites. Even AI sources currently predominately pull from such sources. The issue is that in many cases these are often written by non–experts — an extremely prominent and distinguished hospital renowned for their medical practice was found to be employing current undergraduate students in premedical fields to write medical blogs and authoritative postings on diseases (in some cases even attributing the writing to well–known or prominent clinicians). As editorials are not typically reviewed by experts — where the authors arguments and perspectives would be critically evaluated, clarified, and potentially suppressed if not backed by sufficient evidence — the authors have free rein to make whatever claims they want.

Case Studies reflect a type of publication where a single individual will be followed and assessed. While insightful, it is important to keep in mind that such an individual usually represents an abnormal responder or rare circumstance that may not generalize well to the public. There are also criticisms in some research areas regarding authors excessively publishing highly–related case studies to artificially inflate their total number of publications or hide the absence of a true finding had the authors combined all of the individual cases into a larger sample to assess. **Cross–sectional Studies** are publications that examine a snapshot of a given population at a particular moment. While such sources of information can provide key insights into differences that might be present between groups; they lack the ability to assert any causal claims as any differences may actually have occurred randomly or could be reflective of some other factor.

Prospective and Retrospective Studies are publications that incorporate a longitudinal component to enable greater insight into how a factor of interest might contribute to differences between groups emerging. Prospective research will typically assess the individual for the factor of interest (such as consumption of a particular substance) and then follow up with them after some period of time (typically years) to determine if that factor relates to the question they are looking at (such as risk of diabetes). Alternatively, retrospective research will assess the individual for the question they are looking at (such as presence of diabetes) and then will utilize historical sources of information (such as medical records) to assess the factor of interest (such as birth weight).

Although prospective and retrospective studies provide greater insight into how a factor might contribute to changing a particular outcome, the general guidance is that to establish a causal relationship it is necessary to conduct a **Clinical Trial** (also known as a Randomized Controlled Trial) where individuals are randomly assigned to particular groups and those groups are provided an intervention that specifically manipulates the factor of interest (such as administration of a vaccine) to determine how it relates to the outcome of interest (such as incidence of measles). Sources of information such as editorials, case studies, cross–sectional studies, prospective and retrospective studies, and clinical trials are considered **unfiltered sources** as they reflect single sources that may present a skewed or inconsistent perspective with that of the rest of the body of evidence in a field. Thus, while caution is warranted in interpreting them; they generally exist on a continuum with editorials serving as the weakest source of evidence and clinical trials serving as the strongest source of evidence.

A general tendency that has emerged over the last several decades — coinciding with pushes for evidence–based medicine — is a perspective that without a clinical trial specifically showing the benefit of a particular treatment or approach that we should not be doing it. While certainly we can acknowledge that other research designs may lack the ability to provide causal claims and represent weaker designs, at what point does the weight of evidence counteract a lack of a clinical trial? If 20,000 studies using a variety of weaker designs suggest a benefit; should we refrain from utilizing such evidence to change our practice if there are only 2 clinical trials — what if those trials found minimal benefits? A popular real world example of this is if it is necessary to conduct a clinical trial to determine if parachutes prevent death from jumping out of a plane. Should we recommend that individuals who are going to jump out of a plane not wear a parachute given that there are findings from a clinical trial that found no difference in death or injury rate between those who jumped out of the plane wearing a parachute and those who jumped out of the plane

without a parachute — the study was actually conducted to highlight to absurdity of this tendency and had participants jump out of a plane that was on the ground with participants falling less than 5 feet.

It is also important to keep in mind that the term clinical trial is itself nuanced as there are several different types of clinical trials referred to as **Phases**. Broadly speaking, **Phase I clinical trials** aim to provide an initial assessment of an intervention (e.g., a drug, diagnostic test, device) to determine if it is safe, how to implement the intervention, identify any side effects or problems, and determine maximum safe dosages. These trials usually utilize a very small number of participants (typically less than 30) and cycle through new groups of participants while increasing dose of the intervention while also assessing for side effects or problems. This helps to determine what the maximum safe dosage might be or at least characterize the issues that might occur if the clinical trial progresses to the next stage. As **Phase I clinical trials are focused on safety**, they do not typically assess if the intervention has an impact on the outcome. Phase I trials are considered as exploratory trials as the impacts of the intervention are unknown.

Phase II clinical trials aim to establish how the intervention impacted the outcome of interest — referred to as efficacy. The efficacy of the intervention reflects how well it worked under a controlled ideal setting. These trials will usually utilize a moderate number of participants (typically 30 to 100) to provide an initial assessment of the potential benefit of the intervention while also monitoring for any side effects or problems. Phase II clinical trials represent the broadest category of types of clinical trials and modern research approaches do not always clearly fit within these traditional `phase' descriptors, but classically this phase would be reflective of what is known as a **single–arm clinical trial**. Single–arm clinical trials are research designs where only a single group is used — so there is no control group. Modern research approaches — particularly for drug trials — will use multiple arms (groups) with different groups receiving different dosages (called non–comparative arms) and may even incorporate control groups (called comparative trials). Nevertheless, **the focus is on the magnitude of the change in the outcome variable of interest** — referred to as the effect size. The goal is to determine what interventions have sufficient impact on the outcome variable to warrant more extensive investigation **while also understanding the risk of potential side effects and issues and the safety of the intervention**. Phase II trials are typically considered as exploratory trials as the impacts of the intervention are unknown, but some interventions go through multiple Phase II trials to refine and confirm the effects.

Phase III clinical trials aim to **prove if the intervention actually works**. Phase III clinical trials are what most people think of in regards to a clinical trial. Although modern research approaches can utilize much more complex designs, the typical characterization is that participants are randomly assigned to an intervention group or a control group. The outcome variable of interest (such as blood pressure) is assessed before the start of the intervention, potentially at various points after that, and again after stopping the intervention — and potentially at various points after halting the intervention. Phase III clinical trials are considered as confirmatory trials as the purpose is to confirm if the effect of the intervention is better than the effects observed in the control group.

Depending upon the particular intervention, the control might utilize a **Placebo** or **Sham** control to ensure that any observed effects are not the result of expectancy or changes in behaviors unrelated to the intervention. A placebo is an inert substance or treatment that looks and/or tastes like the active treatment but lacks the ingredient of focus for the intervention. So taking a pill that looks and tastes like the drug that is being tested but lacks the key drug. A sham is a simulated or fake medical treatment/device. So a sham control for a surgical technique might have the animal model still be cut open, but the actual surgical technique not take place.

Although placebo or sham controlled trials are critical for evaluating the efficacy of new interventions, in some cases it may be amoral to use. Consider the situation of a new treatment for a particularly aggressive form of cancer, one group would be assigned to receive the new cancer treatment, but would it then be acceptable to assign the other group to receive a placebo or sham treatment that you know will have no benefit — meaning their aggressive form of cancer will be free to progress? Outside of more mechanistic studies that are trying to tease apart why an intervention works/or doesnt work; most modern Phase III clinical trials use what is called a **non–inferiority** or **standard of care** approach. In these approaches, the new intervention is specifically tested against the current medical treatment approach (the one that would continue to be used if the new intervention fails).

The benefit of non–inferiority or standard of care approaches is that the control group is able to continue to receive treatment at the level they might expect if they were not participating in a research study. It also facilitates knowledge translation as the trial is able to determine if the new approach is better (or has a similar effect with fewer side effects/issues). Consider the situation where a new drug is tested against a placebo control and found to result in a 50% reduction in symptoms. By itself that sounds great, but if the existing treatment results in an 80% reduction in symptoms then the new treatment is

actually worse than the current standard of care. Without testing them against each other though, it would be possible to claim that we don't actually know that the new drug is worse as there is always some degree of variation in efficacy (standard error). The non–inferiority or standard of care approach means that we only have to test it once instead of testing it against a placebo and then again against the existing treatment.

Phase IV clinical trials aim to assess **the long–term safety and effectiveness of the intervention**. While the term **efficacy** characterized how large of an effect there was under ideal controlled circumstances, **effectiveness** characterizes the ability of an intervention to produce the effect in a real–world setting — where people do not always remember to take their pills or follow the prescribed dosing pattern. Phase IV clinical trials typically occur after a new intervention has obtained regulatory approval and has been implemented within clinical practice. Drugs that are pulled from the market are typically done so in this phase as additional side effects or issues begin to emerge that were not observed in earlier phases.

A common misconception surrounding clinical trials is that they need to have tested hundreds of thousands of individuals in order to be valid. The reason Phase I and Phase II clinical trials typically have a small number of individuals in them is due to safety concerns. In these phases, the potential for side effects and issues is not fully known so ethically it is important to minimize the potential for harm by keeping the number of participants small. Once the potential for side effects and issues is better known (after progressing through Phase I and II trials), the benefit of having larger sample sizes in Phase III and IV clinical trials is that it increases the likelihood for potential side effects and issues to emerge. As it is not possible to test every person or situation in the world, it is necessary to rely upon a subset of individuals and infer that they reflect upon the rest of the population.

Thus, while having larger samples gives greater insight into the safety profile of a given intervention; it has little impact upon the effect of the intervention. The exception being if the clinical trial sample grossly neglected a particular population subgroup — but that is a sampling issue not a sample size issue. **There is no universal minimum number of participants that are needed to be obtained in order to obtain a valid statistical inference regarding how the intervention changes the outcome variable**. Just because a study uses only a few individuals does not make their findings any less valid. In general, very strong or large effects require a much smaller number of participants for the effects to be apparent. Very weak or small effects require a much larger number of participants for the effects to be apparent.

For example, if a study was comparing the effect of Methylphenidate (an ADHD drug known as Ritalin) against a placebo on attention; it would take very few participants for the effects to become clearly visible. If a study was comparing the effect of Acetaminophen (Tylenol) against Naproxen (Aleve) to determine which was more effective in pain management; it would take a substantially larger number of participants for the effects to become visible. If a Phase III clinical trial requires hundreds of thousands of participants to show an effect, the magnitude of the effect is likely to be minimal — because why would they spend that much time and money if they could show the effect with a smaller group. **When the magnitude of the effect is small, questions regarding the clinical significance of the effect begin to occur**.

Additional Resources:

Yeh, R. W., Valsdottir, L. R., Yeh, M. W., Shen, C., Kramer, D. B., Strom, J. B., … & Nallamothu, B. K. (2018). Parachute use to prevent death and major trauma when jumping from aircraft: Randomized controlled trial. BMJ, 363, k5094. https://doi.org/10.1136/bmj.k5094

How do we know where to start?

Health People Initiative

- Started in 1979 from the report: Healthy People: "The Surgeon General's Report on Health Promotion and Disease Prevention"
  - Described the present state of the nation's health
  - Provided a list of objectives that should be addressed to promote greater population health and wellbeing.
- Healthy People 2030 is the fifth iteration of the initiative.

Healthy People 2030

Key Health Objectives

Health Conditions

Diseases and disorders which have prominent impacts upon mortality and morbidity.

- Addiction
- Arthritis
- Blood Disorders
- Cancer
- Chronic Kidney Disease
- Chronic Pain
- Dementias
- Diabetes
- Foodborne Illness
- Health Care-Associated Infections
- Heart Disease and Stroke
- Infectious Disease
- Mental Health and Mental Disorders
- Oral Conditions
- Osteoporosis
- Overweight and Obesity
- Pregnancy and Childbirth
- Respiratory Disease
- Sensory or Communication Disorders
- Sexually Transmitted Infections

Healthy People 2030

Key Health Objectives

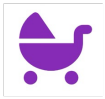
Health Behaviors

Physical activity, nutrition, drug, alcohol, tobacco, emergency preparedness, preventative care, sleep, vaccinations.

- Child and Adolescent Development
- Drug and Alcohol Use
- Emergency Preparedness
- Family Planning
- Health Communication
- Injury Prevention
- Nutrition and Healthy Eating
- Physical Activity
- Preventive Care
- Safe Food Handling
- Sleep
- Tobacco Use
- Vaccination
- Violence Prevention

Healthy People 2030

Key Health Objectives



Specific Populations

Critical outcomes within specific populations (infants, children, individuals with disabilities, older adults)

- Adolescents
- Children
- Infants
- LGBT
- Men
- Older Adults
- Parents or Caregivers
- People with Disabilities
- Women
- Workforce

Healthy People 2030

Key Health Objectives

Settings and Systems

Environmental health, healthcare services, schools, housing, and transportation.

- Community
- Environmental Health
- Global Health
- Health Care
- Health Insurance
- Health IT
- Health Policy
- Hospital and Emergency Services
- Housing and Homes
- Public Health Infrastructure
- Schools
- Transportation
- Workplace

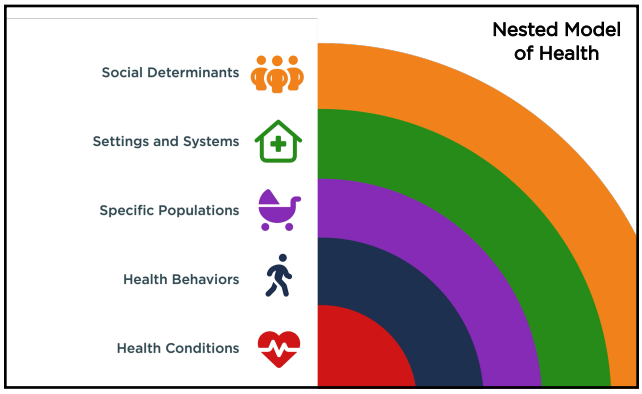
Healthy People 2030

Key Health Objectives

Social Determinants

Family, friends, coworkers, economic stability, access to quality health and educational services.

- Economic Stability
- Education Access and Quality
- Health Care Access and Quality
- Neighborhood and Built Environment
- Social and Community Context



Health Literacy

A priority area for disease prevention and health promotion in Healthy People 2030

Personal Health Literacy

The degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.

Organizational Health Literacy

The degree to which organizations equitably enable individuals to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.

Personal Health Literacy

The degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.

Below Basic Health Literacy

Requires very clear instructions, very few explanations. Information should be at a 2nd grade reading level or lower, 2-3 sentences maximum.

Personal Health Literacy

The degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.

Basic Health Literacy

Reading ability at a 6th grade or less equivalent. Reading comprehension limited. Information should be short, clear, and no more than 1 page in length.

Personal Health Literacy

The degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.

Intermediate Health Literacy

Proficient reading ability and able to extract information from a clear graphic. Difficulty with medical terminology, and synthesis of information across multiple sources.

Personal Health Literacy

The degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.

Proficient Health Literacy

Can integrate, synthesize, and analyze information across multiple sources. Has sufficient skills to find more information if they do not understand something.

Personal Health Literacy

- **36%** of the population has a basic or less level of Personal Health Literacy.
- **53%** of the population has an intermediate level of Personal Health Literacy.
- **12%** of the population has a proficient level of Personal Health Literacy.

Proficient Personal Health Literacy

- Scientific and medical information requires translation into common language.
- Conflict is often more about nuance and small details.
  - Experts arguing about when to use something and how to implement.
- Click-bait presentation of information often misses the point in favor of entertainment.
- Repetition of simple details on social media often entirely misses the main point.

Organizational Health Literacy

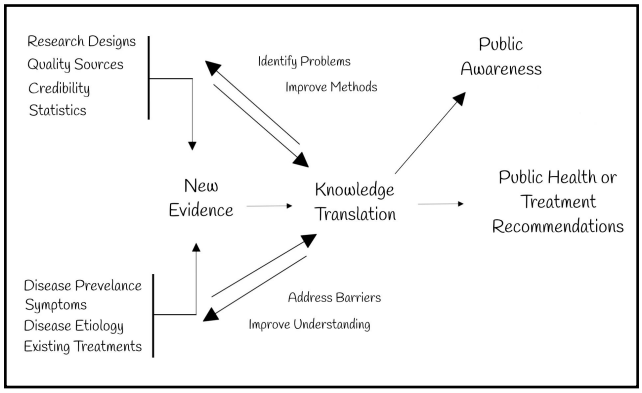
Recognizing and addressing barriers to effective communication.

- Technical or medical terminology is most often misinterpreted/misunderstood — a characteristic marketing companies capitalize on.
- Influencers, celebrities, and politicization surrounding some words (e.g., pandemic, immunize, family planning), can cause break downs in communication and health-related messaging can be lost.

Organizational Health Literacy

3 Major Ways to Improve Organizational Health Literacy

1. Use Plain Language
   Nearly a 1/3 of the population is at or below a basic level of health literacy.
2. Consider the health literacy level of the intended audience
   Phrasing, detail, word choice all matter.
   Seek out those in the community at that level and have them help you refine it.
3. Focus communication efforts on what we want the public to do



Sources of Information

Systematic Reviews

Expert summaries of how other studies fit together.

Authors have selected studies based on pre-established criteria, removing studies of poor quality or with clear flaws.

Can point out what the literature actually means and its flaws.

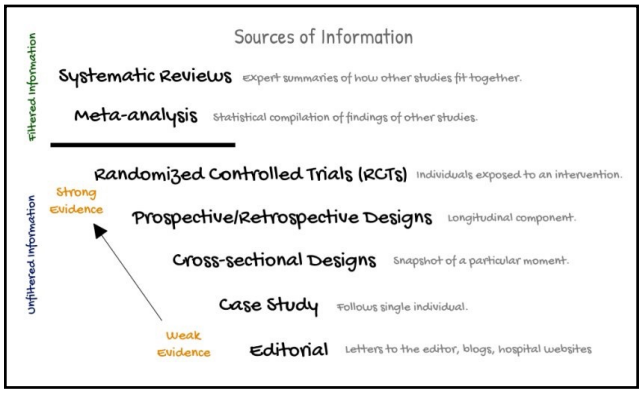
Meta-analysis

Statistical compilation of findings of other studies.

Authors have selected studies based on pre-established criteria.

Can point out consistent findings and consider other factors that might be important.

Only as good as the studies it includes.



Phase I Clinical Trial

Purpose: Provides an initial assessment of safety

- How do we best implement this?
- Are their side effects or problems that occur?
- What would be the maximum safe dosage?

- Usually use a small number of participants (<30) to minimize potential for harm.
- Considered Exploratory as the impacts are unknown.

Phase II Clinical Trial

Purpose: Provides an initial assessment of efficacy

- How well does it work under a controlled/ideal setting?
- Are their side effects or problems that occur?

- Usually use a moderate number of participants (30-100) to minimize potential for harm.
- Considered Exploratory as the impacts are unknown.

Phase II Clinical Trial

Purpose: Provides an initial assessment of efficacy

- Simplest form uses a single arm design.
  - Single group without any control comparison.

- Modern drug trials use non-comparative arms.
  - Multiple groups but each group is assessed by itself.
  - The focus is on the magnitude of the change in the outcome variable.

Phase III Clinical Trial

Purpose: Prove if the intervention works

- Random assignment to intervention or control.
- Statistical tests to see if the groups actually differed.
- Side effects/problems are not always assessed.

- Considered Confirmatory as the impacts are known prior to the start.

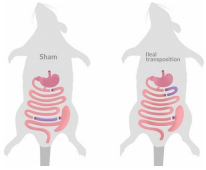
What if just being in a trial makes you better?

Placebo Control

Inert substance or treatment that looks and/or tastes like the active treatment but lacks the ingredient of focus.

Sham Control

Simulated or face medical treatment/device.



Phase III Clinical Trial

Purpose: Prove if the intervention works

- Placebo/sham controls are typically used for studies about mechanisms and why something works/doesn't work.
- Most trials use a Non-Inferiority or Standard of Care as a control condition.
  - The new intervention is tested against the current best treatment.

Phase IV Clinical Trial

Purpose: Track long-term safety and effectiveness

- Does it work in the real-world setting?
- Usually implemented after the drug/treatment has obtained regulatory approval and has been implemented into practice.

Phase I and Phase II Clinical Trials

The effects are not known.

A smaller number of participants are used to intentionally reduce the potential for harm.

Phase III and IV Clinical Trials

We have a decent idea of the side effects/problems that could occur.

The use of a larger sample increases the likelihood of rare or uncommon side effects to occur.

Inferential Statistics

The process of inferring a relationship or effect for the world (population) based upon a sample of data.

- We cannot test every person or situation in the world, so we use a subset of observations and infer that it applies beyond that sample.

Inferential Statistics

There is no universal minimum number of samples that must be obtained for the inference to be valid.

- Just because a study only uses a few individuals does not necessarily make the inference any less valid.
- Very strong/Large effects require a small number of samples.
- Very weak/Small effects require a large number of samples.

Knowledge Translation Worksheet

1. Environmental health is considered as a part of what area of the Healthy People 2030 objectives?

2. What are the 3 innermost layers of the Nested Model of Health (from deep to superficial)?

3. What are the 3 outermost layers of the Nested Model of Health (from deep to superficial)?

4. What percent of the population has a Proficient level of personal health literacy?

5. An individual who can only understand information written in small 1 page or less segments written with common everyday words would have what level of personal health literacy?

6. What are three ways for improving organizational health literacy?

7. What is the difference between a systematic review and a meta-analysis?

8. A position statement written by a panel of experts would be considered as what type of information source?

9. What is the primary purpose of a Phase I clinical trial?

10. What is the primary purpose of a Phase II clinical trial?

11. What is the primary purpose of a Phase III clinical trial?

12. A randomized controlled trial was conducted in a sample of 30 individuals to determine the efficacy of a new drug using a single arm design. What phase of clinical trial is this likely to be?

13. A randomized controlled trial was conducted comparing the effects of a new medical device against a device that looked and felt like the new medical device. What type of control is being used?

14. What is the reason a non-inferiority control is viewed as superior to a placebo control in the context of a clinical trial?

15. Vaccine B is being tested against the current standard of care Vaccine A as a non-inferiority control. Although no differences in the safety or efficacy were observed between Vaccine B and Vaccine A; Vaccine A has been previously shown to have greater efficacy than a placebo control group. What is our interpretation of Vaccine B?

16. What is the difference between Efficacy and Effectiveness?