CLINICAL & MEDICAL BENEFITS

Procedures & Guidelines

Diagnostic procedures ▸

Definition: **Methods and techniques performed to diagnose disease, disorders, or conditions.** Biological samples such as blood, urine, or saliva are used to detect the presence of bacteria, fungi, or other markers to diagnose a disease, disorder, or condition.

Rationale: Diagnostic procedures that are accurate and reliable make for a more efficient health care system by streamlining treatment and recovery, enhancing the quality of patient care, and reducing health care costs.

Investigative procedures ▸

Definition: **Research methods used in preclinical, clinical, and other scientific studies.** Investigative procedures commonly involve interaction between a researcher and patients. Examples include procedures to assess the safety, efficacy, or effectiveness of a medical device or treatment. Research methods used in preclinical, clinical, and other scientific studies.

Rationale: Investigative procedures are the cornerstone of scientific discovery using the scientific method to test a theory, model, or hypothesis. New avenues of investigation bring innovation and efficiency to laboratory, genomic, clinical, and epidemiologic study design.

Guidelines ▸

Definition: **Formal recommendations or principles to assist with patient care for specific clinical circumstances.** Guidelines are issued by professional organizations, government agencies, and nonprofit organizations (*e.g.*, American Academy of Pediatrics, American Medical Association, World Health Organization, U.S. Preventive Services Task Force).

Rationale: Guidelines promote quality and effectiveness of health care services and procedures. Development of guidelines is based on extensive and systematic review of the literature to provide the evidence to support recommendations. Guidelines can serve as helpful evidence of translational research efforts that translate into improved health care services and procedures.

Therapeutic procedures ▸

Definition: **Methods and techniques that pertain to interventions, treatment, or prevention of diseases, disorders, or conditions.** Therapeutic procedures are performed to improve a diagnosed health concern. They encompass a variety of procedures, ranging from the administration of prescription drugs to surgical procedures to psychotherapy.

Rationale: Therapeutic procedures that improve efficiency and/or efficacy can improve the quality of health care, and reduce long-term costs.

Tools & Products

Biological factors & products ▸

Definition: **Biological substances used to indicate, diagnose, prevent, or treat diseases or medical conditions.** Examples include vaccines, blood or blood components, gene therapy, tissues, and protein therapies such as antibodies.

Rationale: By its definition, biological factors and products play important roles in each of the translational stages. Biological products are especially critical to advance research for a variety of health conditions for which no treatment is currently available.

Biomedical technology ▸

Definition: **Technological applications for measuring, diagnosing, and treating health conditions, including tools, methods, strategies, and devices.** Examples include artificial limbs or organs, new imaging systems to detect cancer, genome sequencing and editing, and nanotechnology.

Rationale: Biomedical technology translates basic science discoveries into improved patient health. This technology is often focused on finding novel ways to detect or treat illnesses that were previously untreatable.

Drugs ▸

Definition: **Pharmaceutical products for human or veterinary use intended to diagnose, treat, cure, or prevent health conditions.** They may be prescribed by a doctor or available for purchase without a prescription.

Rationale: New drugs developed as a result of translational research are a critical component to shorten the time from scientific discovery to useful clinical applications.

Equipment & supplies ▸

Definition: **Apparatus, instruments, and materials for diagnostic, surgical, therapeutic, and scientific procedures.** Equipment and supplies include scientific instruments used for basic discovery and clinical applications.

Rationale: Improvements in basic scientific instruments enhance the capacity of clinical researchers to make discoveries. Improvements in medical equipment translate scientific advances into improved patient outcomes by reducing instrument fatigue, improving recovery times, and reducing risk of injury.

Software technologies ▸

Definition: **Computer programs or software installed on mobile or other electronic devices.** Software technologies include software for diagnostics and treatment, desktop or server-installed software to track clinical trials and patient care, and mobile applications for community use.

Rationale: Software technologies span a wide range of translational benefits for patients, clinical researchers and the overall community. Software technologies help scientists diagnose and treat health conditions. They can also translate diagnostic methods and treatment guidance for community members to better manage their own health.

COMMUNITY & PUBLIC HEALTH BENEFITS

Health Activities & Products

Community health services ▸

Definition: **Diagnostic, therapeutic, and preventive health services provided for individuals in a community.** Examples include clinics, tobacco cessation, or mobile mammography vans.

Rationale: Community health services can substantially impact the population health of a community and involve community members, researchers, and physicians working together to provide services that benefit the community.

Consumer software ▸

Definition: **Digital and mobile technologies used by or for consumers to improve health care delivery and outcomes.** Consumer software runs mostly on hand-held devices (*e.g.*, smartphones and tablets, but not limited to immobile computers). These applications include allowing access to health care visit summaries, activity or calorie tracking, and diabetes treatment.

Rationale: Consumer software can inform doctors about patients' environment and behaviors, deliver health care in real-time, and provide personalized data to inform future treatments and be aggregated for population-level analysis. Consumer software can potentially provide the data necessary to create methods/interventions for treatment and patient behavior.

Health education resources ▸

Definition: **Educational resources that lead to the improvement of health of individuals, populations, or communities.** These often take the form of websites, toolkits, and print materials promoting health programs and activities that individuals themselves can do to improve their health, including resources for healthy recipes & active living.

Rationale: Heath education resources serve as potential evidence of knowledge translation to patients and the community. They also serve as preventive strategies that go beyond scientific translation by informing patients and community members of health benefits and risks through audience-targeted delivery and execution.

Health Care Characteristics

Health care accessibility ▸

Definition: **Increased equity and ability for all to gain entry to and to receive services from the health care system, regardless of race, ethnicity, age, income, ability, sex, gender, sexual orientation, geographic location, or health status.** Access to health care consists of three core elements: access to the health care system (through insurance coverage), services located nearby, and access to a provider with whom the patient trusts and can communicate.

Rationale: Health care accessibility increases the impact of translational science by helping innovations reach as many people as possible, especially vulnerable, at-risk populations. Strategies that enhance health care accessibility demonstrate coordinated translational science efforts among scientists, health care providers, insurers, government regulators and the community to optimize community health outcomes.

Health care delivery ▸

Definition: **Improved provision and distribution of health services to a patient population.** Delivery systems typically include healthcare providers, insurers, and government regulators. Health care delivery is measured in terms of cost, method of payment, regulation, and quality of care.

Rationale: Effective and efficient mechanisms to deliver health services to a target population require transdisciplinary collaboration and widen the impact of evidence-based medicine and health practices.

Health care quality ▸

Definition: **Improved general characteristics and quality of the health service or care provided based on accepted standards of quality.** Health care quality is measured in terms of effectiveness of care, equity of care to patients with different characteristics, patient experience, complications, unplanned readmissions, and delays in receiving care. Data on these characteristics must be regularly collected to maintain and improve quality.

Rationale: Health care quality informs entire health care systems and is constantly being redefined based on new research and changing patient characteristics. Clinical science uses health care quality to identify strengths and weaknesses of interventions through both qualitative (patient satisfaction) and quantitative (patient remittance rates) measures. Translational science uses health care quality definitions to interpret interventions across different fields with similar health care quality standards.

Health Promotion

Disease prevention & reduction ▸

Definition: **Resources that enhance health promotion and disease prevention in communities or populations.** Disease prevention resources focus on reducing the development and severity of disease, such as vaccination and maternal and child health programs. Health promotion resources focus on empowering people to take control of their own health by increasing healthy behaviors, such as nutrition counseling services or support groups. Other indicators can have implications for disease prevention, including community health services, health education or policies.

Rationale: Disease prevention & reduction advances are created through clinical research, but the methods of that research are instructed by how it will be adapted into the population and practice-based evidence (translational research). Meaningful disease prevention & reduction research is informed by clinical and translational research. For example, a very expensive vaccine that has 100% efficacy rate will not translate into as effective disease prevention and reduction intervention as an inexpensive vaccine with 90% efficacy rate.

Life expectancy & quality of life ▸

Definition: **Improvement in the average age of death or how often illness and injury impedes everyday life for a particular population.** Life expectancy measures how long a person can expect to live. Quality of life can be measured in terms of living conditions, physical health, mental health, social relationships, level of independence, economic security, safety, or basic human rights.

Rationale: Enhancement of well-being among community members is a key goal of clinical and translational research. Increases in life expectancy and quality of life are frequently used to assess community health.

Public health practices ▸

Definition: **Organization or delivery of public health services benefits to communities or populations.** Examples include routine public health surveillance, emergency response activities such as contact tracing during disease outbreaks, and program evaluation.

Rationale: Public health practices apply scientific knowledge to improve the health of a specific community through activities to reduce the incidence and severity of diseases and injuries. Public health practices are typically designed to benefit the community from whom information is gathered.

ECONOMIC BENEFITS

Commercial Products

License agreements ▸

Definition: **Governmental permits based on intellectual property.** Washington University defines a license as "a contract which awards to a party other than the owner(s) of the intellectual property the right to make, use, sell, or import products or services based on the owner's intellectual property. Licenses may be awarded on an exclusive or nonexclusive basis and may provide for payment of license fees, milestones, royalties, or other income to the owner(s) of the intellectual property."

License agreements may be awarded for vaccines, drug deliveries, medical devices, imaging, software, algorithms, blood and tissue products, cellular and gene therapy, among others.

Rationale: Researchers develop new technologies to diagnose and treat disease, which may have possible commercial use. A license allows for exploration of applications for potential human benefit. License agreements also document use of intellectual property that leads to real-world impacts.

Non-profit or commercial entities ▸

Definition: **Creation of businesses or non-profit organizations. Nonprofit organizations often focus on a specific disease, supporting preclinical and clinical development and increasingly, overseeing project management.** Commercial entities support the production, distribution, and marketing of a wide variety of research products and services to bring them to the market. Examples include organizations that could connect basic scientists and clinicians in specific areas to move studies forward, aid in the dissemination of new diagnostic procedures, or help increase access to services in low-resourced communities.

Rationale: Creating a commercial or nonprofit organization helps increase the translational impact of scientific discoveries by helping to reach more people. Organizations that are established as a result of an existing need in translational research or a need identified through clinical and translational research can have benefits all along the translational research continuum.

Patents ▸

Definition: **Government authority or licenses based on intellectual property.** Patents may be secured for many components of the research process, including novel laboratory techniques, devices, drugs, or unique biological materials such as cell lines or proteins. Patentable inventions must be novel, useful, and not obvious to trained researchers.

Rationale: Patents serve as a useful indicator of innovation and future economic potential. Patents also document the use of intellectual property that leads to real-world impacts.

Financial Savings & Benefits

Cost effectiveness ▸

Definition: **Improvement in the benefits of a program relative to its cost.** Cost-effectiveness analysis takes into account differences in medical costs, productivity, health outcomes with and without the intervention in place. Cost-effectiveness can be assessed for drugs, devices, programs, or other services.

Rationale: Cost effectiveness is used as an analytic tool to assess which medical care should be provided by comparing the cost and effectiveness of different interventions. It helps to inform healthcare decision-making as to allocation of funding and finding ways to deliver healthcare more efficiently.

Cost savings ▸

Definition: **Reduced financial costs of services or goods to providers or consumers.** Examples of healthcare cost savings include generic drugs, at-home testing kits, or advances in surgery techniques or equipment that allow procedures to be done at outpatient facilities.

Rationale: Cost savings for patients, medical professionals and scientists from scientific research constitute direct benefits that are measurable through comparing costs of newly developed and established drugs, procedures, and other interventions. For example, less expensive but equally effective drugs developed through translational science lower purchase costs for patients and decrease disparities in access to care.

Societal & financial cost of illness ▸

Definition: **Reduced social and economic costs of acute or chronic disease or other health conditions.** Examples include general productivity losses, reduced quality of life, and lowered resources.

Rationale: New procedures, interventions, policies, and other benefits from translational science hold the potential to alleviate undue societal and community burden, provide opportunities for reallocation of resources, and increase quality of life.

POLICY & LEGISLATIVE BENEFITS

Advisory Activities

Committee participation ▸

Definition: **Participation in advisory, standards, or other governmental or nongovernmental committees.** Researchers may contribute to a wide range of committees, such as advisory committees, ethics or oversight committees, or topic-specific subcommittees. Participation is often voluntary, but sometimes paid, and can be a significant time commitment in addition to regular scientific activities.

Rationale: Through participation in expert committees, researchers can contribute to recommendations for a range of levels, including operations of institutions, grant funding, device manufacture, and drug regulation.

Expert testimony ▸

Definition: **Formal presentation of data or results to governmental, judicial, or other regulatory bodies.** Examples include written or oral testimony before a legislative committee or a criminal or civil court case.

Rationale: Presentation of research data or results in expert testimony is evidence of potential influence on the policy-making process.

Scientific research reports ▸

Definition: **Non-technical, evidence-based documents geared toward audiences who intend to use the information for policy/behavioral change.** Target audiences include practitioners, policy makers, public health educators, and the general public. Examples include but are not limited to reports published by the National Institutes of Health, Institute of Medicine, or the Robert Wood Johnson Foundation.

Rationale: Ranging from identification of health problems to intervention evaluation summaries, these documents often provide actionable recommendations based on scientifically-derived findings.

Policies & Legislation

Legislation ▸

Definition: **Bills, laws, statutes, and ordinances passed through formal legislative bodies such as congress, parliaments, state or provincial legislatures, and county and city councils.** International legislative bodies or inter-governmental bodies may also pass legislation (*e.g.*, the United Nations or World Health Organization).

Rationale: Incorporation of clinical or translational scientific findings into new or amended laws can improve public health.

Policies ▸

Definition: **Procedural rules formally adopted and mandated by governmental agencies or private or non-profit organizations.** These include what are commonly referred to as big "P" policies (governmental) and little "P" policies (non-governmental organizational). Examples include state health board policies, hospital policies, or university policies. Policies can also include government regulations, such as those for food safety, or regulations by other organizations, such as business regulations adopted by chambers of commerce.

Rationale: Policies are produced by governmental agencies or other organizations to guide decision-making. Findings resulting from clinical and translational science can result in new or amended policies to provide a course of action or statement of principles to guide actions to effect change or build consensus. Policies differ from procedures and guidelines that serve to provide instructions or recommendations.

Standards ▸

Definition: **Formal designations of levels of quality defined by industry, occupational groups, or governmental bodies.** Standards are often developed at the national level, such as public health performance standards, product standards, hospital accreditation standards, or occupational safety standards. Standards may also be set at other levels, such as state level quality standards for clinical facilities or internal standards set by a health system.

Rationale: Standards can provide guidance for a range of activities, from laboratory testing procedures to facility operations, with the goal of improving patient and public health outcomes.