

The Gold-Standard Approach In Health Care Research

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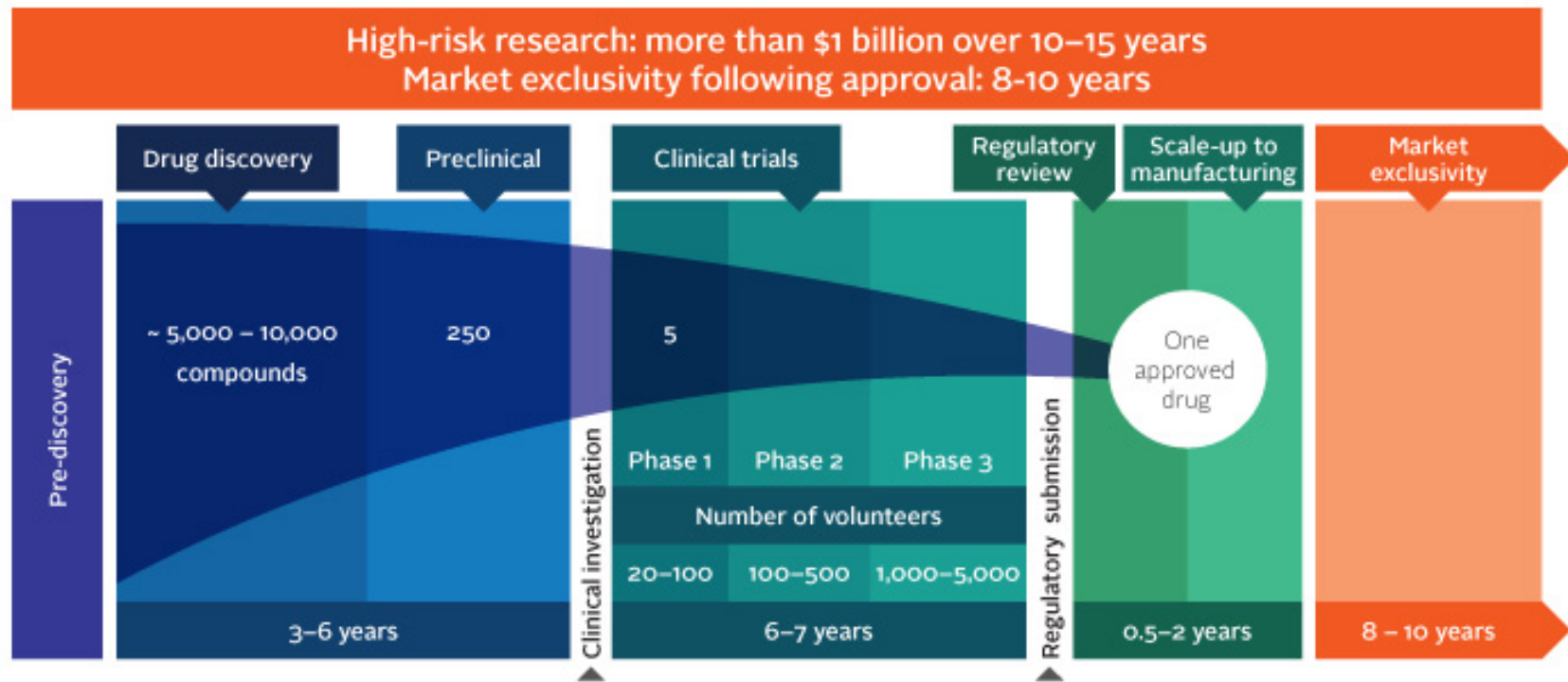
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Rigorous Research, Comprehensive Review and Evaluation

- Pharmaceutical Research
 - Phase 1 – safety, dose ranging and pharmacokinetic studies
 - Phase 2 – best dose(s) and pharmacodynamic studies - small scale efficacy and safety
 - Phase 3 – large scale efficacy and safety (double-blinded placebo controlled)
- Drug Approval – Standardized Submission and Review

New Drug Discovery & Development



After Approval

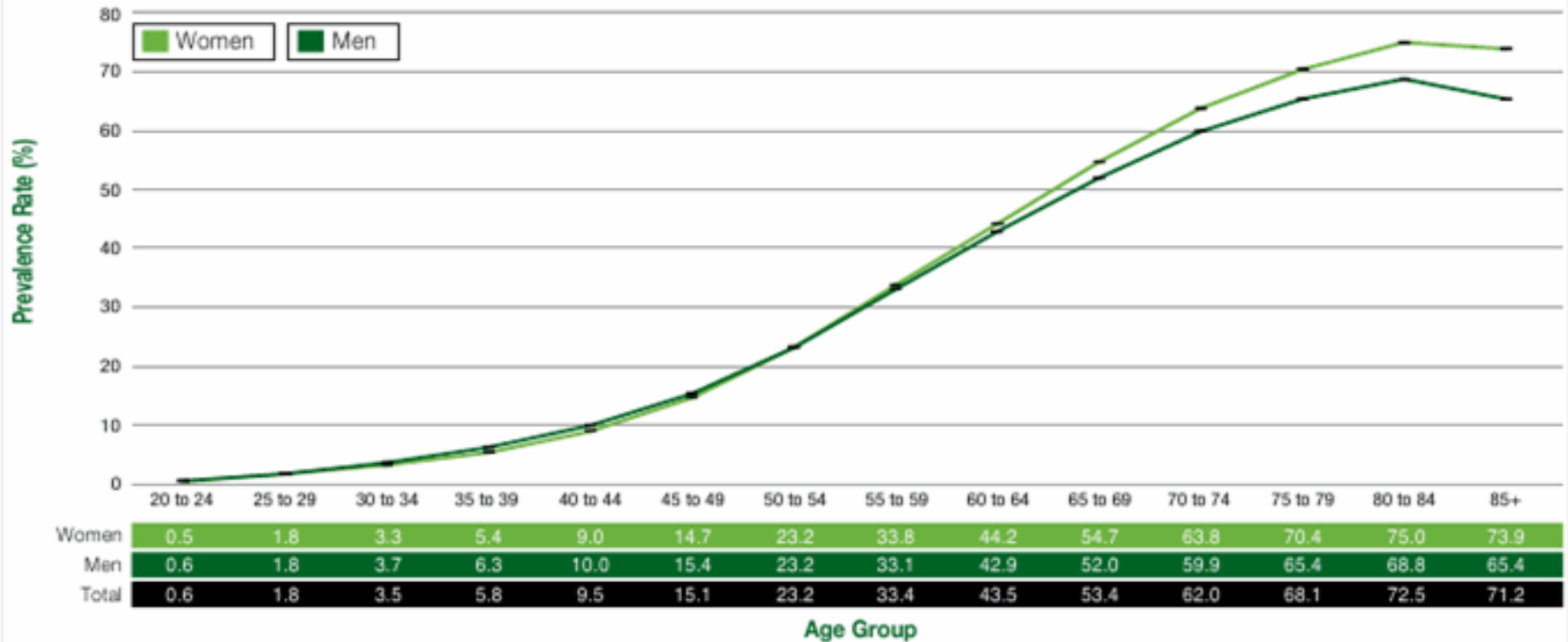
- Clinical Practice Guidelines
 - Specialists, Practitioners, Allied Health, researchers, levels of evidence, recommendation level, expert opinion
- Post-marketing surveillance / Phase 4 trials

Application of Research

- Evidence-Based Practice
 - Synthesizing and interpreting the evidence
 - Mimicking the study situation - predictability
 - Applying to the real world
- Evidence-Informed Health Policy
 - Healthcare funding is not limitless
 - how to get the most without spending the most
- Clinical Judgment / Art of Medicine

Hypertension is very common in the elderly

Figure 2. Prevalence Rates of Diagnosed Hypertension among People Aged 20 Years and Older, by Age Group and Sex, Canada,* 2006/07



Source: Public Health Agency of Canada, using CCDSS data files contributed by provinces and territories as of September, 2009.
 * Data for Nunavut and Québec were unavailable.

Pre-2008 meta-analyses show treating elderly (age 70-82) +/- efficacy with side effects, likely no clinical outcome benefit and ADRs with treatment

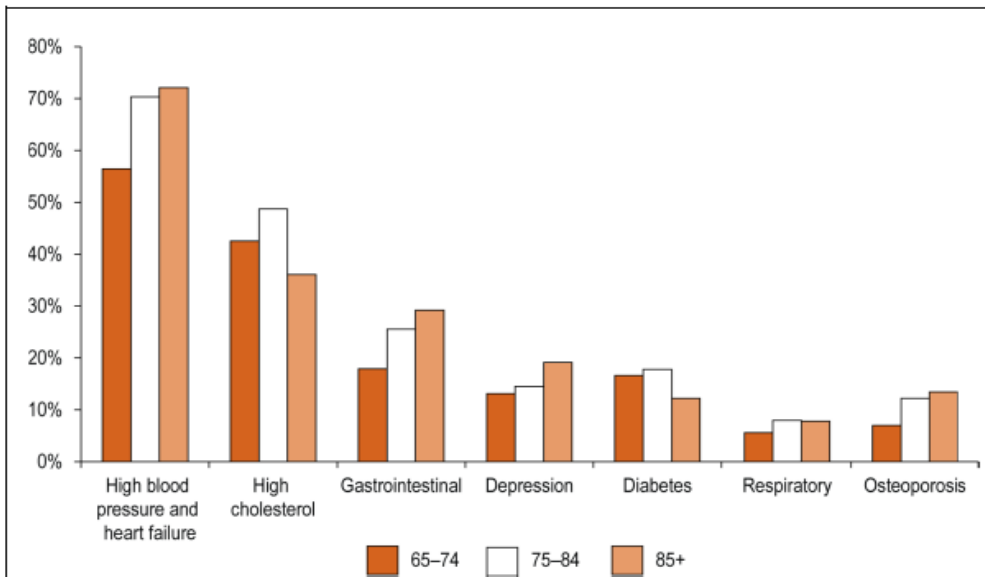
Studies in ≥ 80 are rare

- HyVET study (NEJM 2008) study looked at outcomes; whether or not to treat hypertension in the oldest old
- DB-RCT compared the anti-hypertensive medications indapamide/perindopril vs. placebo in 3845 subjects who were ≥ 80 years old - > **reduced death and events & lower rate of serious ADRs** (death=NNT 40, ADR=NNT 20)

TREATMENT DECISION IN ≥ 80 Hypertension

- Pay/use the **1)** drugs studied; **2)** another lower cost drug in the drug class; **3)** lower cost drug in another drug class; **4)** other combo of drug ; **5)** no drug and diet/exercise only

Figure 2: Percentage of Seniors on Public Drug Programs With Chronic Use for Selected Conditions,* by Age Group, Selected Jurisdictions,† 2012



Note

* Eight jurisdictions submitting claims data to the NPDUIS Database as of March 2013: Prince Edward Island, Nova Scotia, New Brunswick, Ontario, Manitoba, Saskatchewan, Alberta and British Columbia. FNIHB is excluded due to the limited availability of age data.

Source

National Prescription Drug Utilization Information System Database, Canadian Institute for Health Information.

Table 5: Top 10 Drug Classes by Rate of Use Among Seniors on Public Drug Programs, by Age Group, Selected Jurisdictions,* 2012

Drug Class	Common Uses	65-74	75-84	85+
Angiotensin converting enzyme (ACE) inhibitors, excluding combinations	High blood pressure, heart failure	25.5%	30.9%	31.9%

- * Not “reproducing the study situation ” and leaps of faith can lead to unintended consequences (ie. unclear health outcomes, impact to health research ecosystem)
- * Assess potential selection and bias of data analyses