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How to Assess Values in Drug Development?

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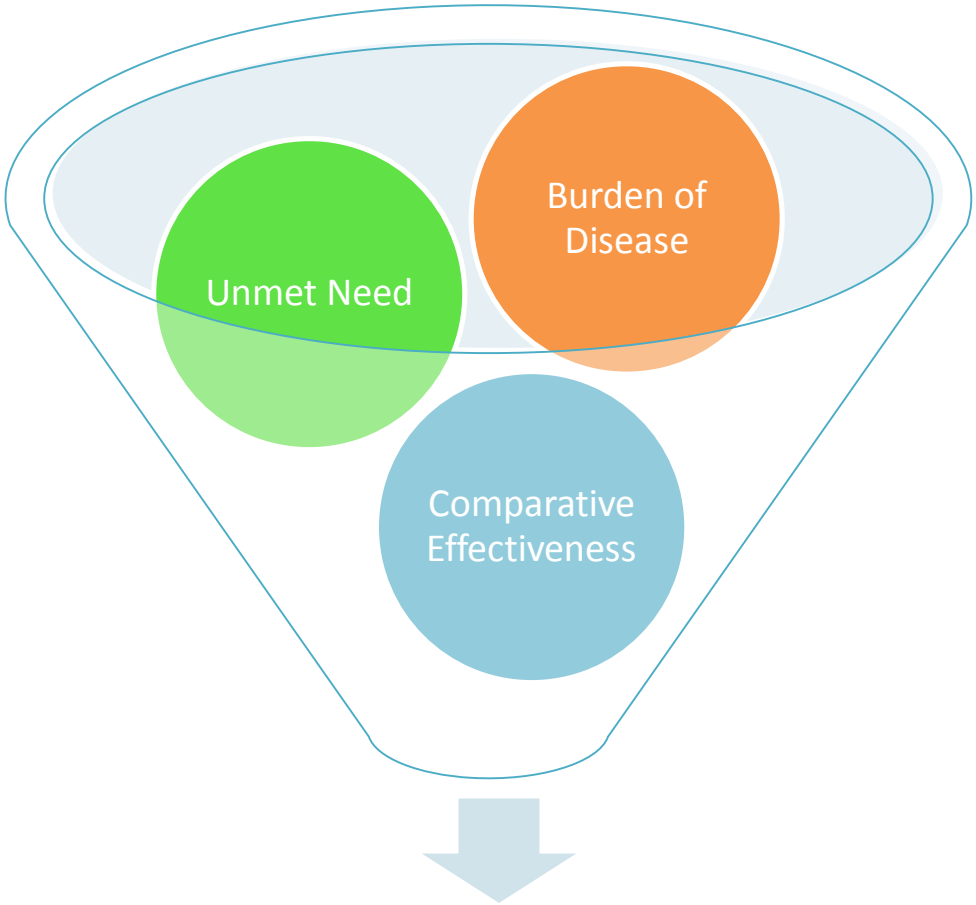

Value of Innovation

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Burden of Disease

Payor Burden

- Resource Use
- Cost of care

Patient Burden

- Impact on work life
- Impact on Quality of Life
- Economic burden (Co-pay etc)
- Caregiver burden

System Burden

- Public health implications
- Lost productivity

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Direct and Indirect Cost Burden of Chronic Hepatitis C	
Key Objective	• To estimate the direct healthcare and indirect work-loss cost burden of chronic HCV
Method	• Data Source: Health insurance claims from 60 self-insured Fortune 500 US companies covering 13 million individuals • Cohorts were matched and were compared for direct (pharmacy and medical services) and indirect (disability and medically related absenteeism) costs using per patient per year (PPPY) incremental costs (IC).
Key Findings	• Overall, HCV patients incurred significantly greater direct and indirect costs versus non-HCV patients (PPPY direct costs: $16,721 vs $6063; IC, $10,503 [95% CI, $9683-$11,361]. PPPY indirect costs: $3310 vs $1723; IC, $1523 [95% CI, $1248-$1794]). • The direct IC associated with HCV increased with disease • The indirect IC associated with HCV also increased with disease severity (non-cirrhosis
Reference	N. Tandon et al, Direct and Indirect Cost Burden of Chronic Hepatitis C. The American Journal of Pharmacy Benefits. 2015;7(4): e90-e100.

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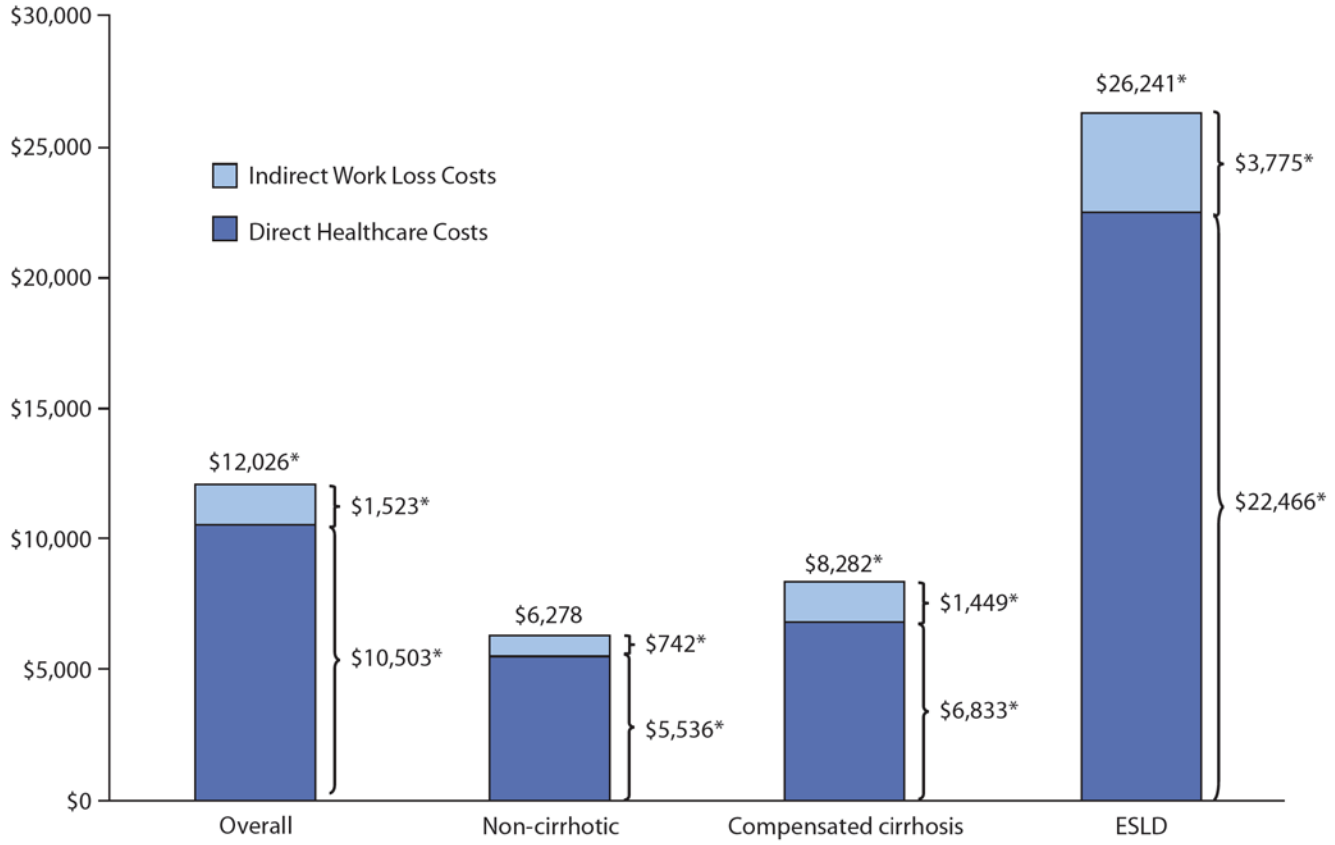
HCV Direct/Indirect Cost Burden: Incremental PPPY Costs Associated with HCV Stratified by Liver Disease Severity



- Annual all-cause direct healthcare costs were $10,503 higher (95% CI: 9,683-11,361, *P*<0.001) in HCV vs. non-HCV cohort (PPPY direct costs: $16,721 vs. $6,063)
- Incremental costs increased with disease severity (cost difference [95% CI]: non-cirrhosis=$5,536 [4,844-6,333]; compensated cirrhosis=$6,833 [5,326-8,474]; ESLD=$22,466 [20,182-24,729])

*Denotes statistically significant comparison (*P*<0.001) of HCV vs. non-HCV patients; PPPY: per person per year; ESLD: end stage liver disease

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Unmet Need

- Current treatment patterns
- Effectiveness of current treatments
- Drivers of cost
- Impact on co-morbidities

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	Impact of Chronic Hepatitis C (CHC) Treatment on Post-Therapy Healthcare Costs
Key Objective	• To evaluate the healthcare cost alleviation associated with treatment of CHC.
Methodology	• Data Source: Health insurance claims from 60 self-insured US companies were analyzed (01/2001–03/2012). • During the post–48-week treatment period, cohorts were compared for healthcare resource utilization using rate ratios (RRs), as well as healthcare costs using per-patient per-year (PPPY) cost differences.
Key Findings	• A total of 1017 patients who completed and 953 patients who discontinued interferon therapy were identified. • Relative to the discontinued therapy cohort, the completed therapy cohort had significantly fewer hospitalizations, outpatient visits and ER which translated into significantly lower total healthcare costs PPPY and hospitalization • Non–CHC-related costs accounted for 55% and CHC-related costs accounted for 45% of the all-cause cost difference between cohorts.
Reference	N. Tandon et al, Impact of Chronic Hepatitis C (CHC) Treatment on Post-Therapy Healthcare Costs. Journal of Medical Economics. Vol. 17, No. 12, 2014, 862–871.

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Impact of Chronic Hepatitis C (CHC) Treatment on Post-Therapy Healthcare Costs

Table 4. Comparison of PPPY healthcare cost between all beneficiaries in the complete vs discontinued HCV therapy cohorts.

PPPY healthcare costs (US $2012)	Complete therapy cohort	Discontinued therapy cohort	Complete vs discontinued therapy cohort		
			Unadjusted cost difference	Adjusted cost difference[a] (95% CI)	*p*-value
Number of patients, *n*	1017	953			
Observation period[b], days, mean (SD)	1395 (999)	1257 (962)			
All-cause healthcare costs	$13,294 (28,106)	$17,834 (38,328)	−$4540	−$3687 (−6503, −822)	0.0080
Hospitalizations	$3347 (14,965)	$6386 (28,754)	−$3039	−$2726 (−4734, −821)	0.0020
ER visits	$223 (607)	$286 (913)	−$63	−$56 (−119, 4)	0.0661
Outpatient visits	$5062 (14,602)	$5847 (10,477)	−$785	−$535 (−1537, 603)	0.3884
Pharmacy dispensing	$4663 (8039)	$5315 (10,009)	−$652	−$371 (−1099, 366)	0.3223
CHC-related healthcare costs	$3535 (10,285)	$5286 (21,240)	−$1750	−$1644 (−3138, −148)	0.0220
Hospitalizations	$953 (7852)	$2661 (19,825)	−$1708	−$1734 (−3202, −400)	0.0060
ER visits	$1 (15)	$3 (35)	−$1	−$1 (−4, 1)	0.2142
Outpatient visits	$450 (868)	$544 (1039)	−$94	−$88 (−178, 9)	0.0761
Pharmacy dispensing[c]	$2131 (5782)	$2077 (6341)	$54	$179 (−286, 639)	0.4525

PPPY, per-patient per-year; HCV, hepatitis C virus; SD, standard deviation; CHC, chronic hepatitis C; CI, confidence interval; ER, emergency room; RBV, ribavirin.
[a]Adjusted cost differences are obtained using ordinary least-squares regressions, adjusting for baseline characteristics including age, gender, type of beneficiary, geographic region, payer type, year of index date, Quan-Charlson comorbidity index, and healthcare costs. Confidence intervals (95% CI) and *p*-values were calculated using a non-parametric bootstrap with 999 replications.
[b]The observation period spanned from 48 weeks past the index date until the earliest date between the end of insurance coverage or the end of data availability.
[c]CHC-related pharmacy dispensing costs were identified with NDC codes for any of these medicated treatments: peginterferon alfa-2a or alfa-2b, interferon alfa-2a or alfa-2b, or interferon alfacon-1, RBV, telaprevir, and boceprevir.

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	Predictors of high healthcare resource utilization and liver disease progression among patients with chronic hepatitis C
Key Objective	• To identify demographics and clinical characteristics associated with high healthcare resource utilization (HRU) and liver disease progression among CHC patients
Methodology	• Data Source: Health insurance claims from January 2001-March 2013 • Generalized estimating equations were used to identify the demographic and clinical characteristics of being in the 20% of patients with the highest HRU. Factors predicting liver disease progression were also identified.
Key Findings	• In the study population (n = 4898), liver disease severity and both CHC- and non-CHC-related comorbidities and conditions were strong predictors of high healthcare costs • CHC- and non-CHC-related comorbidities and conditions were also strong predictors of liver disease progression
Reference	J. LaMori et al, Predictors of high healthcare resource utilization and liver disease progression among patients with chronic hepatitis C. *Journal of Medical Economics.* Vol. 19, No. 4, 2016, 364–373.

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Predictors of high healthcare resource utilization and liver disease progression among patients with chronic hepatitis C

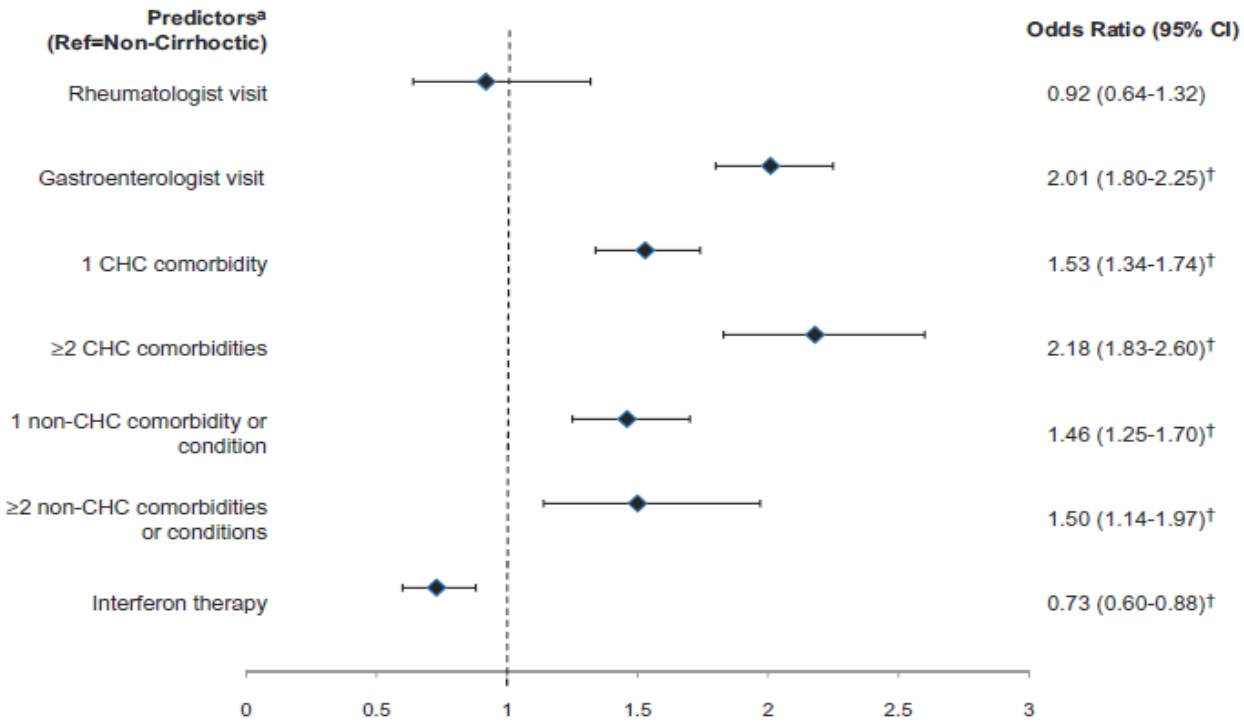

Figure 3. Predictors of patients with CHC being diagnosed with compensated cirrhosis or ESLD ($n = 4676$). CHC, chronic hepatitis C; ESLD, end-stage liver disease; CI, confidence interval. †Denotes statistical significance. *Additional predictors not reported include the following: age group (i.e., ≤45, 45–65, >65 years), female, type of beneficiary, type of insurance (i.e., health maintenance organization, point of service, preferred provider organization, indemnity), region (i.e., Northeast, Midwest, South, and West), and the index year (i.e., 2001–2013).

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Comparative Effectiveness & Budget Impact Models

- Cost per response
- Cost per QALY
- Budget Impact

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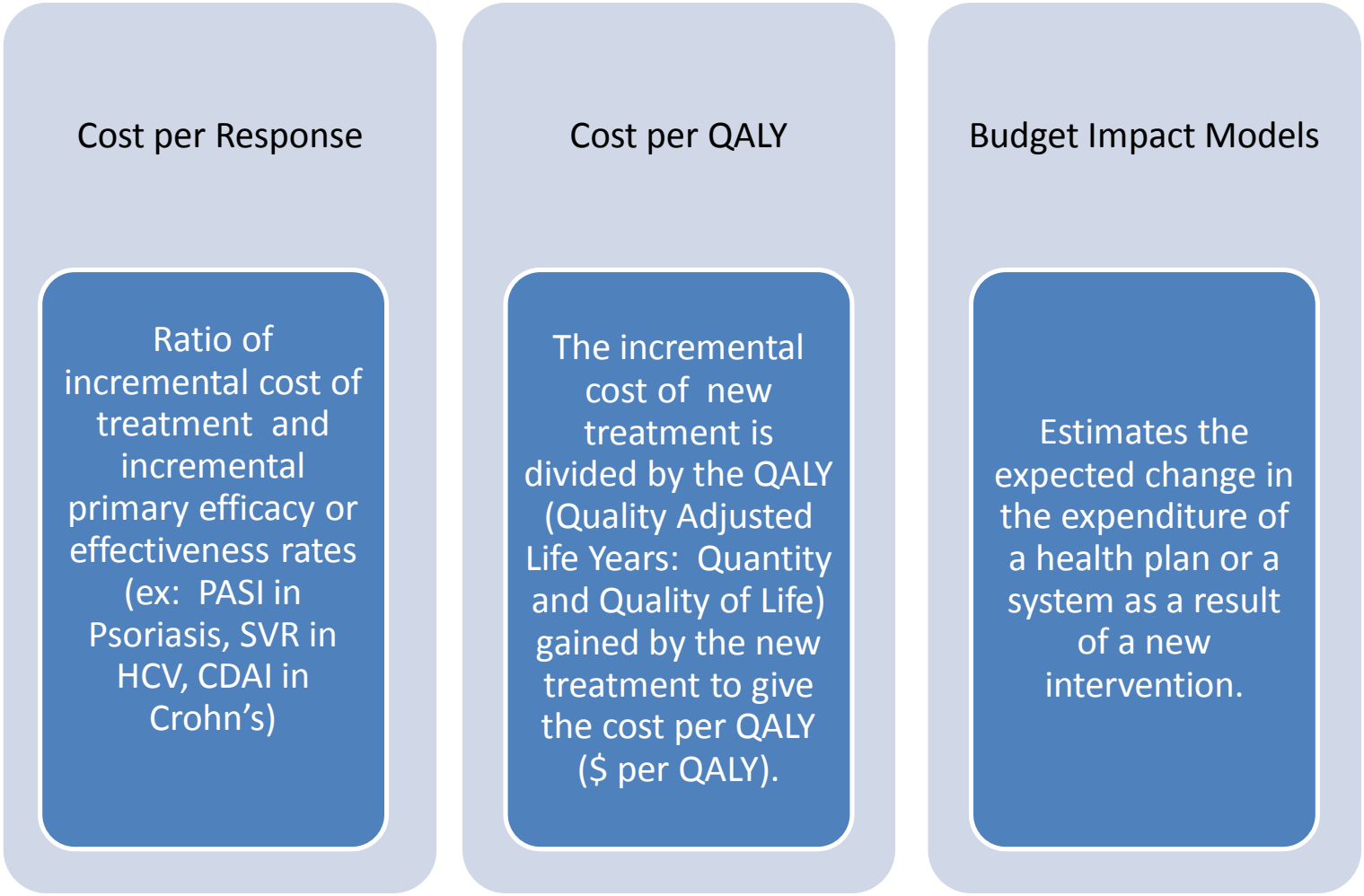
Models for Health Technology Assessments



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