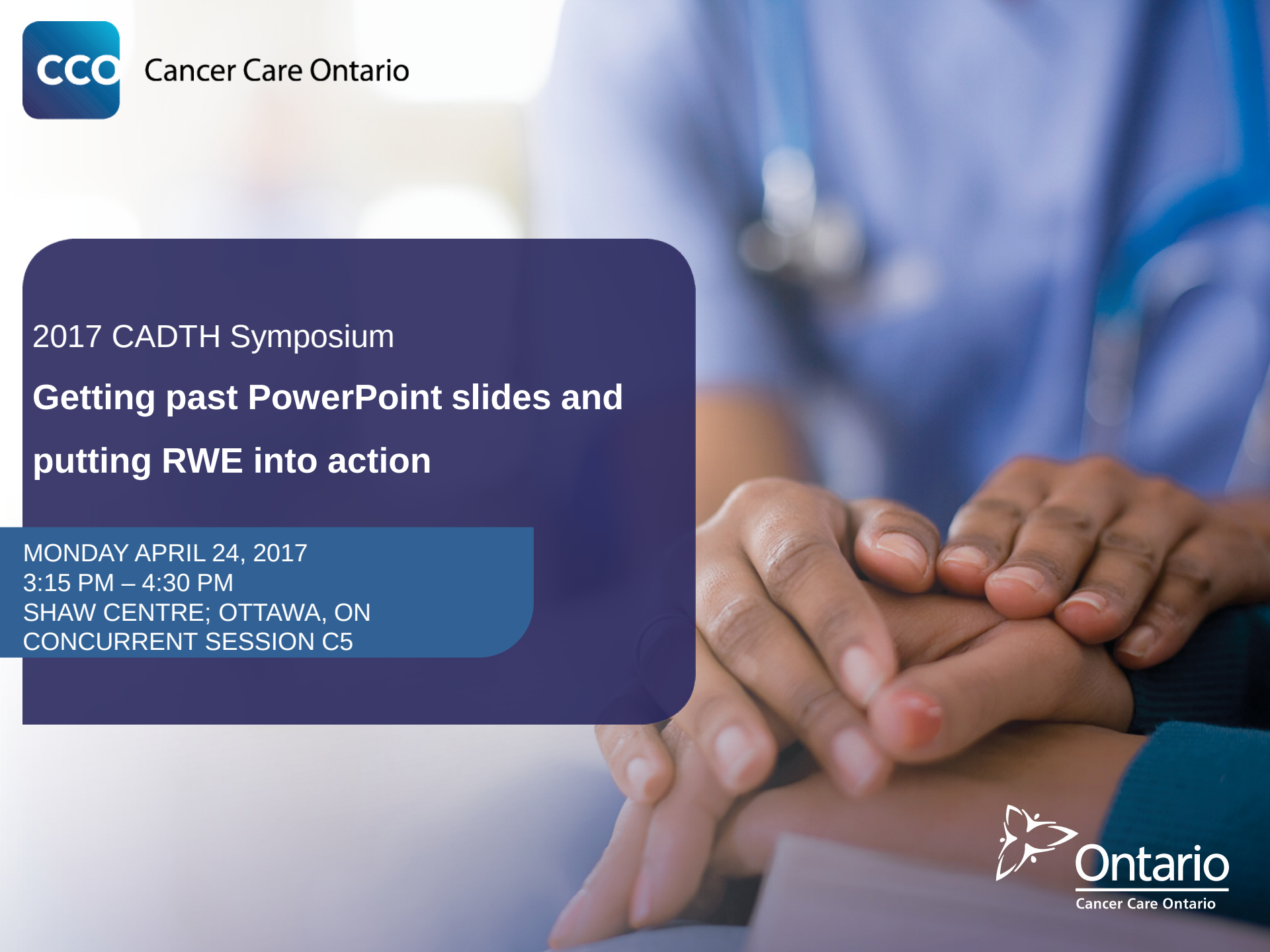
Cancer Care Ontario

2017 CADTH Symposium

Getting past PowerPoint slides and putting RWE into action

MONDAY APRIL 24, 2017
3:15 PM – 4:30 PM
SHAW CENTRE; OTTAWA, ON
CONCURRENT SESSION C5



Ontario
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Getting past PowerPoint slides and putting RWE into action

AGENDA

- Welcome / Housekeeping
- Introductions
- Objectives
- Panel presentations
- Q&A / Discussion

Disclosure

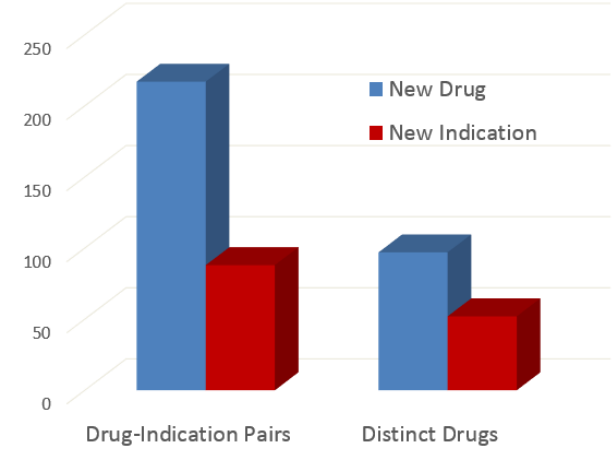
Neither of the panel members have actual or potential conflict of interest in relation to this topic or presentation.

Objectives

- Provide a background on Cancer Care Ontario's work in RWE
- Review the components of an RWE framework that are most relevant to the panel members' perspectives (payer, cancer agency, healthcare researcher, pharmacoeconomist)
- Review the Azacitidine study as an example of how one RWE analysis was conducted

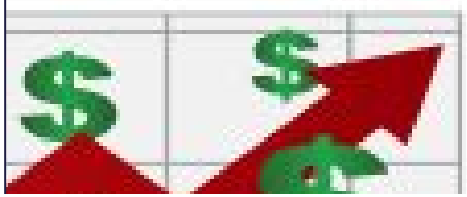
Sustainability Challenge

Overview of Current Pipeline Drugs Tracked by pCODR



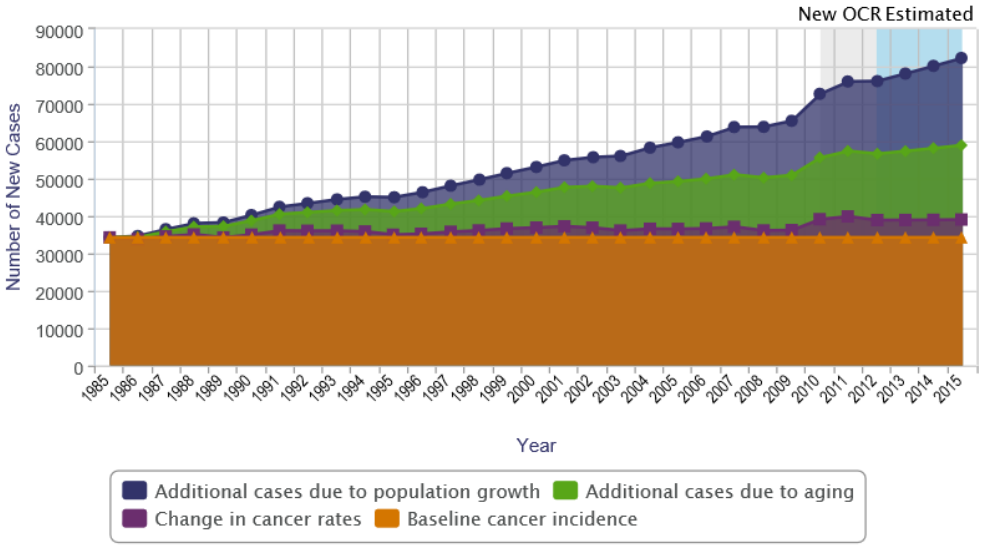
- 32 manufacturers
- 149 distinct drugs
  - 97 new molecular entities
  - 52 pre-existing drugs
- 305 drug-indication pairs
  - 217 new molecular entities
  - 88 new indications for pre-existing drugs

Source: CADTH-pCODR



Cancer Incidence

Figure 1: Growth in new cancer cases, Ontario, 1985–2015



Cancer Care Ontario

Report Date: February 2015
Source: Cancer Care Ontario (Ontario Cancer Registry, 2014)
Prepared by: Cancer Care Ontario, Prevention and Cancer Control (Population Health and Prevention)

Background and context

- In June 2015, the Cancer Quality Council of Ontario hosted a Programmatic Review on Drug Funding Sustainability

- The objective of this Programmatic Review was to:
  - identify and review the critical success factors of a sustainable drug reimbursement program with international, pan-Canadian and internal input;
  - reach agreement on a core set of recommendations for CCO that may be relevant to other reimbursement programs, on strategic directions and improvements, in order to maximize the effectiveness of cancer drug use; and
  - support overall system sustainability in a patient-centred way.

- The output of the review was a set of recommendations to support a drug funding system that is more sustainable, while ensuring high quality of care.

CQCO Recommendations

1. **Stakeholders should not only be engaged but also be enabled to participate fully in a transparent drug funding decision making process.**
   Accountabilities: CCO, MOHLTC, CCS

2. **The pan Canadian Oncology Review (pCODR) should consider further refining its prioritization process through the development of an algorithm for review of drug submissions based on unmet need and/or breakthrough drugs (i.e., "game-changer").**
   Accountabilities: pCODR/CADTH, CCO, MOHLTC, CAPCA

3. **A process should be developed to ensure that practitioners incorporate new agents and use existing agents appropriately and according to current best evidence in order to support system sustainability.**
   Accountabilities: CCO, MOHLTC, CAPCA

4. **A consistent approach to gathering and analyzing real world evidence should be developed. This includes systematically capturing and incorporating patient-reported outcomes (e.g., quality of life, toxicity) into real world data collection (note, this recommendation is linked to recommendation #5).**
   Accountabilities: CCO, MOHLTC, CAPCA
5. **Real world evidence (RWE) should be used to inform and monitor the effects of funding decisions (this includes validating assumptions, evaluating the benefits of funded therapies, revisiting funding decisions, informing future funding decisions).**
   Accountabilities: CCO, MOHLTC, CAPCA

6. **A consistent process for disinvestment (or "reinvestment") and renegotiation of prices with buy-in from the public, patients and clinicians should be explored (i.e., delisting drugs should be considered alongside the prioritization of new drugs).**
   Accountabilities: CCO, MOHLTC, CAPCA, pCODR/CADTH

7. **A process should be established by the provinces to maximize harmonization in cancer drug funding coverage decisions.**
   Accountabilities: CCO, MOHLTC, pCODR/CADTH, CAPCA

CQCO Recommendations for RWE

4. **A consistent approach to gathering and analyzing real world evidence should be developed. This includes systematically capturing and incorporating patient-reported outcomes (e.g., quality of life, toxicity) into real world data collection (note, this recommendation is linked to recommendation #5).**
   Accountabilities: CCO, MOHLTC, CAPCA
5. **Real world evidence (RWE) should be used to inform and monitor the effects of funding decisions (this includes validating assumptions, evaluating the benefits of funded therapies, revisiting funding decisions, informing future funding decisions).**
   Accountabilities: CCO, MOHLTC, CAPCA

Commitment to RWE

Sustainability

BY 2019...

- We will have begun implementation of the chronic disease prevention strategy and have developed the evaluation framework.
- Participation in breast, cervical and colorectal cancer screening programs will be increased and followup for those with an abnormal screening result will be improved.
- Drugs funded through the Provincial Drug Reimbursement Program will be evaluated for the greatest benefit to patients and impact on healthcare resources.
- Innovative person-centred models of care will enable the right provider to deliver the right care, at the right time, in the right place.
- Data-driven, system-level plans will be used to allocate key health human, infrastructure and financial resources for all cancer services.

Effectiveness

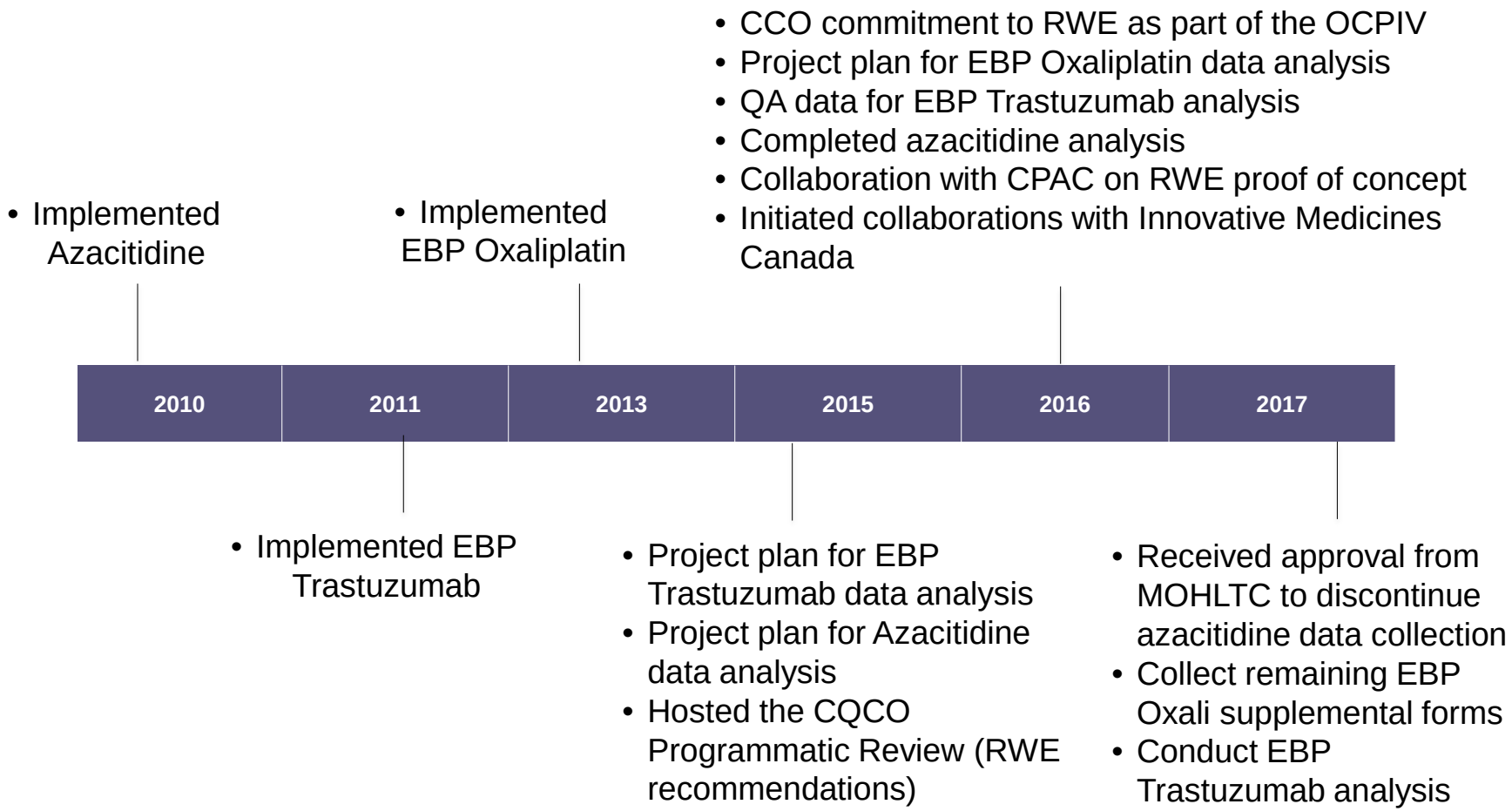
GOAL

Ensure the provision of effective cancer care based on best evidence

STRATEGIC OBJECTIVES

- Expand measurement of clinical and patient-reported outcomes to enable effective, high-quality care.
- Expand our performance management model to include non-hospital healthcare organizations and performance at the provider level in order to be more effective with our quality and access programs across the system.
- Leverage and expand the use of evidence-based guidance to improve the appropriateness of care.
- Develop a unifying strategy for personalized medicine for cancer care including personal and tumour genetics, and incorporate recommendations into clinical practice.

CCO RWE Timeline



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Ministry of Health and Long-Term Care Perspective

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Healthcare Researcher Perspective

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Real world azacitidine use: an evaluation of 1101 higher-risk MDS/low blast count AML patients treated in Ontario, Canada

Kelvin Chan MD

2017 CADTH Symposium

April 24, 2017

Shaw Centre, Ottawa, ON

From: Drs. Rena Buckstein and Lee Mozessohn Presentation to CCO and MOHLTC on September 12, 2016

Background

- Myelodysplastic syndromes (MDS) are stem-cell disorders characterized by ineffective hematopoiesis, cytopenias and progression to acute myeloid leukemia (AML)
- Median age at diagnosis: 72 years[1]
- Allogeneic stem cell transplant only curative option
- Most patients not candidate for transplant:
  - Age
  - Comorbid diseases
  - Absence of suitable donor

Rollison et al., Blood 2008

Azacitidine in higher-risk MDS

- AZA-001 trial:
  - 358 intermediate-2/high-risk patients randomized to azacitidine (AZA) versus conventional care regimens (CCR)
  - Included low blast count AML (20-30% blasts)
- Primary endpoint was OS
- Median OS:
  - 24.5 months (AZA) vs. 15.0 months (CCR) [HR 0.58; 95% CI 0.43 – 0.77, p = 0.0001)
- Median time to AML transformation:
  - 17.8 months (AZA) vs. 11.5 months (CCR) [HR 0.50; 95% CI 0.35 – 0.70, p < 0.0001]

Fenaux et al., Lancet 2009

Azacitidine in Ontario

- Health Canada Indications:
  - Adult patients not eligible for stem cell transplant with:
    - Int-2 and high-risk MDS
    - AML with 20-30% blasts
- Approved for funding in Ontario in June 2010 based on Health Canada indications
- Administered subcutaneously
  - Lyophilized powder (100 mg of AZA per vial)
  - Dose: 75 mg/m^2 for 7 consecutive days (1 cycle) every 28 days as per AZA-001 for a minimum of 6 cycles
  - Given until disease progression

From: Drs. Rena Buckstein and Lee Mozessohn Presentation to CCO and MOHLTC on September 12, 2016

Azacitidine in Ontario

- Many cancer Centres unable to administer chemotherapy on weekends
- Allowed administration based on 3 dosing schedules:
  - 7 consecutive days
  - 6 consecutive days
  - 5 consecutive days, followed by weekend break, followed by 2 consecutive days (so-called 5-2-2)
- NDFP mandated prospective data collection:
  - Validate equivalence of dosing schedules
  - Validate drug efficacy

From: Drs. Rena Buckstein and Lee Mozessohn Presentation to CCO and MOHLTC on September 12, 2016

Rationale for evaluation

Audit Ontario AZA usage in all patients with higher-risk MDS/low blast count AML with the following objectives:

1. Validate different dosing schedules
2. Validate efficacy seen in AZA-001
3. Examine for differences in outcomes based on centre type and volume of AZA patients treated
4. Evaluate quality/compliance with response documentation

From: Drs. Rena Buckstein and Lee Mozessohn Presentation to CCO and MOHLTC on September 12, 2016

Methodology

- Data provided from CCO (June 1, 2010 to March 2, 2016):
  - Variables included on the AZA enrollment form (i.e., information on disease/patient characteristics prior to AZA initiation)
  - Variables included on the AZA supplemental forms (i.e., disease response)
    - Completed after every 6 cycles of treatment
  - List of all treatments and doses received
  - Date of diagnosis of acute leukemia in OCR (linked via OHIP number) based on histology codes
  - Date of death (from OCR)

Methodology

- Variable/outcome definitions:
  - Primary outcome: OS (from time of first AZA treatment to death)
  - Secondary outcomes:
    - Time to AML development (from time of first AZA treatment to AML code in OCR)
    - Disease response as per supplemental forms every 6 months
  - Number of cycles
    - Each cycle should be 6 or 7 doses of AZA with each cycle lasting 28 days
    - Defined as 25 days between one treatment and next with no more than 7 doses of drug given per cycle

From: Drs. Rena Buckstein and Lee Mozessohn Presentation to CCO and MOHLTC on September 12, 2016

Statistical analysis

- Survival curves generated by Kaplan-Meier method
- Also examined predictors of survival such as:
  - Administration schedules
  - Centre size (i.e., volume of patients treated)
  - Centre type (regional cancer centre vs. community centre)
- Univariate and multivariable Cox proportional hazard model use to determine predictors of survival
- Hazard ratios and generalized R^2 (higher R^2, stronger association with OS) also calculated

From: Drs. Rena Buckstein and Lee Mozessohn Presentation to CCO and MOHLTC on September 12, 2016

Baseline characteristics

- Provided data on 1448 patients
- Excluded patients (n):
  - Treatment “denied” (54)
  - Treatment “under review” (79)
  - Received AZA prior to funding approval (123)
  - No treatment data provided (51)
  - Duplicate patients (12)
  - Calculated IPSS low/INT-1 despite reported INT-2/high (28)
- Left with 1101 patients after exclusions

From: Drs. Rena Buckstein and Lee Mozessohn Presentation to CCO and MOHLTC on September 12, 2016

Baseline characteristics

Characteristic	CCO registry (n = 1101)	AZA-001 (n = 179)
Age, years (range)	74 (19 to 99)	69 (42 to 83)
Male, No. (%)	718 (65)	132 (75)
IPSS classification (calculated)		
INT-2 risk, No. (%)	552 (64)	76 (43)
High risk, No. (%)	306 (36)	82 (46)
AML, No. (%)	276 (25)	55 (31)
Previous chemo, No. (%)	168 (15)	---
Intended dosing schedule		
7 consecutive days, No. (%)	272 (25)	179 (100)
6 consecutive days, No. (%)	137 (12)	---
5-2-2, No. (%)	692 (63)	---

Fenaux et al., Lancet 2009

Baseline characteristics

Characteristic	CCO registry (n = 1101)	AZA-001 (n = 179)
Transfusion dependence, No. (%)	714 (66)	111 (62)
Enrollment site		
Non-regional centre, No. (%)	421 (38)	---
Regional cancer centre	680 (62)	---
Number of patients treated at site		
≤ 50 patients, No. (%)	439 (40)	---
> 50 patients, No. (%)	662 (60)	---

Fenaux et al., Lancet 2009

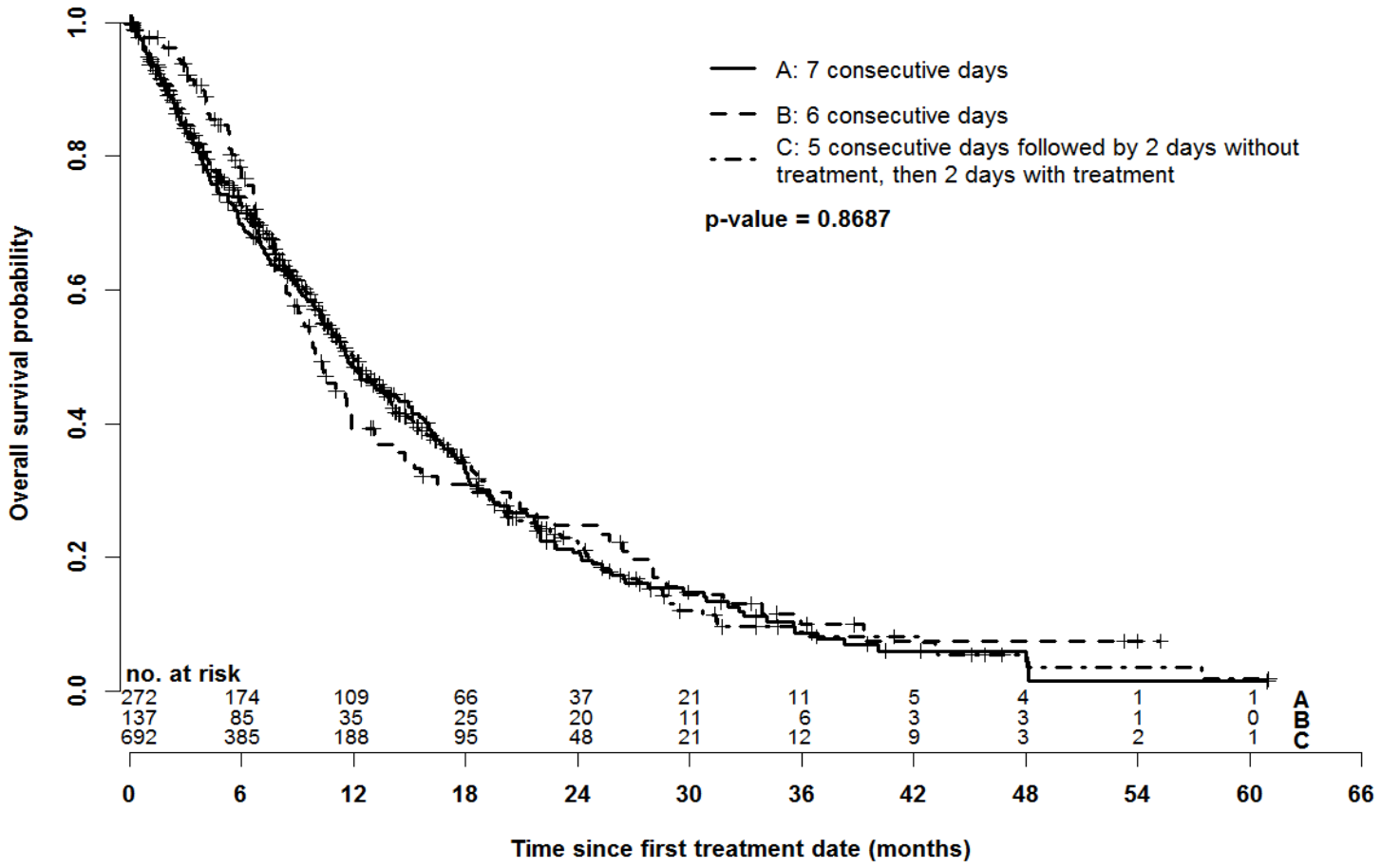
Results

Outcome	CCO registry (n = 1101)	AZA-001 (n = 179)
Median number of cycles (IQR)	6 (3 to 11)	9 (4 to 15)
Median number of cycles for those receiving at least 4 cycles (IQR)	8 (6 to 14)	---
Best response		
Complete response, No. (%)*	49 (17)	30 (17)
Partial response, No. (%)*	31 (11)	21 (12)
Hematologic improvement, No. (%)**	166 (20)	87 (49)***
Overall survival, months	11.6****	24.5

*Of those with marrow done (n = 293)
**Of those with supplemental form (n = 814) and no CR/PR/PD on marrow
***Included those with CR/PR
****If therapy-related MDS excluded: 12.4 months (95% CI, 11.4 to 13.7)

Fenaux et al., Lancet 2009

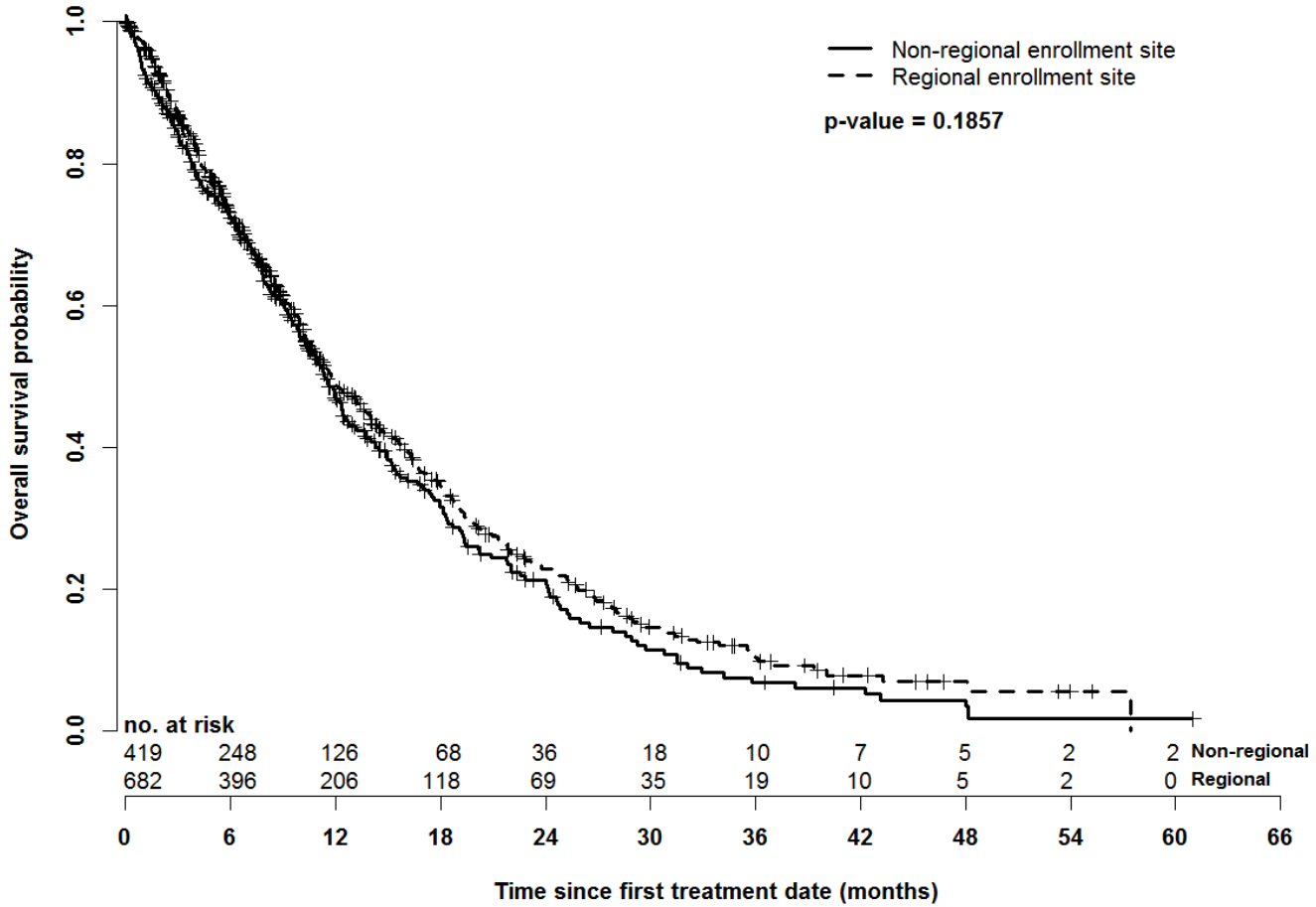
Results: OS based on dosing schedule



- Using non-inferiority margin of 15% (1.7 months) with 90% power (one-sided alpha 2.5%):
  - 7 days vs. 6 days: 125 patients in each arm
  - 7 days vs. 5-2-2: 105 patients in each arm

From: Drs. Rena Buckstein and Lee Mozessohn Presentation to CCO and MOHLTC on September 12, 2016

Results: OS based on centre type



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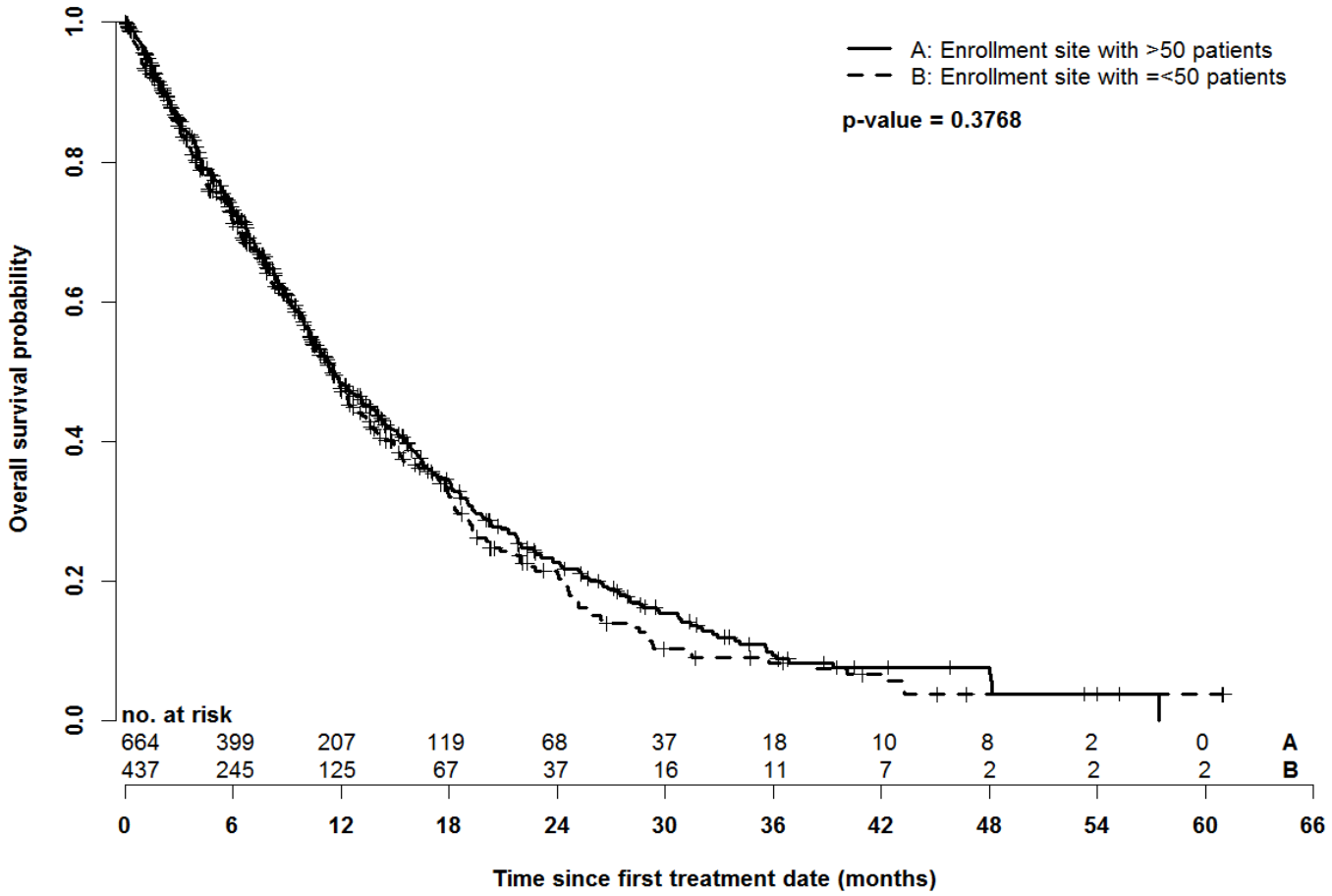
Results: OS based on centre volume



From: Drs. Rena Buckstein and Lee Mozessohn Presentation to CCO and MOHLTC on September 12, 2016

Issues with CCO data

- Unable to determine time to development of AML due to data accuracy/completeness
- Mismatch on calculated versus reported IPSS score:
  - 155 patients had mismatched score
  - 113 patients had mismatched IPSS group
- Excluded 28 patients with calculated IPSS as low/INT-1
- Supplemental form completion
  - 187 patients (of 1101) had no supplemental forms (20 of which were on active treatment and $\leq$ 6 cycles received)
  - 107 patients (of 455) had only 1 supplemental form yet should have had at least 2 complete
- Could not capture number of cycles

From: Drs. Rena Buckstein and Lee Mozessohn Presentation to CCO and MOHLTC on September 12, 2016

How does our data compare to others?

Outcome	AZA-001[1]	CCO	GFM[2]	GESMD[3]	PHAROS[4]
Number of patients	179	1101	282	251	121
Median number of cycles	9	6	6	6	8.5
Best response					
CR, No. (%)*	30 (17)	49 (17)	38 (14)	N/A	8 (12)
PR, No. (%)*	21 (12)	31 (11)	9 (3)	N/A	2 (3)
Heme improvement, No. (%)	87 (49)**	166 (20)	43 (15)	N/A	26 (39)**
Overall survival, months	24.5	11.6	13.5	13.4	16.9

*Of those with marrow done (n = 293)
**Included those with CR/PR

[1]Fenaux et al., Lancet 2009; [2]Itzykson et al., Blood 2011; [3]Bernal et al., Leukemia 2015; [4]Dinmohamed et al., Leukemia 2015

From: Drs. Rena Buckstein and Lee Mozessohn Presentation to CCO and MOHLTC on September 12, 2016

Azacitidine Real World Evaluation – Key Activities

- **MOHLTC provided approvals:**
  - To continue funding the 3 dosing schedules (7-day, 6-day, 5-2-2 regimen)
  - To discontinue further data collection for AZA

- **Memo sent to hospital sites on March 8, 2017:**
  - Background on azacitidine funding
  - Study results - No significant difference in OS by dosing schedule
  - Additional findings regarding treatment duration and dose reductions
  - Discontinuation of data collection

From: Drs. Rena Buckstein and Lee Mozessohn Presentation to CCO and MOHLTC on September 12, 2016

Cancer Agency Perspective

- Operationalizing real-world data collection
- Challenges / lessons learned

In the beginning…

- Develop Analysis Plan and data collection forms
- Educate sites
- Inform of data collection requirement

In the middle…

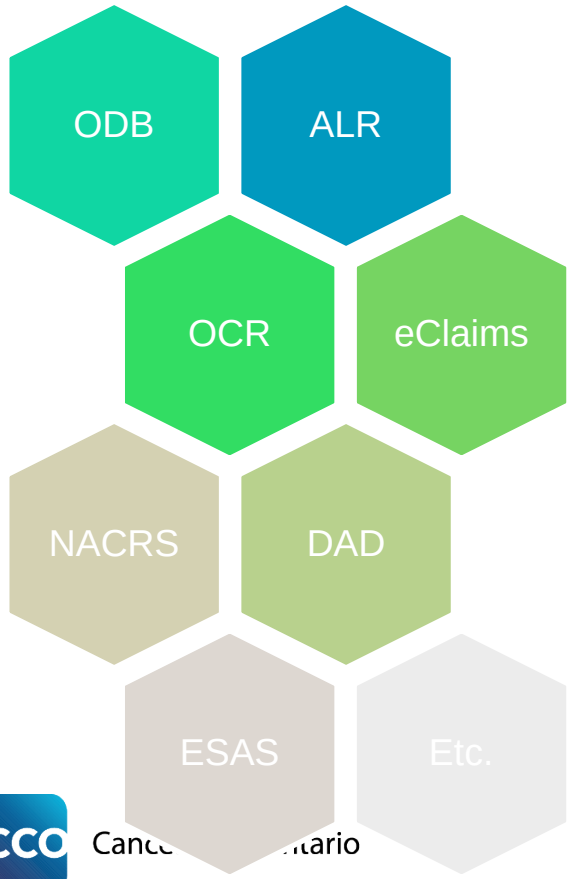
- Develop Analysis Plan and data collection forms
- Educate sites
- Inform of data collection requirement

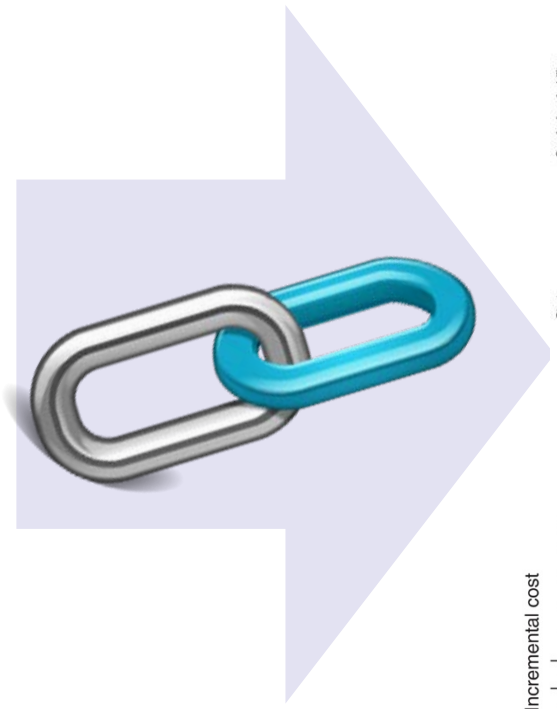
- Sites submit paper enrolment
- Transitioned to electronic data collection (eClaims)

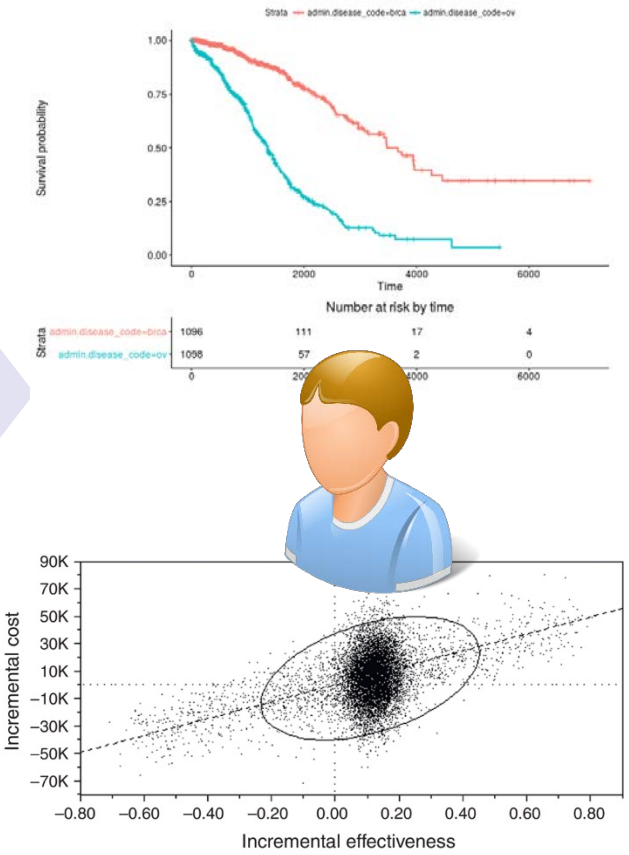
So what is eClaims?

eClaims is an online tool used to adjudicate enrolment and treatment claims for injectable cancer drugs funded through the NDFP and EBP in Ontario

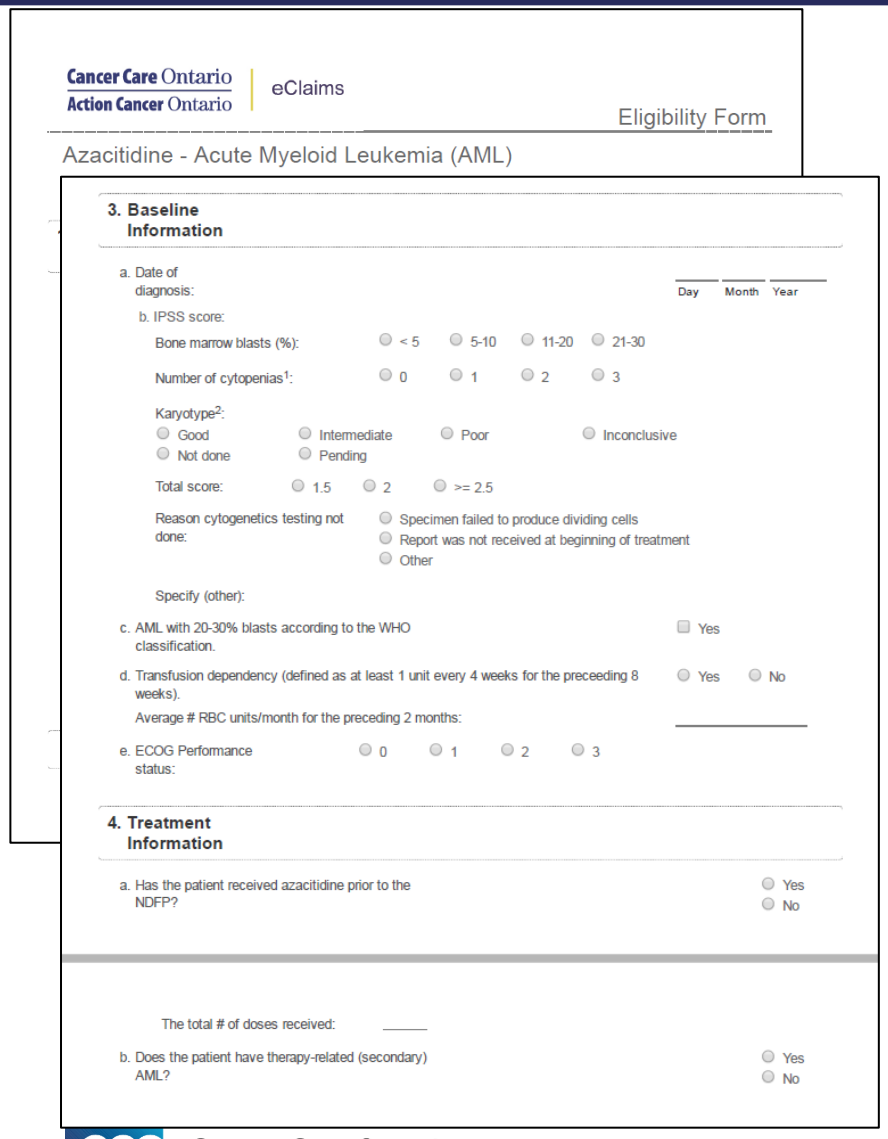
eClaims is capturing real world <u>data</u> along with other databases







How eClaims collects RWD… enrolment forms



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Eligibility Form

Azacitidine - Acute Myeloid Leukemia (AML)

3. Baseline Information

a. Date of diagnosis: Day Month Year

b. IPSS score:

Bone marrow blasts (%): < 5 | 5-10 | 11-20 | 21-30

Number of cytopenias[1]: 0 | 1 | 2 | 3

Karyotype[2]:
Good | Intermediate | Poor | Inconclusive
Not done | Pending

Total score: 1.5 | 2 | >= 2.5

Reason cytogenetics testing not done:
Specimen failed to produce dividing cells
Report was not received at beginning of treatment
Other

Specify (other):

c. AML with 20-30% blasts according to the WHO classification. Yes

d. Transfusion dependency (defined as at least 1 unit every 4 weeks for the preceeding 8 weeks). Yes | No

Average # RBC units/month for the preceding 2 months:

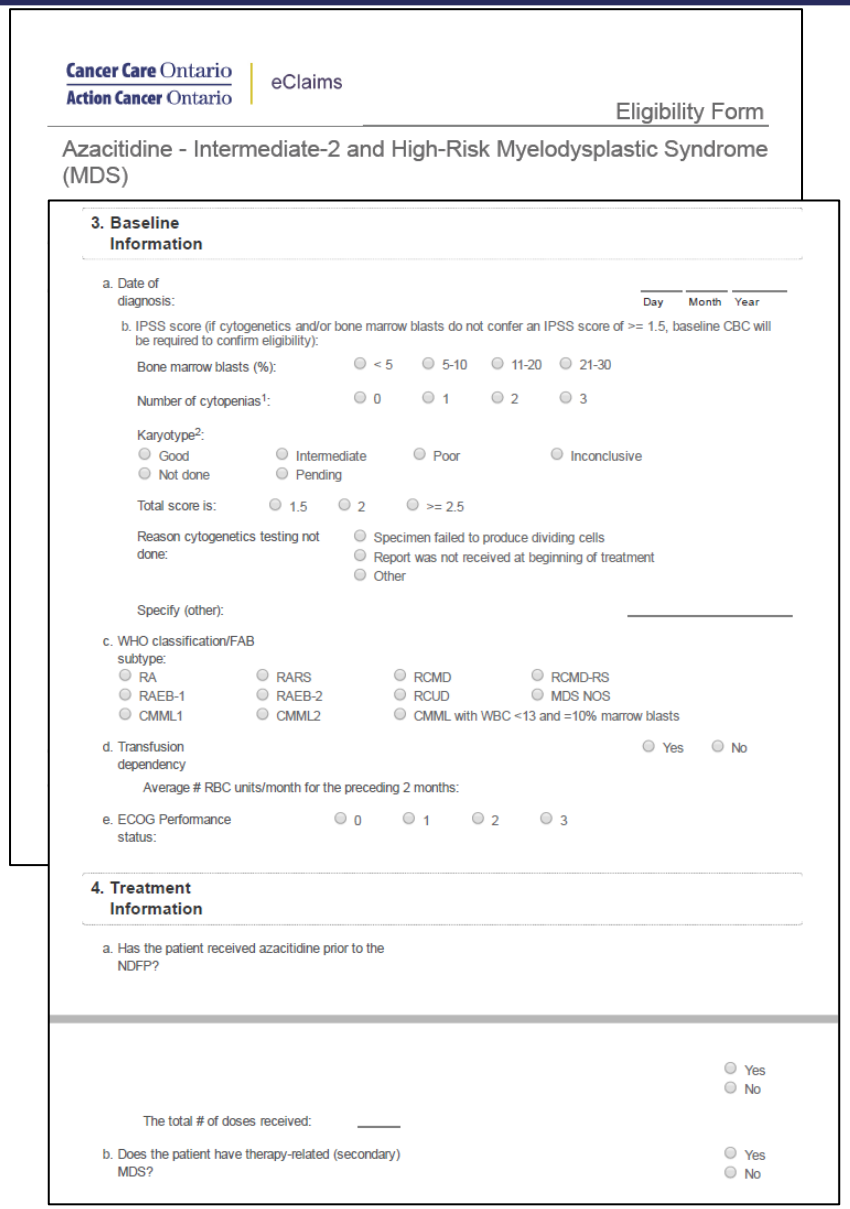
e. ECOG Performance status: 0 | 1 | 2 | 3

4. Treatment Information

a. Has the patient received azacitidine prior to the NDFP? Yes | No

The total # of doses received:

b. Does the patient have therapy-related (secondary) AML? Yes | No



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Eligibility Form

Azacitidine - Intermediate-2 and High-Risk Myelodysplastic Syndrome (MDS)

3. Baseline Information

a. Date of diagnosis: Day Month Year

b. IPSS score (if cytogenetics and/or bone marrow blasts do not confer an IPSS score of >= 1.5, baseline CBC will be required to confirm eligibility):

Bone marrow blasts (%): < 5 | 5-10 | 11-20 | 21-30

Number of cytopenias[1]: 0 | 1 | 2 | 3

Karyotype[2]:
Good | Intermediate | Poor | Inconclusive
Not done | Pending

Total score is: 1.5 | 2 | >= 2.5

Reason cytogenetics testing not done:
Specimen failed to produce dividing cells
Report was not received at beginning of treatment
Other

Specify (other):

c. WHO classification/FAB subtype:
RA | RARS | RCMD | RCMD-RS
RAEB-1 | RAEB-2 | RCUD | MDS NOS
CMML1 | CMML2 | CMML with WBC <13 and =10% marrow blasts

d. Transfusion dependency Yes | No

Average # RBC units/month for the preceding 2 months:

e. ECOG Performance status: 0 | 1 | 2 | 3

4. Treatment Information

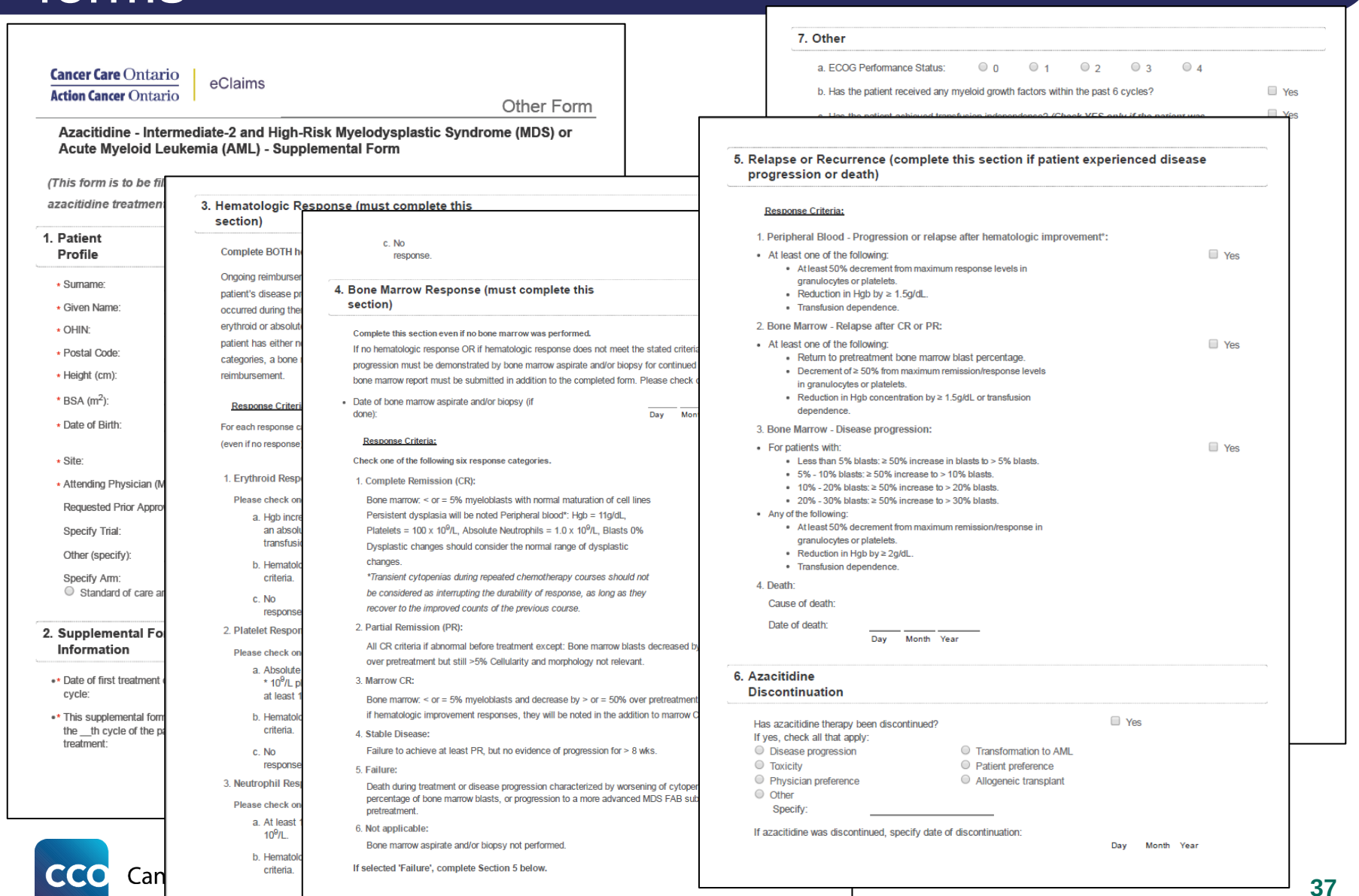
a. Has the patient received azacitidine prior to the NDFP?

Yes
No

The total # of doses received:

b. Does the patient have therapy-related (secondary) MDS? Yes | No

How eClaims collects RWD… supplemental forms



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eClaims

Other Form

Azacitidine - Intermediate-2 and High-Risk Myelodysplastic Syndrome (MDS) or Acute Myeloid Leukemia (AML) - Supplemental Form

(This form is to be fil
azacitidine treatmen

1. Patient Profile

- * Surname:
- * Given Name:
- * OHIN:
- * Postal Code:
- * Height (cm):
- * BSA (m^2):
- * Date of Birth:
- * Site:
- * Attending Physician (M
- Requested Prior Appro
- Specify Trial:
- Other (specify):
- Specify Arm:
  - Standard of care ar

2. Supplemental Fo Information

- * Date of first treatment (cycle:
- * This supplemental form the __th cycle of the pa treatment:

3. Hematologic Response (must complete this section)

Complete BOTH h

Ongoing reimburser patient's disease pr occurred during the erythroid or absolut patient has either n categories, a bone reimbursement.

Response Criteri

For each response c (even if no response

1. Erythroid Resp

Please check on

a. Hgb incre an absolu transfusi

b. Hematolo criteria.

c. No response

2. Platelet Respor

Please check on

a. Absolute * 10^9/L p at least 1

b. Hematolo criteria.

c. No response

3. Neutrophil Resp

Please check on

a. At least 1 10^9/L.

b. Hematolo criteria.

c. No response.

4. Bone Marrow Response (must complete this section)

Complete this section even if no bone marrow was performed.

If no hematologic response OR if hematologic response does not meet the stated criteria progression must be demonstrated by bone marrow aspirate and/or biopsy for continued bone marrow report must be submitted in addition to the completed form. Please check

- Date of bone marrow aspirate and/or biopsy (if done): ____ ____ Day Mon

Response Criteria:

Check one of the following six response categories.

1. Complete Remission (CR):

Bone marrow: < or = 5% myeloblasts with normal maturation of cell lines
Persistent dysplasia will be noted Peripheral blood*: Hgb = 11g/dL, Platelets = 100 x 10^9/L, Absolute Neutrophils = 1.0 x 10^9/L, Blasts 0%
Dysplastic changes should consider the normal range of dysplastic changes.
**Transient cytopenias during repeated chemotherapy courses should not be considered as interrupting the durability of response, as long as they recover to the improved counts of the previous course.*

2. Partial Remission (PR):

All CR criteria if abnormal before treatment except: Bone marrow blasts decreased by over pretreatment but still >5% Cellularity and morphology not relevant.

3. Marrow CR:

Bone marrow: < or = 5% myeloblasts and decrease by > or = 50% over pretreatment if hematologic improvement responses, they will be noted in the addition to marrow C

4. Stable Disease:

Failure to achieve at least PR, but no evidence of progression for > 8 wks.

5. Failure:

Death during treatment or disease progression characterized by worsening of cytoper percentage of bone marrow blasts, or progression to a more advanced MDS FAB sub pretreatment.

6. Not applicable:

Bone marrow aspirate and/or biopsy not performed.

If selected 'Failure', complete Section 5 below.

5. Relapse or Recurrence (complete this section if patient experienced disease progression or death)

Response Criteria:

1. Peripheral Blood - Progression or relapse after hematologic improvement*:
   - At least one of the following: ☐ Yes
     - At least 50% decrement from maximum response levels in granulocytes or platelets.
     - Reduction in Hgb by ≥ 1.5g/dL.
     - Transfusion dependence.
2. Bone Marrow - Relapse after CR or PR:
   - At least one of the following: ☐ Yes
     - Return to pretreatment bone marrow blast percentage.
     - Decrement of ≥ 50% from maximum remission/response levels in granulocytes or platelets.
     - Reduction in Hgb concentration by ≥ 1.5g/dL or transfusion dependence.
3. Bone Marrow - Disease progression:
   - For patients with: ☐ Yes
     - Less than 5% blasts: ≥ 50% increase in blasts to > 5% blasts.
     - 5% - 10% blasts: ≥ 50% increase to > 10% blasts.
     - 10% - 20% blasts: ≥ 50% increase to > 20% blasts.
     - 20% - 30% blasts: ≥ 50% increase to > 30% blasts.
   - Any of the following:
     - At least 50% decrement from maximum remission/response in granulocytes or platelets.
     - Reduction in Hgb by ≥ 2g/dL.
     - Transfusion dependence.
4. Death:
   Cause of death:
   Date of death: ____ ____ ____ Day Month Year

6. Azacitidine Discontinuation

Has azacitidine therapy been discontinued? ☐ Yes
If yes, check all that apply:

- ○ Disease progression
- ○ Toxicity
- ○ Physician preference
- ○ Other
  Specify: _____
- ○ Transformation to AML
- ○ Patient preference
- ○ Allogeneic transplant

If azacitidine was discontinued, specify date of discontinuation:
Day Month Year

7. Other

a. ECOG Performance Status: ○ 0 ○ 1 ○ 2 ○ 3 ○ 4

b. Has the patient received any myeloid growth factors within the past 6 cycles? ☐ Yes

Benefits of eClaims

- Faster online submission and tracking of documentation
- Easier to modify forms and ensure version control
- Improved data quality
- Allows secure communications to sites

Nearing the end…

- Develop Analysis Plan and data collection forms
- Educate sites
- Inform of data collection requirement

- Sites submit paper enrolment
- Transitioned to electronic data collection (eClaims)

- Data sharing agreements with an external analytics group (EAG)
- Data Linkages
- Data transfer

The end is just the beginning

- Azacitidine findings have been presented, but there are several lessons learned from CCO's perspective
- The challenges and opportunities will be used to shape similar efforts moving forward

Opportunities specific to conducting RWE analyses

- Identify and engage analysts in advance of data collection
- The usage of supplemental forms creates an administrative burden
- Use administrative databases, when feasible
- An electronic means of collecting the data is ideal

RWE in general requires …

- Integration with evolving drug funding processes
- Significant investment from all stakeholders
- Robust governance and operational oversight
- Support for collaboration across ministries and agencies
- Ongoing engagement with expert review committees (i.e., pERC) and the pCPA
- Infrastructure that ensures findings are used to inform decision-making

Envisioning the future state for cancer RWE

Current State

- Consideration of drugs individually and sequentially
- Rare reassessments of funding
- RWE proposals and consideration come late in evaluation process
- RWE, when it occurs, tends to focus on utilization and costs
- Financial risk wholly assumed by payer
- Few pan-Canadian data linkages
- Lack of dedicated resources
- Limited coordination & cooperation

Possible Future State

- Established pan-Canadian governance structure for RWE, managing infrastructure and resources.
- Early planning of RWE approach that is built into the decision-making process
- Disease-pathway consideration of drugs
- All funding is “conditional”
- Pan-Canadian data linkages in place
- RWE examines outcomes and value
- RWE evaluations routinely inform funding reassessments
- More sophisticated risk-sharing in LOIs

Pharmacoeconomist Perspective

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Q & A