The Design and Delivery of the IN-HOME Study

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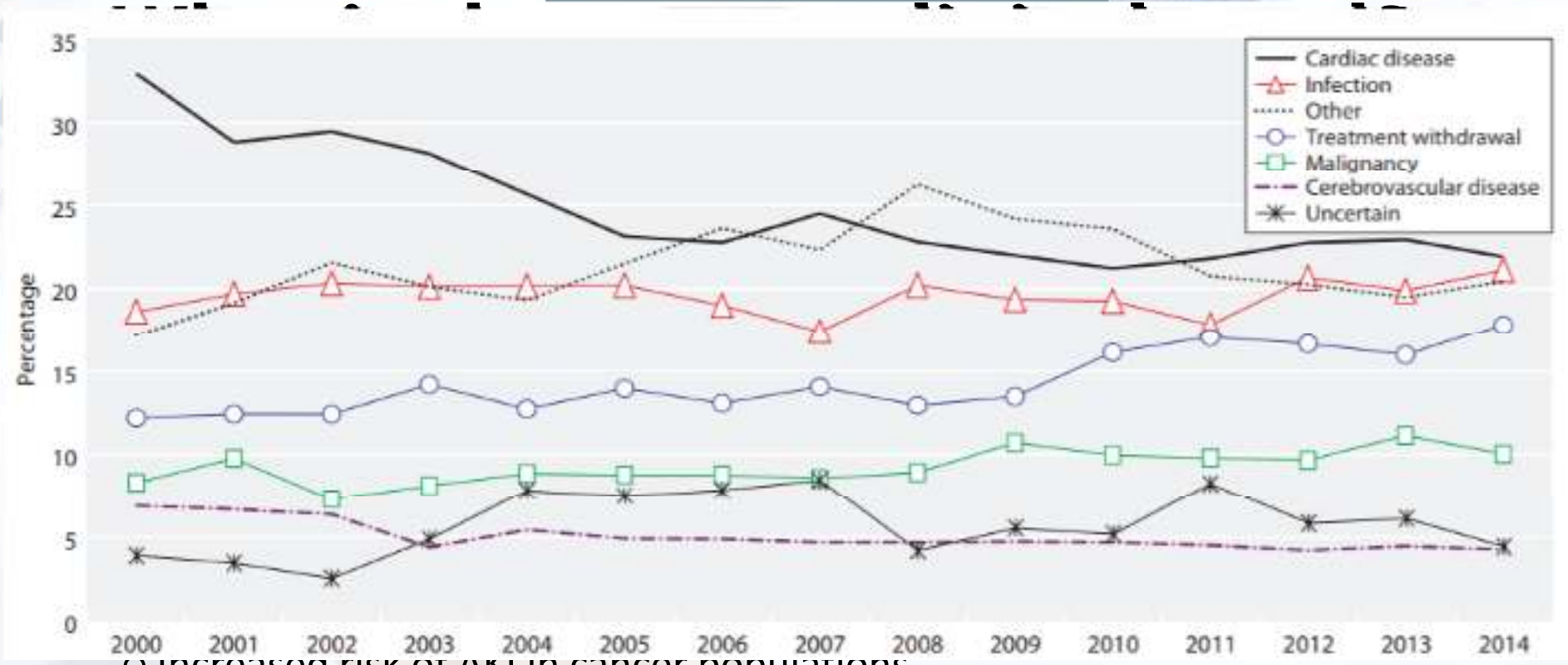
CDDF WORKSHOP

27 - 28 September 2021

ONLINE WORKSHOP

Digital Tools and Artificial Intelligence in Oncology Drug Development

- Background & unmet clinical need
- Possible solution
- Design of Study
- Practical Delivery
- Challenges



↑ Increased risk of AKI in cancer populations

1 Cengiz, K. Increased incidence of neoplasia in chronic renal failure (20-year experience). *Int. Urol. Nephrol.***33**, 121–6 (2002).
2 Wong, G. *et al.*Association of CKD and cancer risk in older people. *J. Am. Soc. Nephrol.***20**, 1341–50 (2009).
3 Weng, P.-H. *et al.*Cancer-specific mortality in chronic kidney disease: longitudinal follow-up of a large cohort. *Clin. J. Am. Soc. Nephrol.***6**, 1121–8 (2011).

- Clinical Trials – recruitment and barriers
  - Increasing difficulty in recruitment of patients that reflect to real-world cancer population to cancer clinical trials
  - Perceived and actual risk of nephrotoxicity in patients with pre-existing CKD concerning
  - Standard inclusion criteria CrCl >60mls/min leads to 20-45% patients being excluded
  - Wider problems with recruitment into cancer clinical trials
- Further understanding of risk of nephrotoxicity from anti-cancer agents

Table 1.

Reasons for non-participation in clinical trials (n = 139)

	n (%)
Inclusion criteria[a]	94 (34[b])
Impaired renal function (GFR <60 ml/min)	42 (45)
History of secondary malignancy	24 (26)
ECOG PS >2 or life expectancy <6 months	24 (26)
Co-morbidity	19 (20)
Chemotherapy started at another hospital	9 (10)
Understanding the study	5 (5)
Time from surgery to randomisation >6 weeks	5 (5)
Investigators' decision	17 (9[c])
Age	10 (59)
Co-morbidity	6 (35)
Participation refused	28 (16[c])

a Multiple options possible.

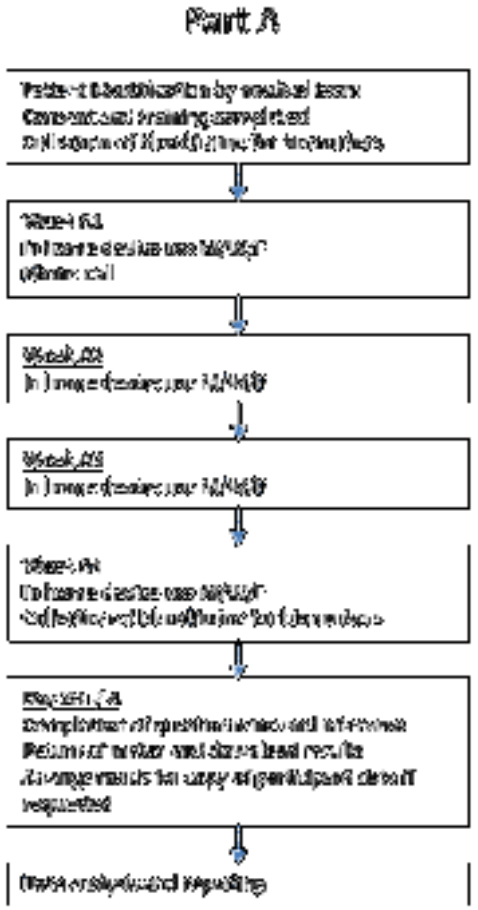
Table 1: P. Harter et al., *Annals of Oncology*, 16:11, 1801–1803
1 Murthy, V. H., Krumholz, H. M. & Gross, C. P. Participation in Cancer Clinical Trials. *JAMA* 291, 2720 (2004).

- AKI and e-alerts/self-monitoring [1,2]
  - Published results m
  - Some success for se anti–coagulation pc
  - Testing of e-alerts i limited

Our Study
- **Single site, interventional RCT**
- **Using POCT device at home when patients receiving chemotherapy**
- **Is AKI diagnosed sooner with more intensive monitoring**

- **Would utilising self-monitoring of kidney function lead to earlier detection of AKI in patients receiving cancer treatments? Will this be acceptable to patients and clinicians?**
- **In turn could this lead to improved inclusion of patients with CKD to clinical trials in an acceptable and safe way?**

- Patients participating in Part A of the trial were asked to complete intensive home-monitoring of whole-blood creatinine for 4 weeks
- Patients were identified by the Head and Neck team at The Christie and approached during clinics
- The PIS is given with the intention to then arrange consent, screening and baseline assessments ideally before starting treatment
- Patient blood and urine samples were taken at baseline and at week 4



Objectives	Outcome Measures	Timepoint(s) of evaluation of this outcome measure (if applicable)
Primary Objectives **Part A:** To evaluate patient acceptance of intensive home-monitoring of whole-blood creatinine.	Interview Absolute number of creatinine readings received-expected vs actual Time sample taken vs. time expected to take Value sent/received vs. value on device (when downloaded at the end of the study period)	Week 4
Exploratory Objectives **Part A**: Using data gathered to improve and test amended AKI algorithm	Amended algorithm outcome vs clinician assessment Feedback and analysis from interviews and questionnaires	On completion of Part A

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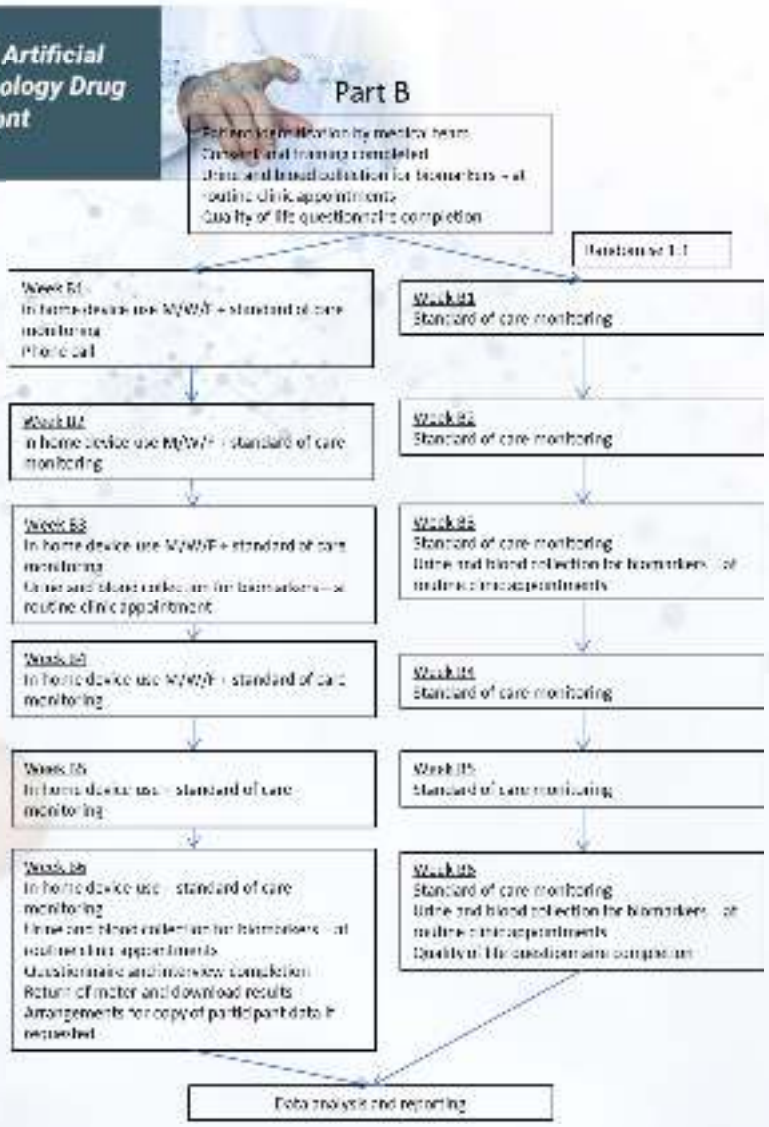
- Part B randomised to either the intensive monitoring (device) group or the standard of care monitoring group, in a 1:1 ratio

- Participants in the intensive monitoring group will upload their creatinine reading three times per week (Mon/Wed/Fri) for 6 weeks



Objectives	Outcome Measures	Timepoint(s) of evaluation of this outcome measure (if applicable)
Primary Objectives **Part B**: To evaluate the potential for earlier diagnosis of AKI/change in renal function with intensive home-monitoring of whole-blood creatinine.	Time from beginning of current cycle treatment to detection of AKI by amended algorithm or clinician/laboratory reading Severity of AKI at detection (as per Kidney Disease Improving Global Outcomes AKI Work Group staging) Overall change in renal function from beginning to end of study period	Throughout study period

Objectives	Outcome Measures	Timepoint(s) of evaluation of this outcome measure (if applicable)
Secondary Objectives **Part B:** To assess whether intensive monitoring influences the change in kidney function over the study period compared to standard of care	Comparing kidney function at the beginning and end of the study	Weeks 1 and 6
Part B: To assess whether home monitoring of kidney function has a positive impact on a patient's quality of life.	Medical outcomes study short form 36 (SF-36) questionnaire	Week 6

Objectives	Outcome Measures	Timepoint(s) of evaluation of this outcome measure (if applicable)
Secondary Objectives **Part B:** To evaluate the adherence of patients to intensive home monitoring regimen	Absolute number of creatinine readings received Time sample taken vs. time expected to take Value sent/received vs. value on device (when downloaded at the end of the study period)	Week 6

Objectives	Outcome Measures	Timepoint(s) of evaluation of this outcome measure (if applicable)
Exploratory Objectives **Part B:** To explore the value of novel renal biomarkers in the cancer population for early detection and monitoring of AKI.	Urine and serum analysis	Throughout study period
Part B: Document any other issues that patients may have experienced during the study period.	Patient interview	Week 6

Objectives	Outcome Measures	Timepoint(s) of evaluation of this outcome measure (if applicable)
Exploratory Objectives **Part B**: Clinician opinions towards home monitoring and the impact it could have on their treatment schedules for patients.	Clinician interview	Week 6
Part B: Are there ethical/justice considerations in carrying out studies which require access to smart phones/socioeconomic factors	Analysis of demographic information of patients enrolled, and those who declined, in study and those who decline to take part Patient interview	Week 6

Delivery of IN-HOME

- Team approach
- Clinicians/research practiconer/research nurses/admin and tech support
- Strong links with parent clinical teams

Challenges

- Devices
- Regulations and Ethics
- Local challenges
- Recruitment
- Covid

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Thank you

Engaging patients, driving decisions

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